

Resources Needed to Implement ICRP 60 Recommendations at the National Level and Resources that May Be Needed to Implement Those of ICRP 103

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Report to the 69th CRPPH meeting (17-19 May 2011)

Prepared for the ad-hoc Expert Group on ICRP Implementation costs (EGIIC) by Dr. Jack Valentin and Mrs. Wendy Bines

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SUMMARY

At its 68th meeting, the CRPPH decided to pursue the question of resources needed to implement ICRP Recommendations, and after the meeting, the NEA Secretariat contracted Wendy Bines and Jack Valentin to perform a survey on this issue. In consultation with the US NRC and the Secretariat, the consultants developed a questionnaire which was used to investigate issues through interviews with regulators and operators in the UK and in Sweden.

Based on the experience of these initial interviews, a slightly simplified version of the questionnaire was distributed to all CRPPH members. Members were asked to fill in the questionnaire and, if possible, to arrange for answers to be provided also from operators.

This yielded information from regulatory agencies in 11 member countries and some operators/licensees in four countries.

Little quantitative, monetary, information is available. The qualitative information obtained indicates that in most countries, the costs of implementing ICRP 60 were regarded as relatively modest (or at least tolerable), both by regulators and – after some initial concerns – by operators. Some of the costs were balanced by improved efficiency resulting from optimisation of radiological protection.

Important factors behind these limited costs included, *inter alia*, considerable lead-in times allowing orderly adaptation to the new requirements, comprehensive consultation, constructive interaction between regulators and operators and, not least, the fact that after careful and perceptive consultation, stakeholders often felt that the ICRP Recommendations made sense.

The cost of implementing ICRP 103 is expected to be even smaller where ICRP 60 is already implemented, since the nominal risk and the dose limits remain essentially unchanged.

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1. INTRODUCTION

For some time, the CRPPH has conducted discussions concerning the resources that were needed to implement the Recommendations of ICRP Publication 60, and the resources that are expected to be necessary to implement ICRP Publication 103.

One of the tasks of the CRPPH Expert Group on Occupational Exposure (EGOE) is to conduct a Case Study ('No. 2') on the implementation of ICRP Recommendations. At its 67th (2009) meeting, the CRPPH requested that the EGOE extend that task by collecting information on the costs of implementing ICRP Publication 60, following its 1990 publication, as a useful comparative tool for assessing the costs of implementing ICRP Publication 103.

EGOE discussed this, but felt that the question was broader than just occupational exposure, and as such suggested that the EGOE should not be the driving force in the preparation of this work. At the 68th (2010) meeting of the CRPPH, it was noted that the EC is obliged to perform an impact assessment before moving forward with the approval of its new BSS Directive to implement, among other things, ICRP Publication 103 and that, while there is no explicit process of assessing the impact of changing the International BSS, this is a question that could be addressed to IAEA member countries.

Based on this discussion, the CRPPH agreed that this work should continue, but not within the EGOE. Subsequently, the Secretariat contracted Jack Valentin and Wendy Bines to perform a survey of several CRPPH members on this issue. A questionnaire was developed by the consultants with assistance from the Secretariat and significant contribution from the US NRC, who had originally asked for this information.

The questionnaire was used by the consultants to interview representatives of regulatory agencies and of various kinds of licensees (nuclear installations, medical establishments, and non-destructive testing companies) in the United Kingdom and in Sweden. The experience obtained during these interviews permitted the consultants to refine the questionnaire, making it slightly shorter, more transparent and therefore easier to complete, and reducing the need for supplementary interviews with respondents.

The revised questionnaire was then sent to all CRPPH members, requesting replies and also assistance to get in touch with operators in at least some of the countries. The present report summarises the responses received and outlines the conclusions that could be inferred.

2. RESULTS

Responses have been received from 11 countries. Most replies come from government agencies (regulatory bodies and/or advisory organisations), but there are also replies from nuclear power plant operators, medical establishments, and a non-destructive testing organisation. Table 1 provides an overview of the respondents.

Table 1. Responses received

Country	Response received from
AUSTRALIA	Regulatory/advisory body
CANADA	Regulatory/advisory body – including ICRP 60 RIA/CBA ^{**)} NPP operator Medical establishment
CZECH REPUBLIC ^{*)}	Regulatory/advisory body
ICELAND	Regulatory/advisory body
REPUBLIC OF KOREA	Regulatory/advisory body
NORWAY	Regulatory/advisory body
SLOVAKIA ^{*)}	Regulatory/advisory body
SLOVENIA ^{*)}	Regulatory/advisory body
SPAIN ^{*)}	Regulatory/advisory body
SWEDEN ^{*)}	Regulatory/advisory body NPP operator Medical establishment NDT company
UNITED KINGDOM ^{*)}	Regulatory/advisory body – including ICRP 60 RIA/CBA ^{**)} NPP operator Medical establishment

^{*)} EU member states ^{**)} Regulatory impact assessment/cost-benefit analysis

In addition, we have received the following supporting material:

- From the European Commission, an Annex to their draft Impact Assessment concerning the next EURATOM Basic Safety Standards Directive (attached as Annex D). This provides much background information, but no actual estimate of the anticipated costs of implementing ICRP 103;
- From a large European nuclear power plant operator, a white paper (attached as Annex F) summarising their perception of and reaction to ICRP 60 (although not providing any estimate of the anticipated costs of implementing ICRP 60);

- From IAEA (Dr John Le Heron), information concerning the results of a study of occupational exposures and radiological protection of staff in interventional cardiology, which illuminates some aspects of dosimetry at medical establishments which may have a bearing on the present analysis.

2.1 The questionnaire

In addition to contact details, respondents were asked to provide information concerning:

- National legislation and RP organisation, ICRP 60 incorporation, stakeholder involvement in the implementation of ICRP 60, guidance, time-scales, burdens, benefits, and costs;
- Scope of the legislation after ICRP 60 implementation, reactions from users (if any) that had not previously been subject to regulation;
- Historical and current dose limits, transition experience, and resulting doses;
- ICRP 60 and specific technical topics including pregnancy, constraints, dosimetry, and radon;
- Training implications of ICRP 60 implementation for regulators and for stakeholders;
- Anticipated changes (if any) to legislation and RP organisation, and anticipated burdens, benefits, and costs when ICRP 103 is implemented;
- ICRP 103 and specific technical topics including pregnancy, constraints, dosimetry, and radon;
- Training implications of ICRP 103 implementation for regulators and for stakeholders; and
- Any other pertinent topic that respondents wish to raise.

The survey yielded a considerable body of useful information, and therefore all of the questionnaires with the complete replies are attached as Annex E (i.e., with countries as the principal basis of division).

In order to permit an initial overview and to facilitate comparisons, Annex A provides somewhat abridged replies organised with questions as the principal basis of division. Thus all country replies to a particular question are listed together, and for each question there is a summary of the range of replies.

Here, the results are presented as an overall summary with comments.

2.2 Organisation and general implementation of ICRP 60

Legislation and organisation. All respondent countries have national laws on radiological protection, delegating regulatory power to their government. In about half of the countries, the government delegates the right to issue binding regulations to the licensing authority/ies. Codes of practice and guidance are issued by regulatory authorities and, at least in one country (UK), also by professional/trade bodies.

Many countries have more than one regulatory authority with responsibilities divided in different ways (health care vs. other sectors; nuclear vs. other sectors; etc.). Consistency is achieved through

consultation and Memoranda of Understanding between the agencies concerned. The replies do not permit an analysis of the number of staff involved in different countries.

Australia and Canada are federations and as such they have the additional complication of regulatory bodies both at the federal level and in the various jurisdictions/provinces. There are mechanisms to ensure harmonised and aligned regulation. In Australia, legislation is homologous in all of the country (e.g., with the same dose limits), but the exact wording of acts and regulations as well as the time when new rules apply may differ between jurisdictions. In Canada, everything to do with nuclear and radioactive materials, and the approval of (but not the use of) devices emitting ionising radiation (e.g., x rays) is regulated at the federal level. The use of radiation-emitting devices which cannot induce radioactivity is regulated in the provinces. Sometimes, this leads to inconsistent requirements and in such cases the stricter of the approaches is applied.

Readers with an interest in the problems posed by having both a federal and a state (jurisdiction, province) level are advised to look at the full replies from Australia and Canada to questions A.1.1-2 in Annex E.

Incorporation of ICRP 60 into national legislation and regulations. All of the respondent countries revised their laws and regulations after 1990, but rarely as a direct result of ICRP 60; instead, when laws and regulations were updated for other reasons, they were also amended to take account of ICRP 60.

In all countries that have provided detailed replies, draft regulations were prepared by regulators in informal consultation with stakeholders, then subjected to formal consultation augmented by information and meetings, then turned into binding regulations (with minor variations because of differing legal systems, etc.) Apparently, considerable effort was spent on information and consultation (although as pointed out from Australia, the process was still less comprehensive than it would be nowadays). No country reports any really serious problems with this mechanism.

Stakeholders and guidance material. All respondent countries involved ministries and regulatory agencies, major licensees, and professionals. Several responses also mention members of the public, but probably the general public was less involved at the time of ICRP 60 than it would be today.

Guidance on the implementation of the ICRP 1990 Recommendations was produced mainly by the regulatory authorities, and to some extent, in a few countries, by professional societies. In most countries, the guidance appears to be largely informal.

Time-scales from proposal to compliance. Table 2 below summarises information regarding 8 countries, extracted from the questionnaires concerning the time of implementation of ICRP 60 in legislation. A ninth country, Slovakia, stated that their regulations came into force only a certain time after they were adopted, but provided no details.

The dates of adoption and coming into force of new legislation are unambiguous, but the starting points of the lead-in times are less clearly defined. Draft legislation was usually the result of discussions with stakeholders which started before any proposed text was released for formal consultation.

Six countries in Table 2 suggested starting dates, at least roughly, but in the absence of direct data for Norway and Spain we assumed that discussions with stakeholders about new legislation started around 1994, based on the following considerations: The first widely publicised indication that significant changes of the fundamental Recommendations of ICRP were to be expected came in 1987,

with the ICRP ‘Como statement’. The revised Recommendations, ICRP 60, appeared in print in 1991. In 1996, Euratom Directive 96/29 made implementation within 4 years of most of ICRP 60 mandatory for European member states.

Table 2. Dates of legislation and lead-in times

Country	First proposal of new legislation	Legislation adopted	Time until being in force	Lead-in time
Australia	1991 (federal recommendation)	1993 to 2002 (different jurisdictions)	0-1 years	3 to 11 years
Canada	Early 1990s	2000	0 years (some requirements 5 years)	9 to 14 years
Czech Rep.	1994	1997	(?)	3 (+?) years
Rep. of Korea	1994	1998	0 years (some requirements 5 years)	4 to 9 years
Norway	(1994?)	2003	2 months (some requirements 3 years)	9 to 12 (?) years
Spain	(1994?)	2001	1 year	8 (?) years
Sweden	1990	1998	2 years	10 years
UK	~1994	1999	1 month (some requirements 5 months)	~6 years

Table 2 shows that total lead-in times for new legal/regulatory requirements appear to have ranged from 3 to about 10 years (or, for selected requirements, even longer). In most countries, the lead time was mainly between first proposal and decision; compliance with new regulations is often required quite soon after adoption of the regulations (although ‘difficult’ requirements are often applied only after an additional delay).

Burdens, benefits, costs. Mandatory cost-benefit analyses of the impact of new regulations were not as common at the time of ICRP 60 as they are now. Cost-benefit analyses of the regulatory impact of ICRP 60 implementation that were performed at the time could be retrieved from Canada and the United Kingdom. These are attached as Annexes B and C, and are summarised below in Section 2.11. None of the respondent countries reported having fully assessed the ‘null alternative’, i.e., the costs, savings, or other implications of not implementing ICRP 60. The Canadian regulator did assess the health implications, but not monetary cost, of the less stringent limit that was selected for pregnant women (cf. Section 2.5).

Regulators and operators agree that the lower dose limits recommended in ICRP 60, compared to earlier ICRP Recommendations, have not caused any significant problems per se. Canada and Sweden reported that increased dose monitoring and upgraded dose registries caused added (but apparently acceptable) costs. Sweden also reported that Diagnostic Reference Levels were perceived as useful

and therefore worth the extra costs; however, DRLs are really an ICRP 73 tool rather than an ICRP 60 issue.

No respondent had identified any reduction of any kind of cost or effort resulting from the incorporation of ICRP 60 into legislation. A lifetime dose limit was introduced in Sweden (and in Germany) in anticipation of ICRP 60. Sweden reports that operators saved some money when a few years later, the Swedish lifetime dose limit was abolished. However, the lifetime limit was never part of ICRP 60.

2.3 Organisation and general implementation of ICRP 103

Legislation and organisation. Most respondents expect to make only minor amendments to their ionising radiation protection legislation/rules if and when ICRP 103 is incorporated in their national systems. If practicable, such amendments are expected to be carried out in connection with ‘regular’ reviews (as was usually also the case with ICRP 60).

Whether this includes changes to Acts of parliaments, or only to government/agency regulations, probably depends more on the national legal system than on the nature of the actual amendments. The federal structure in Australia will lead to varying time frames between jurisdictions. For European member states, the extent of the amendments required can hardly be determined before a revised EURATOM BSS Directive is adopted.

Anticipated amendments frequently include the re-organisation of requirements due to the focus on exposure situations, the new weighting factors, and the added emphasis on optimisation and the use of constraints and reference levels. Several respondents mention new limits on dose to the lens of the eye (technically not a part of ICRP 103, but the new limits, recommended in an April 2011 ICRP statement, were predicted in ICRP 103). Protection of the environment is mentioned only by Spain.

Most respondents expect that the incorporation of ICRP 103 into national legislation will not lead to any changes, or to minor changes only, of the organisation and resources of radiation protection regulators.

A consistency of approach between regulatory organisations will be achieved, where co-ordination is required, by continued contacts along existing mechanisms.

Burdens, benefits, costs. In 7 of the 10 countries that stated whether their regulatory authority expects to perform a cost-benefit analysis of the implications of any new regulations (regulatory impact analysis), such an analysis is a mandatory part of any new rule-making. Korea, Slovakia, and Spain state that they do not plan or expect to provide any cost-benefit analysis.

In a few European countries, an analysis of the ‘null alternative’ (in this case, the costs/savings/implications of not implementing ICRP 103) is regarded in principle as part of a regulatory impact assessment. Nevertheless, there will be little or no analysis of the cost of not implementing ICRP 103 since the updated EURATOM BSS Directive will make ICRP 103 mandatory in member countries.

The cost impact of ICRP 103 and the new EURATOM Directive is expected to be limited, and less than that of ICRP 60. Factors that are expected to have some impact include the new weighting factors provided in ICRP 103, w_R and w_T , and its added emphasis on dose constraints.

The incorporation of ICRP 103 into national legislation could also, in theory, lead to reductions of some kinds of cost or effort. However, little is known as yet about such possible cost reductions. The Slovakian regulator points out that dose reductions can also be regarded as a kind of cost reduction. In Spain, where 5-year averaging of occupational doses is regarded as cumbersome and of little use, it is expected that elimination of such averaging of doses may lead to lower costs.

2.4 Application and scope at the time of ICRP 60

The scope of pre-ICRP 60 legislation. The survey asked whether legislation before ICRP 60 covered all uses and all users of ionising radiation (industrial applications, medical applications, nuclear fuel cycle, research, transport, waste disposal, radon...). In most countries, legislation coverage was comprehensive already before ICRP 60.

Among the exceptions that were reported, some applications were unregulated in some Australian jurisdictions; radon was not covered in Korea; and in Spain ICRP 60 entailed some added requirements on medical and dental services. Australia is the only respondent country reporting explicitly that any amendment to legislation due to ICRP 60 was made in order to close gaps.

Since all sectors were covered already in most countries, there were not many instances of resistance from sectors that had not previously been subject to radiological protection regulations. Some questions were raised by the oil and gas industry in Norway (concerning NORM) and by dental and medical professional organisations in Slovakia (concerning mandatory education and duties in the licensing process). These problems could be solved by explanations and discussions.

Time-frames. In most countries, the time frames for implementation of ICRP 60 were the same, or at least similar, for different sectors. Spain reports that the implementation of regulations for natural radiation sources was delayed by the identification and analysis of sources and development of adequate regulations. In Australia, the time frames differed between jurisdictions.

2.5 Dose limits and dose distribution after implementation of ICRP 60

Historical limits. Before ICRP 60 was incorporated into national legislation, the dose limits in most countries (and certainly those that were EU member states at the time) were in line with ICRP 26, albeit sometimes with additional provisions (e.g., on doses per shorter periods than a calendar year). At least one country, Korea, adhered to ICRP 9.

Current limits. After the implementation of ICRP 60, all respondent countries adhere to the fundamental ICRP 60 dose limits. However, in Canada pregnant workers are subject to a limit on effective dose of 4 mSv for the balance of the pregnancy, while ICRP 60 recommended a limit on equivalent dose to the abdomen of 2 mSv (the 1996 Euratom Directive stated 1 mSv to the fetus).

In most respondent countries, 5-year averaging of occupational doses as recommended in ICRP 60 is an option (albeit only after some kind of special authorisation in several countries). There is a very wide range of experiences of this flexibility, from Sweden where averaging is seen as easily implemented and quite useful to Spain where averaging is regarded as cumbersome and unnecessary (and a corresponding wide range of different opinions about 5-y averaging of occupational doses can be heard in discussions at various international meetings).

Most countries report few or no difficulties, but also that the flexibility is rarely used. Five-year averaging was regarded as important by Canadian and Swedish operators; Swedish nuclear operators also came to consider the lower limits as investments that paid in the longer term.

In contrast, no respondent seems to regard the possibility of 5-year averaging of public doses as important, and at least two countries do not at all permit such flexibility for public doses (Slovakia and Spain). Canada reports a 5 mSv limit for caregivers. This however is not an example of averaging; it is an accommodation to exceptional circumstances which is in line at least in spirit with ICRP 103 thinking (see para. 351).

Transition experience. In all responding countries, information to stakeholders was provided well before the formal implementation of ICRP 60. This permitted operators to adapt to the new limits before they became mandatory and contributed significantly to a smooth transition.

No significant rebuilding requirements were reported. However, in a few countries, more realistic occupancy modelling and/or amended access/occupancy control were used to avoid the need for additional shielding. In Canada, minimal shielding changes were needed in the medical sector, reflecting the frequent application of AECB guidance with design dose limits more stringent than the dose limits following from implementation of ICRP 60. A Swedish medical operator felt that much effort went into the calculations that were required in order to convince the regulator that added shielding was unnecessary. Several operators said that they introduced additional shielding not because of new limits, but as a part of their optimisation of protection.

In the United Kingdom, dose rates at radiotherapy establishments were, and are still, an issue. However, the United Kingdom response to the survey also states that shielding at medical installations was upgraded only in connection with rebuilding for other reasons.

One concern that was raised at the time (and still is raised at times) was that workers exposed to high dose rates might try to evade high recorded doses by ‘forgetting’ to use their dosimeters. However, according to the survey responses, this is not the case; workers in the investigated countries are considered to wear their dosimeters as prescribed.

Resulting doses. Comprehensive reports are usually available concerning nuclear worker doses, at least after ICRP 60. Several countries also have reports on other sectors. In addition to national reports, there are also dose reports from UNSCEAR and, for nuclear workers, ISOE.

In general, doses are reported to be much lower since the implementation of ICRP 60. This general trend towards lower doses is attributed to more rigorous optimisation of radiological protection, and to the discussion, training, and attention to radiological protection generated by the implementation of ICRP 60.

However, there are several variations on the general trend. Thus, Australia reports that doses to miners and to medical staff are reduced, while Norway reports *increasing* doses to medical staff performing interventional procedures (attributed to more patients being treated with radiological rather than surgical procedures, and to more sophisticated equipment).

In Canada, the collective dose to nuclear workers increases (due to more frequent inspections of and refurbishment of older NPPs). The overall trend in Canadian medical occupational exposure has been a decrease since ICRP 60 (due in part to reduced design dose limits at radiotherapy clinics and increased use of brachytherapy afterloading), though some increases were seen in radiology (diagnostic and therapeutic radiologists and physicians) and radiopharmacy.

Sweden points out that dose trends are not linear because planned investments in dose at NPPs (i.e., major refurbishment projects) will achieve later dose reductions. Non-destructive testing staff visiting Swedish NPPs was also getting increasing doses. In the United Kingdom, a factor contributing

to lower doses was the introduction of new mandatory investigation levels of dose. The closure of the last tin mine in the United Kingdom also led to lower average doses.

2.6 Specific technical aspects at the time of ICRP 60

Pregnant workers. When an occupationally exposed worker becomes pregnant, most countries adhere to ICRP 60 (2 mSv to the abdomen) or to the Euratom BSS Directive (1 mSv to the fetus). Canada is an exception in that 4 mSv to the abdomen is tolerated.

Monitoring, modified working conditions, and/or restrictions on entering controlled areas are used as appropriate in all countries to ensure compliance with dose limits. Restrictions for breast-feeding women are mentioned in the Czech and Swedish responses.

All countries except Canada state that the introduction of the 2 mSv limit for the abdomen (ICRP 60) or the 1 mSv limit for the embryo/fetus (Euratom Directive) caused no major problems. However, the smaller, non-nuclear, Swedish operators mention extra costs because it is difficult to find alternative tasks for those concerned.

The one country with significant problems, Canada, neither adopted a 1 mSv fetus limit nor a 2 mSv abdomen limit. The reason given is that female radiation workers protested in view of possible discrimination against them if the ICRP 60 level of protection of the fetus were adopted. However, Health Canada Safety Code 20A recommends that the dose to the surface of the abdomen be kept below 2 mSv for the balance of the pregnancy (=the ICRP 60 level). The medical sector operators report that they have not experienced difficulties meeting this recommendation.

Dose constraints. Six of the 9 countries that responded to this question state that they are now using dose constraints for both occupational and public exposures.

Regulators are using the dose constraint concept only for public exposures in two countries (the Czech Republic and Spain), and not at all in one country (Canada). It is not clear whether some operators in these countries might be using dose constraints for occupational exposures in their internal planning.

Where dose constraints for occupational exposures are used, it took regulators and operators a long time to understand and accept the philosophy; Korea reports that operators are still mistaking dose constraints for additional limits. On the other hand, where dose constraints are now an integrated part of the radiological protection system, they are now considered quite useful.

Regulatory guidance in the United Kingdom points out that dose constraints for occupational exposures are only likely to be appropriate where doses will be a significant fraction of a dose limit. A Swedish hospital considered that it was difficult to assess or measure whether existing shielding was sufficient to comply with dose constraints on public exposure.

Risk constraints. Most countries have not applied formal risk constraints. Regulators in Norway and the United Kingdom report that they can be useful; informal application is reported from Sweden.

Radiation dosimetry. All responding countries require employers to provide workers in controlled areas with personal dosimetry from an approved dosimetry service.

Most countries report that the introduction of ICRP 60 radiation and tissue weighting factors did not lead to any significant problems. The inclusion of internal doses in effective dose is mentioned by Canada and the United Kingdom (although this was recommended already in ICRP 26).

Several operators in Sweden and the United Kingdom confirm that they were able to fit upgrading into their normal calibration/replacement programmes and therefore had no extra costs. However, there are also operator comments from the United Kingdom that they had to wait for new dose-per-intake data [*a similar problem applies to ICRP 103*], and that many published papers used old tissue weighting factors in the absence of comprehensive new data.

Just one country, Canada, reports any significant costs associated with the implementation of the ICRP 60 dosimetric approach (e.g. dose coefficients, modelling, instrument calibration, etc.). The estimated costs were 100k CAD for amendments to the National Dose Registry plus various attendant costs, and initially 5k CAD annually per dosimetry service and some attendant costs. Part of the cost was not 'recoverable' [*i.e., must have been paid by tax- and/or rate payers*].

Radon. There is a wide range of rules and recommendations, from a recommended level of 148 Bq/m³ in public buildings and no other recommendation (Korea) to an absolute limit of 200 Bq/m³ in all buildings (Norway). In most cases, workplaces are treated differently than dwellings; requirements on landlords may also be stricter than those on home-owners. At least in one case (the Czech Republic), state subsidies are available for remediation of unusually high radon levels.

In response to whether the implementation of ICRP 60 caused any new efforts or costs with respect to radon, Spain mentions a lot of work with measurements and development of remediation methods. Most other respondents, including a Canadian operator, do not think that there were significant efforts or costs – at least not due to ICRP 60 (Slovakia and Sweden mention considerable efforts, but also state that those were not directly connected to ICRP 60).

2.7 Specific technical aspects when ICRP 103 is implemented

Pregnant workers. ICRP 103 introduces a limit on equivalent dose to the fetus of 1 mSv during (disclosed) pregnancy, replacing the ICRP 60 limit on equivalent dose to the abdomen of 2 mSv during (disclosed) pregnancy. EU member countries are already subject to the 1 mSv to the fetus limit, because it is prescribed in the current EURATOM BSS Directive.

Four of the countries surveyed are not EU members. Of these, Korea and Norway state explicitly that the new limit is not expected to cause any problems or costs, and Australia has not provided any comment. However, Canada states that their current limit on equivalent dose to the abdomen, 4 mSv, has undergone two major consultations and that therefore, it is not anticipated that the Canadian limit will be changed – i.e., Canada expects to continue to deviate from ICRP Recommendations in this respect.

Dose constraints. ICRP 103 adds emphasis to the use of dose constraints. According to the survey results, this is expected to generate some difficulties in Canada and Spain, where constraints have had little or no use so far, and for waste disposal in the United Kingdom.

In Korea, where operators sometimes tend to mistake constraints for limits, the regulator resolved some difficulties by recommending constraints in a non-mandatory guide. No difficulties, or only limited problems, are expected in countries already using ICRP dose constraints (the Czech Republic, Norway, Slovakia, Sweden, and United Kingdom). The Swedish NPP operator is outright enthusiastic.

Risk constraints. Norway and the United Kingdom were the only respondent countries that reported some degree of formal application of risk constraints after ICRP 60.

ICRP 103 re-iterates the concept briefly and confirms that the generic constraint levels suggested in ICRP 76 are still recommended as starting points for national decisions. However, none of the remaining countries is firmly committed to introducing formal risk constraints due to the implementation of ICRP 103.

Dosimetry. No country seems to expect serious difficulties due to the new radiation and tissue weighting factors in ICRP 103. However, Korea and the United Kingdom mention that there are technical computation problems which may take some time to resolve.

Radon. The views on whether the implementation of ICRP 103 will cause any new efforts or costs with respect to radon differ widely. Replies received range from ‘no efforts/costs’ via ‘not yet known’, ‘miners want new dose coefficients but have expertise in-house’, and ‘there will be costs, but not due to ICRP 103’ to ‘yes, there will be significant efforts and costs’.

2.8 Training at the time of ICRP 60

Regulators. All respondents describe extensive internal training programmes, using people with first-hand experience of ICRP and EURATOM discussions if possible and sometimes including participation in international meetings. A stratified approach in Sweden included a brief and simple introduction for everyone including support staff.

The survey did not reveal many problems associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping/reporting. The use of non-SI units in some Canadian installations caused and still causes confusion. The contribution of skin dose to effective dose was a source of some discussion in the United Kingdom.

So as to ensure that stakeholders were aware of and understood the new legislation, all responding regulatory bodies participated in training and information of licensees, users of ionising radiation, and employers of radiation workers. Written guidance material was produced, there were joint meetings with large licensees and with professional bodies representing smaller licensees, regulator staff gave lectures, etc. Many regulators also mention open meetings and other activities aimed at the general public. The Swedish NPP operator also provided information to the public [*and probably many other large operators did so too*].

Stakeholders. All respondents refer to extensive internal training programmes at operators. Most of this was integrated into operators’ existing training and information schedules, but the Swedish hospital interviewed had to spend additional efforts.

2.9 Training when ICRP 103 is implemented

Regulators. In order to ensure that relevant members of staff are aware of and understand the revised legislation, most respondents expect to carry out much the same kind of training programme as with ICRP 60.

No significant problems are expected with the implementation of new terminology, dose coefficients, calculation methods or record keeping/reporting. The United Kingdom mentions that the term ‘representative person’ will need careful explanation.

All regulator respondents expect to participate in stakeholder involvement. Basically, the same procedures as with ICRP 60 are envisaged, but some countries mention that internet technology (not available at the time of ICRP 60) will facilitate this significantly.

Stakeholders. Respondents expect that operators will be able to fit the training into existing programmes. This is also the opinion of the Swedish hospital where training for ICRP 60 required more effort. A caveat, that the imminent EURATOM Directive may change conditions, is added by the United Kingdom.

2.10 Additional comments from survey respondents

Achieving consensus and compliance. Australian operators regard ARPANSA documents as binding, even when this is not strictly the case. When possible, and particularly in the medical area, ARPANSA works through professional bodies – this is time-consuming but worth the effort. In Sweden, there is a clear tradition of constant improvement based on operator-regulator collaboration. Swedish nuclear operators will accept extra costs if these increase safety and/or reduce doses; the health care sector is also keen on collaboration but cost becomes an issue more often.

Cost estimates. In the Czech Republic, ICRP 60 was implemented at a time of considerable political change with much more profound changes to legislation, so the costs of ICRP 60 were regarded as trivial. Further major changes to legislation are expected at the time of ICRP 103 implementation so specific costs of ICRP 103 will be difficult to project. Slovakia points out that legislation, supervision, and licensing, all through the Public Health Authority, are supported financially by the Ministry of Health.

Impact of ICRP 103 on medical practice. The Canadian hospital respondent expects minimal impact on current medical practice. However, doses to patients (apart from those due to device malfunction) are not addressed in legislation so standards for patient doses provide guidance for practitioners only. Should the regulatory framework be changed to include patient doses, this will have considerable impact.

2.11 Regulatory impact assessments for ICRP 60 implementation

Canada. Annex B comprises a Canadian Regulatory Impact Assessment Statement concerning the Nuclear Safety and Control Act which established CNSC as the regulator for nuclear and radioactive materials and incorporated ICRP 60 for this sector (i.e., the assessment does not cover the impact of ICRP 60 implementation on users of x-ray equipment etc.). The Canadian analysis was subjected to public consultation and the amended version attached as Annex B includes corrections resulting from the consultation. The 2001 population of Canada was 31M people.

The overall costs were estimated to be:

- (a) Once-for-all cost to implement new requirements: 5.9M CAD of which 46% for new security requirements (i.e., about 3.2M CAD for other new requirements than those relating to security);
- (b) Annual incremental cost due to the new requirements: 4.5M CAD of which 56% for new security and 22% (990k CAD) due to ICRP 60 dose limits;

- (c) Training of CNSC staff: direct costs 370k CAD per year for 3 years (covered through re-allocation of existing funds), plus staff time corresponding to 9 full-time employees per year for 3 years (also covered by re-allocation).

United Kingdom. Annex C comprises a UK cost-benefit assessment concerning the revised Ionising Radiation Regulations (IRR 99) that implemented most of EURATOM Basic Safety Standards Directive 96/29, and thereby incorporated ICRP 60. The United Kingdom analysis is the original version, intended to be subjected to public consultation. It is not clear whether the consultation resulted in any amendments. The 2001 population of the United Kingdom was 59M people. In January 2000, 1 GBP corresponded to about 2.35 CAD.

The overall costs were estimated to be:

- (a) Once-for-all cost to implement new requirements: 839k GBP (about 2M CAD) of which 78% to operators and 12% to the regulator;
- (b) Annual incremental cost due to the new requirements, including salary costs: 1.2M GBP (about 2.8M CAD) of which 99.7% to operators and 0.3% to the regulator;
- (c) Some additional, unquantified but probably small, costs.

2.12 Cost-benefit background, EURATOM BSS Directive (implementing ICRP 103)

Dr Augustin Janssens of the European Commission has kindly provided a collection of background data which will be used as the basis for a cost-benefit analysis concerning the planned revision of the EURATOM BSS Directive (and some additional Directives). The new Directive will implement most of ICRP 103 in European Community member states.

This background material is attached as Annex D. It does not provide any immediate information about costs or benefits of ICRP 103, but it may be useful as a reminder concerning relevant factors when others are preparing cost-benefit assessments.

2.13 Other information obtained

French NPP operator on ICRP 60. Annex F comprises a ‘White-book on radiological protection’ produced by a large French NPP operator in 1993 in response to ICRP 60, with a view to Chernobyl, and anticipating the 1996 EURATOM Basic Safety Standards Directive.

At the time, individual annual worker doses in the operation were increasing due to aging plants, while ICRP 60 recommended lower dose limits. The document aims to show the commitment of top management to continuous improvement of radiological protection, the goals in terms of future doses, and the plans on how those goals were to be attained.

ISEMIR observations on personal dosimetry. We have had informal discussions with Dr John Le Heron of IAEA concerning the Working Group on Interventional Cardiology of ISEMIR, the Information System on Occupational Exposure in Medicine, Industry and Research. He has discovered that in some countries, regulatory bodies may not be the best source of dose data, and in some countries, compliance with wearing dosimeters is an issue. This has a bearing on our questions concerning dose distributions after ICRP 60 and also burdens, benefits, and costs.

3. ANALYSIS

3.1 Limitations of the study

Sample size. The survey is far from all-inclusive, but it does include many different kinds of country from four continents, ranging from very small to very large, some with a federal structure, and with different cultural and economic conditions. Thus, the range of countries surveyed is probably sufficient to provide a reasonable basis for conclusions.

Respondent types. Most replies were received from regulators, but only from one regulatory body in each country (often, a nuclear regulator) even though the regulatory duties concerning radiological protection are shared between different agencies in most of the countries surveyed. The replies may therefore be biased towards conditions in the nuclear sector.

Perhaps the most serious drawback is that we have relatively few replies from operators. Still, there are questionnaire replies from NPP operators in three countries (plus a somewhat pertinent document from an NPP operator in a fourth country), from big medical establishments in three countries, and from a rather big non-destructive testing organisation in one country. Furthermore, the replies from operators of a particular kind are relatively consistent between countries, and in reasonable agreement with the views of the regulator in their own country. We have no replies from small operators; on the other hand small operators are unlikely to be licensed to use major radiation sources.

3.2 The process of implementing ICRP Recommendations

Organisation and legislation. There are vast differences between countries, but the differences do not seem to cause any significant problems in the implementation of ICRP Recommendations. The time-scales may vary between sectors (if subject to regulation under different laws) or between jurisdictions in federal countries; some planning may be required to avoid problems due to this.

Consultation and time-scales. All countries surveyed report considerable efforts on achieving 'buy-in' through careful, comprehensive, and unhurried consultation at the time of ICRP 60. The lead-in times from first proposal to legally binding requirements were often long (up to 10 years or, for specific requirements, even longer). This allowed licensees to adapt their operations in an orderly manner and certainly contributed to the successful implementation of ICRP 60; a similar approach is envisaged for ICRP 103 and will undoubtedly simplify the implementation.

Training. This is an important part of the implementation process and requires time and effort both within regulatory bodies and for operators. Again, long lead-in times were important to ensure that sufficient training could be provided at the time of ICRP 60, and not least, that it could be arranged as part of normal existing training programmes so that it did not necessitate significant extra expenditure.

3.3 Costs and benefits

Questionnaire responses. Regulators and licensees appear to agree that the resources needed to implement ICRP 60 were reasonable and included investments that led to lower costs in the long run.

For instance, much of the dose reduction required at nuclear installations was achieved simply by better advance planning of tasks, which also led to cost savings. Investments to achieve lower dose rates at crucial locations in the plants quickly paid back because they permitted safety-related jobs to be performed by fewer and less worried staff working longer hours.

Formal analyses. Cost projections are performed in most countries, and by the European Commission, before the introduction of new legislation/regulations. However, such documentation from the 1980s concerning ICRP 60 does not now seem to be easily retrievable. It was also hinted to us that perhaps the reliability of those projections was limited.

Two formal cost-benefit analyses of the impact of implementing ICRP 60 were obtained, from Canada and from the United Kingdom. It might be argued that these could be used to predict costs in other countries. However, we consider that there are a number of reasons why any extrapolation from these analyses to present-day costs in other countries is likely to be invalid.

For instance, the costs listed in the Canadian analysis refer to nuclear and radioactive materials operators and their regulator, not to all uses of ionising radiation (x-ray machines and similar devices and their use are regulated under other Canadian legislation). Furthermore, the estimates include other costs than those resulting from ICRP 60. The analysis indicates the proportion of the annual incremental cost regarded as attributable to the new dose limits, but it would be difficult to assess the costs attributable to other new aspects in ICRP 60.

In both countries, incorporating ICRP 60 in connection with planned other amendments to legislation will have reduced costs, compared to an update solely and specifically to take account of ICRP Recommendations. Taking the different population sizes into account, the total costs projected in the two countries are, very roughly, in the same order of magnitude (although it is not self-evident that costs are linearly related to the population size – for instance, the much larger area of Canada may well affect costs).

Extrapolating costs from these assessments is not straightforward, even if it were assumed that they provide a correct and comprehensive picture of the actual costs (and we are by no means convinced that they do). With hindsight, it appears unlikely that the costs were really as high as projected in those analyses. For instance, the annual costs in real terms supposedly remained constant forever – in reality, operators and regulators probably found ways to streamline procedures and render them more efficient, resulting in diminishing costs.

Furthermore, neither analysis appears to have given a realistic view of the benefits and savings resulting from the implantation of ICRP 60. The UK analysis correctly noted that health benefits were expected to be small since most doses were already below the new limits. However, focusing on health effects the analysis overlooks other beneficial effects. Judging from the response by the Swedish NPP operator, the positive effects on working conditions, efficiency, and hence economy, were considerable. This is at least not contradicted by the white-book from the French NPP operator.

Also, neither of the two analyses provides a realistic estimate of the cost of the ‘null alternative’ of not implementing ICRP 60. For instance, radiological protection is an international science, and different rules in different countries would inevitably lead to added costs for operators (and probably to strained labour relations).

French NPP operator on ICRP 60. While the EdF ‘White-book’ does not contain any cost assessments, it is interesting in the present context because it emphasises the operator’s conviction that it would make sense to comply with ICRP 60 – even though they doubted the scientific validity of the

ICRP model of risk at very low doses. This was because the primary objective of ICRP 60 was to improve radiological protection, because there was international consensus, and because optimisation of radiological protection also led to improved efficiency.

These observations by the French operator are in line, we feel, with the Swedish NPP operator's positive attitude to optimisation. An NPP operator will not necessarily be convinced that improved radiological protection is needed because of radiation risk considerations, but improved radiological protection will be good for the operation as such and therefore it can be regarded as an investment rather than just a cost.

3.4 Dose limits

Five-year averaging. Averaging of occupational doses is the issue where we encountered the most diverging views, from those who regard the five-year averaging as indispensable and very useful, to those who feel that it is costly and a meaningless burden. The dividing line is not primarily between regulators and operators, nor between different kinds of operators – the main difference is between countries, and the hottest arguments on both sides appear to come from operators.

Broadly speaking, it is in the nuclear industry that averaging may take place. Operators who are in favour of averaging do not primarily argue that they need to expose workers to more than 20 mSv in a year, but that planning for, say, 18 mSv they want to be sure that a deviation from plan leading to 21 mSv is not an infraction as long as they adapt next year's plan accordingly. Operators in favour of strict application of a flat rate of 20 mSv per year quote costs of cumbersome record-keeping as an important factor.

There are various conceivable reasons behind these variations. We have encountered explanations based on different reactor technologies and on different national registration systems; there may well be other and perhaps more important issues. In any case, it seems desirable that international agreements leave the option of averaging of occupational doses open while national legislation may include or exclude this option, depending on local conditions and preferences.

The possibility of averaging of doses to members of the general public seems never to have been used and is not, as far as we can understand, desired by any respondent in our survey.

Pregnancy. Rules aimed at protecting the unborn child will inevitable cause more discussions concerning working conditions for females than for males. If this makes employers less keen in hiring women, it leads to a conflict of interest between the rights to equality of the female workforce and the health of the unborn child.

Most countries adhere to ICRP Recommendations (or EURATOM Directive rules aiming at the same level of risk), and their experience is that keeping doses below pertinent levels does not pose major technical problems. It is essentially a labour relations issue to ensure that female workers are not deprived of their rights because of the limit on dose during pregnancy.

Canada however has adopted a higher (less restrictive) dose limit. It thus gives more emphasis through legislation to equality of female workers, even though the country is often regarded as strong on civil rights anyway. On the other hand, below the formal limit there is a Health Canada recommendation to keep doses at the ICRP 60 level. Since the medical sector has not experienced any difficulty in following this recommendation, they do adhere to ICRP 60 in practice.

3.5 Constraints on optimisation

Constraints are tools provided for operators to use in optimisation. In the context of occupational exposures, ICRP expects operators to take full responsibility by setting their own constraints, and operators may be using constraints even if this is not prescribed by the regulator.

Dose constraints. There is a considerable range of views on the utility or otherwise of dose constraints in occupational exposure situations. In countries where dose constraints in the ICRP sense are already in use, the tool is now regarded as useful in optimisation (although ICRP may have been less than lucid when explaining it) and valuable as a means to confer responsibility on operators.

Other countries express their reservation, perhaps because they envisage or are already using something else: a constraint on dose, perhaps set by the regulator, which would act as an additional limit. Such an alternative constraint may well be a useful regulatory instrument, but it is not the ICRP constraint on optimisation.

In the occupational context, sometimes the lowest collective dose is achieved if a few workers get a fairly high individual dose. This causes a conflict of interest between the interest of individual workers and the interest of society (or at least all concerned workers). The most common purpose of using a dose constraint in occupational contexts is to add protection of the individual (as prescribed by deontological duty ethics) while strict minimisation of collective dose protects society and emphasises utilitarian consequence ethics. The choice of dose constraint decides the balancing of duty versus consequence ethics. At the same time, since operators are supposed to make the choice, it encourages them to assume more responsibility.

In the context of public exposure, ICRP dose constraints on optimisation more frequently serve the purpose of ensuring that the combined exposure from several sources remains acceptable. This usually requires that the dose constraint is set by the regulator. Such use of constraints in public exposure contexts is more unanimously accepted and seems to cause less confusion.

Risk constraints. As yet, few countries are using formal risk constraints. The United Kingdom does use risk constraints, which is in line with ICRP experience: ICRP 76 provides genuine (albeit simplified) risk constraint calculations as applied by actual operators, with a UK cyclotron as one example.

Another ICRP 76 example concerned a Canadian irradiation installation where the operator had set a risk constraint. The Canadian regulator answering the questionnaire reported that risk constraints are not used formally; this may reflect that large operators use risk constraints even if not required formally to do so, or irradiators may be regulated by another agency.

3.6 Other technical issues

Dosimetry. At the time when ICRP 60 was presented, several dosimetrists expressed concern over the regulatory review needed and the costly upgrading of instruments required. The survey results show that with the ample time that was permitted for the transition, there were no serious problems. Instrument upgrading could be handled as part of the normal replacement programmes and thus did not cause extra costs. However, it does remain a problem that ICRP did not produce, and still has not produced, all of the necessary new dose coefficients at the time when ICRP 103 was published.

A somewhat different source of concern was that lower (stricter) dose limits would tempt workers with high doses to avoid wearing their dosimeters, for fear of exceeding dose limits and thereby incurring unwanted consequences for themselves and/or their employers.

The survey results do not support this assumption; respondents who commented on this issue were adamant that workers in the countries surveyed are wearing their dosimeters as prescribed. However, the situation may be different in other countries. Based on the ISEMIR study mentioned above, John Le Heron of IAEA was not surprised that we had not noted any serious problems in the health care sector in the countries we studied. However, he had observed different attitudes towards radiological protection issues and methods, including the proper use of dosimeters, in some other countries.

Radon. The projected costs vary widely, as expected since the potential for radon problems differs a lot between countries. A more semantic issue is that ICRP 103 did not really say anything new about radon; instead, amended recommendations are given in a November 2009 ICRP Statement. Thus, if there are any problems, strictly speaking they are not due to ICRP 103.

Shielding. Where ICRP 60 is not yet implemented, concern has been expressed repeatedly that the new dose limits might lead to calls for extremely costly and not very meaningful ‘back-fitting’ of improved shielding, particularly at radiotherapy installations.

Our survey results do not indicate that this has happened. In most cases, existing shielding proved to be sufficient when realistic occupancy factors outside the shielded area was applied and/or suitable access control was imposed. Several respondents mentioned added shielding in other contexts than radiotherapy (other medical, nuclear, and industrial uses), but in most cases the cost seems to have been acceptable. At least one respondent also mentions the availability of new shielding materials.

4. CONCLUSION

Little quantitative information about the cost of implementing ICRP 60 is available. The qualitative information obtained indicates that in most countries, the costs were regarded as relatively modest (or at least tolerable), both by regulators and (after some initial concerns) by operators.

Important factors contributing to this relatively sympathetic perception of the ICRP 60 implementation costs include, e.g.:

- Considerable lead-in times (up to 10 years or more from initial discussions to legally binding obligations), permitting ample time to explain the recommendations and allowing licensees an orderly and timely re-organisation of their operations;
- Considerable efforts on information, discussions, training, and consultation with licensees and professionals before any binding decisions were taken (however, the efforts involving the general public were often less comprehensive than probably expected today);
- At least some stakeholders felt, after the comprehensive consultations, that the recommendations ‘made sense’;
- Legislation and regulations were often updated in connection with scheduled revisions for other reasons rather than ‘ad hoc’, thus reducing the administrative costs;
- In some cases, costs were balanced in part by savings due to improved working conditions in areas with high radiation levels;
- Constructive discussions (e.g., on realistic modelling of shielding requirements) between regulators and operators evaded some costs that had initially worried operators.

The cost of implementing ICRP 103 is expected to be even less where ICRP 60 is already implemented, since the nominal risk and the dose limits remain essentially unchanged.

However, there may be cultural differences that were not revealed by the survey. The respondent countries have a tradition of participation in international work, including ICRP; some countries may not be as involved.

Furthermore, the regulatory system in some of the countries surveyed fosters a mutual trust that may not be as evident in some other countries. As an example, some nuclear licensees interviewed in the survey claimed that they pride themselves of being ‘ahead of the regulator’. Operators in some other countries may be more keen to question any new regulatory requirements, at least until a level of mutual trust can be achieved between regulators and operators.

5. REFERENCES

This list comprises such documents, cited in the questionnaire replies, the bibliographical details or provenance of which may not be immediately obvious (i.e., ICRP Publications and Euratom Directives, which will be well known to readers of this report, are not listed here). Copies of the documents are available at the NEA Secretariat.

Ca1. C-122 “Proposed Amendments to the Atomic Energy Control Regulations for Reduced Dose Limits Based on the 1991 Recommendations of the International Commission on Radiological Protection”, July 15, 1991.

Ca2. “A Report on the Effect of the Proposed Amendments to the Atomic Energy Control Regulations (Consultative Document C-122) on the Ontario Cancer Treatment and Research Foundation”, Doug Wyman m PhD – Hamilton Regional Cancer Centre and Doug Salhani, PhD – Ottawa Regional Cancer Centre.

Ca3. Amy Hicks, CNSC , “Canadian Regulatory Perspective – ICRP-103 Recommendations”, presented on January 12, 2010 at the ISOE North American ALARA Symposium/EPRI Radiation Protection Conference.

Ca4. Denis Brown, BB Health Physics Services, Regina SK, “Possible Impact of ICRP 60 on Medical Practice”. Website: accessed on Sept. 2, 2011.

Ca5. Atomic Energy Control Board – “Dose Limits for Pregnant Workers: Rationale for the Limits in the Radiation Protection Regulations”, INFO-0700(E), January 1999.

Ca6. Dave Wilkins, The Ottawa Hospital Cancer Centre (TOHCC) trend: exposure to radiation therapists from training materials presented by Dave Wilkins, Radiation Safety Officer, TOHCC.

Ca7. Jon Aro, Medical Health Physicist, The Ottawa Hospital (TOH), “An Investigation of Trends in Occupational Doses for Radiologists and Physicians at The Ottawa Hospital”, presented at the Canadian Radiation Protection Association Annual Conference, May 2011.

Ca8. Marc Lamoureux, TOH affiliate University of Ottawa Heart Institute trend: exposure to cyclotron staff from report prepared by Marc Lamoureux, Medical Health Physicist, The Ottawa Hospital (currently working at Health Canada).

Ca9. Atomic Energy Control Board – “A Guide to Applicants for Medical Accelerator Licence”. Document AG-5.

UK1. HSC, The Ionising Radiations Regulations 1985, Statutory Instruments No. 1333, HMSO 1985.

UK2. HSC, The Ionising Radiations Regulations 1991, Statutory Instruments No. 3232, HMSO 1991.

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ANNEXES

A. Summary of the survey responses

Responses were obtained from regulatory authorities and operators / licensees. Note that responses are abridged here; for complete and unedited replies, please consult the individual questionnaires in Annex E.

Part A: incorporating ICRP 60: Key impacts/provisions

A1. General
<i>Legislation</i>
<p>Question A1.1: Please describe briefly the hierarchy, if applicable, of ionising radiation protection legislation/rules in your country, e.g. national law, national government regulations; central authority regulations; regional or local authority regulations; other (e.g., professional body) rules. Also, please briefly describe what is covered at each level.</p>
<p><u>Summary</u></p> <p>All respondent countries have national Acts of Parliament providing a platform for radiological protection, and delegating regulatory power to their government. In about half of the countries, the government delegates the right to issue binding regulations to the regulatory (licensing) authority/ies. Codes of practice and guidance are issued by regulatory authorities and at least in one country (UK) also by professional/trade bodies.</p> <p><i>Range of responses:</i></p> <p><u>Australia (AU)</u></p> <p>Each of the eight States and Territories in Australia has its own radiation control legislation, some dating back to the 1950s. ARPANSA was established by the ARPANS Act in 1998 to regulate Commonwealth government entities (e.g. Defence) and given the function of promoting national uniformity of radiation protection and nuclear safety policies and practices. ARPANSA then became the ninth jurisdiction with its own legislation applicable to government bodies.</p> <p>There are no national laws governing radiation protection. Each jurisdiction has a radiation control (or similarly named) Act and Regulations. Some of these explicitly exclude mining and so in those jurisdictions there is separate legislation for that. There is also the Environment Protection and Biodiversity Conservation Act 1999 (EPBC Act) which covers matters of national environmental significance and covers anything that constitutes a 'nuclear action' under that Act (e.g. siting of waste repository). The National Directory for Radiation Protection (NDRP), published in August 2004, whilst not legislation, establishes a uniform national framework for radiation protection. The regulatory elements are adopted in each jurisdiction as opportunity arises, using existing Commonwealth/State/Territory regulatory frameworks. It has the following parts: (Part A) - sets out the agreed overall framework for radiation protection in Australia. It is expected that jurisdictions will adopt these principles as reviews of legislation come forward. (Part B) - contains the uniform regulatory elements, which are to be adopted by each jurisdiction, within its particular regulatory framework. (Part C) - contains guidance that will assist regulators in adopting consistent approaches, but is not regulatory in nature.</p> <p><u>Canada (CA)</u></p> <p>The Canadian Nuclear Safety Commission regulates the use of nuclear energy and materials to protect the health, safety and security of Canadians and the environment; and to implement Canada's international commitments on the peaceful use of nuclear energy.</p> <p>CNSC was established in 2000 under the <i>Nuclear Safety and Control Act</i> and reports to Parliament through the Minister of Natural Resources. CNSC was created to replace the former Atomic Energy Control Board (AECB), which was founded in 1946.</p>

Another federal body, Health Canada, is responsible for the regulation of non-ionizing radiation, radon, and x-rays. In addition, there are provincial/territorial authorities who set requirements. It should also be noted that the Department of National Defense regulates their own activities which involve ionizing radiation and these activities do not fall under the jurisdiction of the CNSC.

Czech Republic (CZ)

Atomic act (No 18/1997 Coll. as amended) – covering position and competences of State office for nuclear safety (as national regulatory body on the field of nuclear safety and radiation protection) and rights and obligations of licensees and other persons involved in this field.

Regulations issued by State office for nuclear safety: Radiation protection regulation (No 307/2002 Coll. as amended) – covering details on handling and other related activities with ionizing sources and radioactive waste, including medical exposure, natural sources etc.

Other regulations (on type approval of sources, qualification and training etc.)

Recommendations issued by State office for nuclear safety (not binding): methodologies and procedures specific for different types of sources and workplaces.

Iceland (IS)

Legislation passed by parliament and regulations by the ministry followed by guidelines by the regulator. Regulator prepares proposals for new legislation and regulations.

Korea (KR)

Atomic Energy Act, Enforcement Decree of the Atomic Energy Act, Enforcement Regulation of the Atomic Energy Act, Regulations on Technical Standards for Nuclear Reactor Facilities, Regulations on Technical Standards for Radiation Safety Control, Ministries Notices for Radiation Protection, etc.

Act on Physical Protection and Radiological Emergency, Enforcement Decree, Enforcement Regulation, and related Ministries Notices.

Medical Act, Enforcement Decree, Enforcement Regulation, and related Ministries Notices.

Norway (NO)

Law about radiation protection and use of radiation (national parliament).

Regulation about radiation protection and use of radiation (central authority – ministry).

Several guides for different topics (national authority – NRPA).

Slovakia (SK)

Act on public health protection.

Governmental Ordinances implementing pertinent Euratom Directives: on Basic Safety Standards; on medical exposure; on protection of outside workers; on control of high-activity sealed sources and orphan sources.

Regulations of the Health Ministry: on radiation monitoring network; on natural radiation; on requirements on practices and activities important from the radiation protection point of view.

Slovenia (SI)

The Ionising Radiation Protection and Nuclear Safety Act (IRPNSA) defines responsibilities and prescribes further regulation (decrees which deal with specific topics). This set of decrees is divided into governmental decrees (use of radiation, allowed levels of radioactivity in the environment, workplace and food & feedstuffs, nuclear matters), decrees from the Ministry of environment (use of sources, workers and expert qualification, rad. waste, operational safety, radioactivity monitoring, shipment of rad. and nuclear materials), decrees from the Ministry of health (use of sources – together with env. ministry, use of radiation in healthcare, dose assessment for population and workers and surveillance for workers, workers and expert qualification, use of KI in case of nucl. accident) and decrees from the Ministry of interior (mostly physical protection).

Spain (ES)

National Law: Very short and general requirements included in Nuclear Energy Act.

National Government Regulations: This is the main regulatory tool. More than twelve Royal Decrees were issued to incorporate into national regulations EU Directives related to radiation protection.

In addition some binding technical regulations were issued by the regulatory authority (CSN) which also issued guidance. These two types of regulations / guidance are to further develop requirements in Royal Decrees to a very detailed level.

Sweden (SE)

The regulatory system is mostly performance-based rather than prescriptive. Laws and government ordinances focus on principles while numeric values are mostly given in authority regulations. The Radiation Protection [licensing] Act aims 'to protect people, animals and the environment against the harmful effects of radiation'. Nuclear installations are licensed according to the Nuclear Technology Act but with some licence conditions according to the RP Act.

Through the Radiation Protection Ordinance, the government authorises the Radiation Safety Authority (SSM) to issue licenses and detailed regulations (radon is regulated by other agencies in consultation with the SSM). The Ordinance also lists exceptions from the RP Act and permits the SSM to issue further exceptions if they agree with the intentions of the Ordinance.

The Regulations of the SSM include general rules on Dose Limits, Discharge Authorisations, etc., as well as specific ones, non-technical ones, and numerous ones on non-ionising radiation.

UK

National law made by Parliament:

Primary legislation (overarching provisions, such as The Health and Safety at Work etc Act 1974 (HSWA) which set out a broad framework for all occupational health and safety);

Secondary, risk, sector or topic specific legislation (such as the Ionising Radiations Regulations (IRRs) made under HSWA, supported where necessary by Approved Codes of Practice (quasi legal status).

The IRRs allow the regulatory authority (the Health and Safety Executive (HSE)) to grant exemption certificates for specific purposes.

Non- statutory guidance may be provided by the regulatory authority or by professional/trade organisations.

Organisation

Question A1.2: Describe the different authorities, and (approximately) how many regulators are involved in making and enforcing radiation protection legislation? Also, if appropriate, please briefly describe how consistency of approach between regulatory organisations is achieved?

Summary

Many countries have more than one regulatory authority with responsibilities divided in different ways (health care vs. other sectors; nuclear vs. other sectors; federal vs. state levels; etc.). Consistency is achieved through consultation and Memoranda of Understanding between the agencies concerned. The replies do not permit an analysis of the number of staff involved in different countries.

Range of responses:**Australia**

Regulatory duties are performed both at the national level, through ARPANSA, and at the state/territory level. States/territories are fairly 'strong' and independent. State regulators are usually either in/under the health or the environment departments; at least two states have two regulators (in the health area and in the mining area). For consistency, see A 1.1 above.

Canada

Federally, the CNSC is the responsible authority for regulating the use of nuclear substances or the operation of nuclear facilities. Health Canada is the federal authority for regulating the use of non-ionizing radiation and x-rays. Provincial authorities (there are 10 provinces and three territories) provide the necessary oversight in radiation protection practices in their jurisdiction. Generally speaking, Health Canada approves x-ray devices and the provinces regulate their use.

Department of National Defence is responsible for the regulation of their own activities related to nuclear substances and devices.

Consistency of approach is achieved through communication. In addition, there is a 'Federal/Provincial/Territorial Radiation Protection Committee whose mission is to advance the development and harmonization of practices and standards for radiation protection within Federal, Provincial and Territorial jurisdictions. The committee meets annually to discuss common concerns with the objective of aligning practices and regulations. In addition, there are memorandums of understanding between the federal bodies which formally document the linkages and respective responsibilities of each party.

Czech Republic

The State office for nuclear safety is the main regulator (an independent authority subordinated directly to the government). Some issues interfere with other departments; especially medical exposure is partly covered by the Ministry of health.

Consistency is achieved on the practical level through sharing findings, results and experiences and on the legislation level through mandatory comment procedures during law and regulation making process (guaranteed by the governmental legislation council).

Iceland

Geislavarnir is the regulator.

Korea

MEST(Min. of Education, Science and Technology)/KINS(Korea Institute of Nuclear Safety) and MHW(Min. of Health and Welfare)/KFDA(Korea Food and Drug Administration). MEST/KINS have ~500, MHW/KFDA ~500 employees.

MEST/KINS are the first to implement ICRP recommendations, MHW/KFDA follows.

Norway

NRPA: 100 persons totally, 20 involved in regulatory/inspection work.

Slovakia

The Ministry of Health; the Public Health Authority of the Slovak Republic (staff of radiation protection department 20 persons); four Regional Public Health Authorities (with 5, 2, 12, and 10 RP staff).

Slovenia

2 authorities: the Slovenian Nuclear Safety Administration (SNSA) and the Slovenian Radiation Protection Administration (SRPA). SNSA is responsible for the nuclear safety, industrial sources and protection of the environment, SRPA for protection of workers and population. In the cases where interests overlap, both bodies are usually involved.

Spain

Public, occupational and environmental Radiation Protection: the Industry Ministry, regional Industry Authorities, the Consejo de Seguridad Nuclear.

Radiation Protection of patients: the Health Ministry, regional Health Authorities.

In each case, the authority in charge of making regulations is also in charge of enforcement.

In every case regulations establish functions and responsibilities for each one of these authorities as

well as the relationship between the different authorities. Those relationships vary from demanding or receiving official binding reports to an open co-operation.

Sweden

The Environment Ministry has some 2 staff involved in RP. The Radiation Safety Authority, SSM, which deals with RP and nuclear safety and security, has almost 300 employees. The SSM delegates some enforcement to the ~290 municipal Environment & Health Protection Boards.

Some regulations concerning radiation are issued by other authorities: The Board of Health and Welfare (SoS) issues advice on radon in existing dwellings, the Board of Housing, Building and Planning (BoV) issues binding regulations on radon in new dwellings, and the Work Environment Authority (AMV) issues binding regulations on radon at workplaces. Other collaborating authorities include, e.g., the Food Administration (SLV) and the Medical Products Agency (LV). Each of these authorities has a handful of people working with radiation issues. Consistency is achieved through consultation with the SSM and formal policy agreements.

The establishment of large installations causing radioactive discharges is also processed in an Environmental Court (5 in Sweden). Decisions there take account of, but are not necessarily consistent with, evidence given by the SSM.

UK

For implementation of the 1996 BSS Euratom Directive, over 12 different government departments and agencies were involved (Health and Safety Commission/Executive; National Radiological Protection Board; Dept. for the environment, food and rural affairs; Environment Agency/Scottish Environmental Protection Agency; Northern Ireland Depts; Gibraltar; Food Standards Agency; Health Depts; Dept. for Trade and Industry; Dept. for Transport). Consistency is achieved by Memoranda of Understanding/Agreement and liaison meetings at appropriate levels, where necessary.

ICRP 60 incorporation (1/2)

Question A1.3: To what extent were legislation and regulations rewritten when ICRP 60 was incorporated?

Summary

All countries revised their laws and regulations after 1990 but rarely as a direct result of ICRP 60; instead, when laws were updated for other reasons, they were also amended to take account of ICRP 60 and facilitate the adaptation of regulations to ICRP 60. Member States of the European Union were required to implement a Basic Safety Standards Directive, made under the Euratom Treaty, that had been revised to take account of ICRP 60. The similarly revised Basic Safety Standards of UN and other international organisations were not generally binding but constituted an incentive for all countries to implement ICRP 60.

Range of responses:

Australia

Considerably.

Canada

ICRP 60 was incorporated into regulations when the CNSC was established in 2000 under the *Nuclear Safety and Control Act and Regulations*. Note that the establishment of the CNSC and the Act were not initiated as a result of ICRP 60. However, the regulatory authority incorporated the recommendations into the new regulatory framework.

<p><u>Czech Republic</u></p> <p>Due to political and social changes in our country the entire law system was revised in the 1990s. The new atomic law and regulations mentioned above were prepared with regard to ICRP 60.</p> <p><u>Iceland</u></p> <p>ICRP 60 did not prompt changes in legislation (changes were introduced at the time of next revision).</p> <p><u>Korea</u></p> <p>Fully implemented in 1998; dose limits, dose constraints, radiation weighting factors and tissue weighting factors, exemption and clearance concept(IAEA BSS 115), etc., but there were 5 years extra time for radiation worker dose limits considering the impacts to the utilities.</p> <p><u>Norway</u></p> <p>To a very large extent – (Former law was from 1938).</p> <p><u>Slovakia</u></p> <p>Almost completely.</p> <p><u>Slovenia</u></p> <p>Not as a result of ICRP 60. Slovenia declared independence in 1991. At first old Yugoslav regulations were applied as a temporary measure. All legislation was rewritten since ICRP 60.</p> <p><u>Spain</u></p> <p>They were fully rewritten following EU Directives.</p> <p><u>Sweden</u></p> <p>The RP Act and Ordinance contain few technical details. They were revised in 1988; not primarily due to ICRP 60, but this paved the way for revision of many ‘SSI’ (now SSM) regulations. The changes did not surprise licensees; they were well aware of the 1987 Como statement and of ICRP drafts and had begun to work along the lines of ICRP 60 before there were any formal regulations.</p> <p><u>UK</u></p> <p>The move from ICRP 26 to ICRP 60, via implementation of the relevant Euratom Directives, was seen as evolution rather than revolution and there was plenty of warning of what the main changes would be so that the impact was generally relatively insignificant. For instance, the UK presaged the likely reduction of dose limits by issuing ACOP guidance on dose limitation and restriction of exposure in the light of ICRP’s Como Statement. Nevertheless, the existing legislation had to be amended and some minor gaps filled by new legal provisions. A legal Direction was issued to the Environment Agency in relation to the public dose limit and dose constraint requirements of the BSS Directive</p>
<p><i>ICRP 60 incorporation (2/2)</i></p> <p><i>Question A1.4:</i> What was the procedure, what problems and efforts were there?</p>
<p><u>Summary</u></p> <p>In all countries that have provided detailed replies, draft regulations were prepared by regulators in informal consultation with stakeholders, then subjected to formal consultation augmented by information and meetings, then turned into binding regulations (with minor variations because of differing legal systems, etc.) Apparently, considerable effort was spent on information and consultation (although less than nowadays – AU). No country reports any really serious problems.</p>

Range of responses:**Australia**

At the time, consultation processes were more cursory than nowadays. ICRP Recommendations tended to be implemented rapidly in practice, even if not necessarily in legislation.

Canada

See A1.3. The CNSC as an agent of the Government of Canada and as Canada's nuclear regulator recognizes and understands the importance of consulting and building relationships with Canada. All amendments to regulations undergo a comprehensive public review process which includes ensuring that key stakeholders are informed and be provided the opportunity to comment on draft regulations.

Czech Republic

The procedure was very specific because radiation protection was "delimited"/moved from the Ministry of Health to the Nuclear Safety Administration and quite new legislation was developed.

Iceland

There were no significant problems in the implementation of ICRP 60 in Iceland.

Korea

KINS first studied ICRP 60 as well as IAEA BSS 115, developed the items of the provision to be revised, held several workshops, meetings, debates and discussions, and then reported the final draft to the MEST. MEST promulgated the revised legislation through another public hearing.

Norway

A proposition for the parliament was prepared and passed.

Slovakia

Without significant problems.

Slovenia

The basic law (IRPNSA) was implemented in 2002 (and amended most recently in 2011). Since then, most of the second level legislation was also rewritten. Most of the second level legislation was written by the regulatory authorities, some by experts from technical support organizations (TSO) and then reviewed by the regulators and governmental legislative authorities.

Spain

For public, occupational, and environmental radiation protection, CSN drafted the new regulations. The Industry Ministry led a working group where draft regulations were discussed / agreed with other authorities and stakeholders (trade unions). For radiation protection of patients, the Health Ministry was both in charge of drafting and leader of the corresponding working group.

There were no problems. Some difficulties were caused by the need (pointed out by trade unions) to accommodate medical surveillance of exposed workers to general regulations on work risk prevention.

Sweden

Draft regulations were prepared by the authority (SSI/ SSM) with informal consultations with licensees' experts, then issued as formal consultation documents, then amended as appropriate and issued as final binding regulations. Considerable effort was spent on meetings at all levels with interested parties, consultations, information documents, and other interactions. A major reason why the transition went smoothly was that most licensees felt that ICRP 60 made sense.

Sweden joined the EU only in 1995; this caused one problem: some regulations, even though already aligned with ICRP 60, had to be revised again to ensure consistency with the Euratom BSS Directive.

UK

For occupational, and to a lesser extent other, radiation protection legislation, draft regulations were (and are) prepared by the regulatory authority in conjunction with stakeholder advisory groups at various levels, then a formal consultative document was (and is) issued on which any interested parties may comment, before finalising the regulations in the light of comments received. The understanding of, and opportunities to comment on, the proposals were augmented by workshops and other meetings with stakeholders. This helped to remove/avoid misunderstandings and prepared employers and workers for the revised requirements. There were no insuperable, and very few significant, problems.

Stakeholders

Question A1.5: Who were the stakeholders (e.g. other ministries, operators, etc.) and how was their involvement achieved?

Summary

All respondent countries involved ministries and regulatory authorities, major licensees, and professionals. Several responses also mention members of the public, but probably the general public was less involved at the time of ICRP 60 than it would be today.

Range of responses:

Australia

[no comment]

Canada

The general process for developing regulatory documents and to involve the key stakeholders is that the CNSC would identify and directly involve key licensees, organized groups and citizens based on past experience. However, in order to allow for a transparent process with access to all Canadians, all changes are identified on the website.

To ensure content integrity and soundness of information, the regulatory document development process at the CNSC follows a detailed process [that is available on request].

Czech Republic

Ministries and other governmental bodies were involved through a mandatory comment procedure.

NPP operators and the professional public (professional societies, universities etc.) were also addressed to make their comments and suggestions.

Iceland

[no comment]

Korea

Stakeholders: utilities (NPP designers, constructors, operators), authorized users of radiation sources, related organizations, intellectuals, public representatives....

They were involved in workshops, meeting and debates of KINS, reviewed and asked to modify the draft, and involved also in the process of public hearing of MEST.

Norway

There is always a process with a broad public hearing when new legislation/regulations are proposed.

<p><u>Slovakia</u></p> <p>Large stakeholders, like the nuclear industry and chambers of medical professionals, were very active in the implementation of basic standards and new requirements.</p> <p><u>Slovenia</u></p> <p>All involved ministries were consulted (primarily environment and health, also interior, agriculture, foreign affairs), NPP operators and the Technical Support Organisation were invited to discuss and comment on relevant legislation. Bilateral and multilateral discussions were organised to achieve the best results.</p> <p><u>Spain</u></p> <p>Many Ministries and bigger trade unions took part in the drafting groups to write the new regulations. In addition operators, professional societies, ecologist organisations and even members of the public received the regulation projects for comments prior to approval.</p> <p><u>Sweden</u></p> <p>Among licensees, nuclear installations and large hospitals were regarded and treated as major stakeholders. Managers as well as RP professionals were contacted, and also the professional societies. Less attention was paid to small operators (although some of them were contacted). Important regulatory stakeholders included the Environment Ministry (but there were few contacts with other Ministries) and the usual collaborating authorities (cf. A1.3). Members of the public were also regarded as important stakeholders, but by today's standards, with web interaction and inquisitive citizens, actions around 1990 to inform the public were rather limited.</p> <p><u>UK</u></p> <p>Stakeholders were government departments and agencies, major operators, health authorities, trades unions, professional bodies, non-departmental government bodies (e.g. the Equal Opportunities Commission). HSE (and others) set up working groups to develop content of IRR99. Representatives of organisations participating in official working groups etc. also invited colleagues (such as health physicists) within their organisations to comment on the drafts to assess the impact of the changes.</p>
<p>Guidance</p> <p>Question A1.6: How was guidance on the implementing legislation developed and by whom (e.g., regulatory authorities, professional societies, trade organisations)?</p>
<p><u>Summary</u></p> <p>Guidance was produced mainly by the regulatory authorities, and to some extent, in a few countries, by professional societies. In most countries, the guidance appears to be largely informal.</p> <p>Range of responses:</p> <p><u>Australia</u></p> <p>The NHMRC publications Radiation Health Series (RHS) contain codes of practice, standards, recommendations and guidelines. ARPANSA took over the revision and development of these publications in 2000 and a new series was begun: the Radiation protection Series (RPS). The RHS series ended with RHS 39 which was then republished as RPS1 (see A1.3).</p> <p><u>Canada</u></p> <p>The radiation protection regulations were drafted largely 'in-house' as the AECB (now the CNSC) had a number of radiation protection experts, including those who were on ICRP committees and task groups. In addition, some Canadian radiation protection experts were consulted for specific reviews such as pregnant worker dose limits. Also, there was comprehensive consultation on the regulations.</p>

<p><u>Czech Republic</u></p> <p>It was mainly developed by the State office for nuclear safety or on its initiative and under its support.</p> <p><u>Iceland</u></p> <p>The regulator prepares guidelines.</p> <p><u>Korea</u></p> <p>KINS (the regulatory authority) issued an explanatory report of the draft legislation and introduced it through workshops, meetings, debates, etc.</p> <p><u>Norway</u></p> <p>In such work a so-called chamber proposal document is prepared to explain the consequences of the legislative proposal – in practice written by NRPA.</p> <p><u>Slovakia</u></p> <p>Official guidance has not been issued. Mainly authorities are involved; some professional societies have organized training and courses.</p> <p><u>Slovenia</u></p> <p>The regulatory authorities.</p> <p><u>Spain</u></p> <p>For public, occupational, and environmental radiation protection: CSN through its planned program to develop regulations and guidance. For radiation protection of patients: Health authorities and professional societies.</p> <p><u>Sweden</u></p> <p>The regulatory authority produced leaflets, reports, and information material but few formal guidance documents - there is no tradition of such guidance. Professional societies arranged seminars, courses, etc., encouraged by the SSI/SSM, but they did not produce formal guidance (and were not expected to do so). Trade organisations do not produce formal guidance.</p> <p><u>UK</u></p> <p>Guidance was developed by government depts/regulatory authorities and trade and professional bodies as appropriate, in conjunction with relevant stakeholders, and finalised after consultation.</p>
<p><i>Time-scales</i></p> <p>Question A1.7: What were the lead-in times for new requirements, i.e., when were they proposed, when decided, when was full compliance by operators required?</p>
<p><u>Summary</u></p> <p>Total lead times appear to have ranged from 3 to about 10 years (or, for selected requirements, even longer). In most countries, most of the lead time was between proposal and decision; once decided, regulations were often binding quite soon. In some cases, some requirements were applied only after an additional delay.</p> <p>Range of responses:</p> <p><u>Australia</u></p> <p>See A.1.1 above and the attached table <i>[in Annex E]</i>.</p>

Canada

The current regulations were initially drafted in the early 1990's. The radiation protection regulations came into effect when the Nuclear Safety and Control Act came into force on May 31, 2000. Some of the regulations were phased in over five years to allow time for licensees to become compliant, such as licensing of dosimetry providers.

Czech Republic

Full compliance was required when the atomic law entered into force in 1997. The new requirements were proposed, discussed and agreed during its preparation process (which started 1994).

Iceland

[no comment]

Korea

KINS issued the first draft in July 1994. MEST (MOST, at that time) promulgated the legislation in August 1998. Full compliance by the utilities was required from August 2003.

Norway

For the majority of requirements: 2 months after they were proposed. For radon in schools, day nurseries, etc.: 3 years.

Slovakia

Many operators complied with many ICRP 60 requirements even before they were implemented in national legislation. Full compliance was required after a period stipulated by the act.

Slovenia

[no comment]

Spain

As Spain is an EU member country, time scales to invoke national regulations were set up in the corresponding Euratom Directives, 96/29 and 97/43.

The main national regulation implementing ICRP 60 requirements was released in July 2001. A time period of one year was set for operators to develop RP manuals and procedures.

For patients, RP quality control requirement regulations on Nuclear Medicine, Radiotherapy and X-ray diagnosis were released in 1997, 1998 and 1998 respectively. Finally a regulation related to justification of medical exposures was released in 2001.

Sweden

Generally, the time-scale for a new requirement varies from 1 up to 10 years from first proposal to full compliance, depending on the nature of the requirement. In this case, the starting point is not easily defined (informal discussions about ongoing work within ICRP? the Como statement? the first informal consultations on ideas for a dose limit regulation?) but the SSM suggests that 6 years is an adequate reply. The EU BSS Directive took another 4 years to implement, with additional transition provisions for some requirements.

UK

Preliminary work on implementation of the 1996 Euratom Directive was started while negotiations were still in progress. The main implementing regulations (IRR99) were made on 3 December 1999 and came into force on 1 January 2000, except for the regulation on authorisation of specified practices which came into force on 13 May 2000. These regulations contained transitional provisions for some specific requirements.

Burdens and benefits

Question A1.8: Did your regulatory authority perform a cost-benefit analysis of the implications of any new regulations, (regulatory analysis) and if so is there a report available (where)?

Summary

Mandatory cost-benefit analyses of the impact of new regulations were not as common at the time of ICRP 60 as they are now. Analyses were performed in three of the respondent countries (CA, SE, and UK; unfortunately it was not possible to retrieve the SE documentation). The two documents that were obtained (attached as Annexes) are discussed in the main body of the present report.

Range of responses:

Australia

Not that we know of.

Canada

Yes, Canadian Law requires that a Regulatory Impact Assessment statement be provided with the regulations and a copy is attached [*constitutes Annex B of the present report*]

Czech Republic

No, it was not mandatory at that time.

Iceland

[no comment]

Korea

No.

Norway

To some extent.

Slovakia

No cost-benefit analysis was performed.

Slovenia

No.

Spain

No.

Sweden

Yes, this is mandatory, but unfortunately it was not possible to retrieve the document.

UK

Yes [*constitutes Annex C of the present report*].

Cost of not acting

Question A1.9: Were the costs/savings/implications of not implementing ICRP 60 assessed? If so, what were they?

Summary

No such analysis was reported, although CA assessed the implications of not implementing the proposed pregnancy limit.

Range of responses:**Australia**

Not as far as we know.

Canada

No (except in relation to not implementing the proposed pregnancy limit of 2 mSv – see formal report [Ref. Ca5] issued by the AECB, which was the federal regulatory body that predated the CNSC).

Czech Republic

No.

Iceland

No.

Korea

No.

Norway

No.

Slovakia

No.

Slovenia

No.

Spain

No.

Sweden

In principle, such analyses should be made in connection with the cost-benefit assessment of new regulations. However, once Sweden joined EU, implementing ICRP 60 was mandatory and the cost of not implementing it was not assessed.

UK

No.

Actual costs (1/2)

ICRP 60 and Euratom Directives 96/29 and 97/43 entailed, e.g., that the annual limit on occupational effective

dose was reduced from 50 to 20 mSv, with an option of 5-year averaging; it was clarified that the annual limit on effective dose to members of the public is 1 mSv, not 5 mSv; effective dose (with new weighting factors w_R and w_T) replaced the effective dose equivalent; the concepts of dose and risk constraints were introduced; diagnostic reference levels were introduced.

Question A1.10: How did these new requirements arising from ICRP 60 impact on operations?

Summary

The lower dose limits have not caused any significant problems per se. Increased dose monitoring and upgraded dose registries caused added (but apparently acceptable) costs in CA and SE. Diagnostic Reference Levels (really an ICRP 73 tool) were perceived as useful and therefore worth the extra costs in SE.

Range of responses:

Australia

[no comment]

Canada

The CNSC did not determine what the actual costs were, other than that identified in the RIAS. Generally speaking though, more worker monitoring was required and changes had to be made to our National Dose Registry. Some operations, notably industrial radiographers and uranium mines had to find means to reduce dose further. Derived release limits were recalculated to one millisievert, however the releases in almost all cases were so low that the new lower limits did not impact the actual effluent releases. The CNSC did not include dose constraints per se, but we did include a somewhat similar concept called Action Levels, which has investigation and reporting requirements if the level is reached. Dose reduction initiatives were already in progress, so impact was minimal in NPPs and hospitals were already complying with more stringent design dose limits..

Czech Republic

No significant problems were identified at the operational level.

Iceland

[no comment]

Korea

The new annual limits on occupational effective dose had no serious impact on the utilities, because the occupational doses were already far below the new limit.

The application of dose constraints and the optimisation process were a little confusing to the utilities as well as the regulatory authority.

Norway

Not very much – most radiation workers had doses significantly lower than 50 mSv (and even below 20 mSv).

Slovakia

The new system of limits had no considerable impact on operators as the individual doses of workers and members of the public were well below the limits.

Slovenia

[no comment]

Spain

New dose limits, constraints and diagnostic reference levels were incorporated without specific impact on operations. From the time the EU directives were released, operators started to use the new values as a trial exercise to be ready when they were incorporated into national regulations.

Sweden

The introduction of ICRP 60 was not perceived as 'expensive'. Major cost items were for education and training and for an upgrade of the nuclear operators' joint dose registry.

NPP operator: ICRP 60 / Euratom 96/29 did not cost NPP operators very much, but the contractor (itinerant worker) companies had to hire additional staff to avoid exceeding 20 (100/5) mSv, and these costs were passed on to us. However, the contractors want to be good employers and the relatively small amount was money well spent. Also, we are keen to do what the regulator wants. Our owners are prepared to cover the costs of any sensible improvement. We are always consulted before new rules are implemented, and if we have genuine concerns the regulator tries to accommodate our views.

Large hospital (physicist): DRLs are very useful. Our hospital has reduced diagnostic doses by 350 manSv, 65% of which can be attributed to DRLs. However, the data collection takes time, and we had to acquire suitable statistical software. The lower occupational dose limits has had a positive impact on doses to interventional radiologists. (*Clinic director*): We started by listing problem areas and identified occupational doses in interventional radiology, for effective dose and even more for eye lens and skin dose. Our physicians required some persuasion to participate in training and reduce their doses, but in the end they all complied and we enjoy improved RP. We attended to doses to members of the public by using mobile equipment more carefully and with mobile shielding where appropriate. DRLs were useful but costly (many measurements, much work, additional staff had to be hired). Since the use of DRLs was sensible and mandatory, extra money was provided by the hospital owners.

Non-destructive testing outfit: No particular impact, all doses from our normal operations are well below 20 mSv in a year. The highest doses occur when we visit NPPs, but then the radiation comes from the tested object, not from our equipment. We have had 3 incidents in the last 20 years but even then no annual dose was above 20, let alone 50, mSv.

UK

Many of the fundamental principles (justification, optimisation and dose limits) were already in place in IRR85 (based on ICRP 26). The 'mantra' at the time was 'evolution not revolution' which was generally the case in practice.

Nuclear industry organisation: The new regulations did not have a significant impact on the operations. Operators were already looking at dose reduction. There were a number of personnel actively involved in ensuring requirements were met, particularly changes in dosimetry requirements.

Actual costs (2/2)

Question A1.11: Did the incorporation of ICRP 60 lead to any reduction of any kind of cost or effort?

Summary

None identified. Some money was saved when a lifetime dose limit that had been introduced in SE (and in Germany) in anticipation of ICRP 60 was removed again, but the lifetime limit was never part of ICRP 60.

Range of responses:**Australia**

[no comment]

Canada

No cost reductions that we are aware of.

<p><u>Czech Republic</u></p> <p>[no comment]</p> <p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>[no comment]</p> <p><u>Norway</u></p> <p>Probably not.</p> <p><u>Slovakia</u></p> <p>We do not have any relevant information that the application of ICRP 60 led to any cost reduction.</p> <p><u>Slovenia</u></p> <p>[no comment]</p> <p><u>Spain</u></p> <p>There has not been any analysis related to this, no evidence of any kind of cost or effort exists. All operators and services companies (dosimetry services...) had (at least) costs related to updating RP manuals and procedures to the new regulations as required by the competent authorities.</p> <p><u>Sweden</u></p> <p><i>NPP operator:</i> The lifetime dose limit that had been introduced in anticipation of ICRP 60 caused us some administrative effort, so we saved some money when the dose limits were fully aligned with Euratom 96/29.</p> <p><u>UK</u></p> <p>No savings or cost reductions have been identified.</p>

A2. Application / scope
Scope (1/3)
<p>Question A2.1: Did pre-ICRP 60 legislation in your country cover all uses and users of ionising radiation, e.g.: industrial applications (including industrial radiography), medical applications (diagnostic and therapeutic), nuclear fuel cycle, research and teaching, transport, radioactive waste disposal, occupational exposure to radon (mining and non-mining), agriculture?</p>
<p><u>Summary</u></p> <p>In most countries, legislation coverage was comprehensive already before ICRP 60. However, some applications were unregulated in some AU jurisdictions; radon was not covered in KR; and ES mentions added requirements with ICRP 60 on medical and dental services.</p> <p><i>Range of responses:</i></p> <p><u>Australia</u></p> <p>Coverage differed between states/territories, thus in some jurisdictions there were certain unregulated</p>

applications.

Canada

Yes, it was previously all covered but as noted above in A1.2, not all uses of ionizing radiation are covered by the CNSC.

Czech Republic

Yes, it covered all listed uses and users.

Iceland

Legislation covers the whole field of radiation safety.

Korea

Yes, except for radon.

Norway

Mainly yes – and including non-ionising radiation.

Slovakia

In general, yes.

Slovenia

[no comment]

Spain

Yes, except exposures to natural radiation.

Sweden

The 1988 RP Act covered all uses and users.

UK

Yes.

Scope (2/3)

Question A2.2: If not, was new legislation introduced to close the previous gaps?

Summary

In most countries, legislation was already comprehensive. The only respondent stating that changes to legislation due to ICRP 60 were made in order to close gaps is AU.

Range of responses:

Australia

Yes.

Canada

[n/a]

<p><u>Czech Republic</u> [n/a]</p> <p><u>Iceland</u> [n/a]</p> <p><u>Korea</u> [n/a]</p> <p><u>Norway</u> The main motive for new legislation was to improve harmonisation with other countries and to update requirements to be more operative.</p> <p><u>Slovakia</u> [n/a]</p> <p><u>Slovenia</u> [no comment]</p> <p><u>Spain</u> [no comment]</p> <p><u>Sweden</u> [n/a]</p> <p><u>UK</u> [n/a]</p>
<p>Scope (3/3)</p>
<p>Question A2.3: Did the timeframe for implementation vary for the sectors described in A 2.1? If so, how?</p>
<p><u>Summary</u></p> <p>Most countries had the same or at least similar time frames for different sectors. ES reports that the implementation of regulations for natural radiation sources was delayed by the identification and analysis of sources and development of adequate regulations. In AU, there were differences between jurisdictions.</p> <p>Range of responses:</p> <p><u>Australia</u> Not between sectors, but between jurisdictions.</p> <p><u>Canada</u> [n/a]</p> <p><u>Czech Republic</u> [n/a]</p>

<p><u>Iceland</u> [no comment]</p> <p><u>Korea</u> [n/a]</p> <p><u>Norway</u> Not much.</p> <p><u>Slovakia</u> No.</p> <p><u>Slovenia</u> [no comment]</p> <p><u>Spain</u> Yes. For exposures to natural radiation, the first steps were to identify activities and facilities where they take place, second determine which of them need a radiation program, third decide a RP program tailored to each activity / facility. This process delayed the effective implementation of the new requirements.</p> <p><u>Sweden</u> [n/a]</p> <p><u>UK</u> [n/a]</p>
<i>Response</i>
<i>Question A2.4:</i> Was there any resistance from those sectors (if any) which were not previously covered? If so, what were the main perceived difficulties and what was done to overcome them?
<p><u>Summary</u></p> <p>In most countries, all sectors were covered already. Some questions were raised by the oil and gas industry in NO (concerning NORM) and by dental and medical professional organisations in SK (concerning mandatory education and duties in the licensing process). These problems could be solved by explanations and discussions.</p> <p><i>Range of responses:</i></p> <p><u>Australia</u> [no comment]</p> <p><u>Canada</u> [n/a]</p> <p><u>Czech Republic</u> [n/a]</p>

<p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>[n/a]</p> <p><u>Norway</u></p> <p>Not much, but some questions from the oil and gas industry concerning NORM.</p> <p><u>Slovakia</u></p> <p>Some opposition from the chamber of dentists and chamber of medical doctors against requirements on education in radiation protection and duties in the licensing process. Explanations and discussions were organised.</p> <p><u>Slovenia</u></p> <p>[no comment]</p> <p><u>Spain</u></p> <p>No, there was no special resistance.</p> <p><u>Sweden</u></p> <p>[n/a]</p> <p><u>UK</u></p> <p>[n/a] Hospitals and Universities etc had already been brought into IRR85 via the Health and Safety at Work etc Act.</p>

A3. Dose limits and dose distribution
<i>Historical limits</i>
Question A3.1: What were your dose limits before you incorporated ICRP 60?
<u>Summary</u>
<p>Most countries, and certainly those that were EU member states at the time, were in line with ICRP 26, albeit sometimes with additional provisions (e.g., on doses per shorter periods than a calendar year). At least one country (KR) adhered to ICRP 9.</p> <p>Range of responses:</p> <p><u>Australia</u></p> <p>[no comment]</p> <p><u>Canada</u></p> <p>Under the previous AECB regulations, there were quarterly and annual dose limits, but there were no 'effective' dose limits <i>per se</i>. The following table provides our former dose limits. In addition to these, with respect to radon progeny, there was a 4 WLM limit per year, 2 WLM per quarter and 0.4 WLM for non-atomic radiation workers.</p>

Maximum permissible doses*						
Organ, Tissue	Atomic Radiation Workers	Female Atomic Radiation Workers of Reproductive Capacity		Any Other Person		
	Rems** per Quarter of a Year	Rems** per Year	Rems** per Quarter of a Year	Rems** per Year	Rems per Year	Rems per Year
Whole body, gonads, bone marrow		3		5	1.3***	5***
Bone, skin, thyroid		15		30	15	30
Any tissue of hands, fore-arms, feet and ankles		38		75	38	75
Other single organs or tissues	8	15			8	15

*The maximum permissible doses specified in this Table do not apply to ionizing radiation
(a) received by a patient in the course of medical diagnosis or treatment by a qualified medical practitioner; or
(b) received by a person carrying out emergency procedures undertaken to avert danger to human life.

**The Board may, where appropriate alternatives are unavailable or impractical, permit single or accumulated doses up to twice the annual maximum permissible doses, unless, in the case of irradiation of the whole body, gonads or bone marrow, the average dose received from age 18 years up to and including the current year exceeds 5 rems per year.

***The dose to the abdomen shall not exceed 0.2 rem per two weeks, and if the person is known to be pregnant, the dose to the abdomen shall not exceed 1 rem during the remaining period of pregnancy.

****The dose to the thyroid of a person under the age of 16 years shall not exceed 1.5 rems per year.

NOTE: In determining the dose, the contribution from sources of ionizing radiation both inside and outside the body shall be included.

Czech Republic

50 mSv/y for effective dose.

Iceland

[no comment]

Korea

50(N-18) mSv and 30 mSv/3months, etc. (i.e., as recommended in ICRP 9).

Norway

50 mSv/y.

Slovakia

Annual limits	Workers	Public
Rems per year	Rems per year	
Whole body, gonads, red bone marrow	5	0.5
Bone, skin, thyroid	30	3
Hands, feet	75	7.5
Other	15	1.5

Slovenia

[no comment]

Spain

Workers: 50 mSv/y. Members of the public: 5 mSv/y.

Sweden

Essentially, those of ICRP 26, but before 1990 dose limits were given as licence conditions rather than in a general regulation. This permitted some variation with respect to the annual limit on effective dose equivalent for members of the public, reflecting that ICRP 26 was somewhat cryptic on this topic. Thus, some licences stated that the limit was 1 mSv while others stated that it was 5 mSv.

UK

As ICRP 26 (via the 1980 Euratom BSS Directive), i.e., whole body in any calendar year:
(a) employees - 50 mSv/y; (b) trainees aged under 18 yrs - 15 mSv; (c) any other persons – 5 mSv.

Current limits (1/3)

Question A3.2: What were your dose limits after implementation of ICRP 60?

Summary

All countries adhere to the fundamental ICRP 60 dose limits (in most cases, including averaging of occupational doses over 5 years; see also A3.3). Deviations in details include the limit on effective dose to pregnant workers in CA (4 mSv for the balance of the pregnancy where ICRP 60 suggested 2 mSv to the abdomen and the 1996 Euratom Directive said 1 mSv to the fetus).

Range of responses:**Australia**

As per ICRP 60.

Canada

CNSC dose limits:

Person	Period	Effective dose (mSv)
Nuclear energy worker, including a pregnant nuclear worker	(a) One-year dosimetry period	50
	(b) Five-year dosimetry period	100
Pregnant nuclear energy worker	Balance of the pregnancy	4
A person who is not a nuclear energy worker	One calendar year	1

Organ or tissue	Person	Period	Equivalent dose (mSv)
Lens of an eye	(a) Nuclear energy worker	One-year dosimetry period	150
	(b) Any other person	One calendar year	15
Skin	(a) Nuclear energy worker	One-year dosimetry period	500
	(b) Any other person	One calendar year	50
Hands and feet	(a) Nuclear energy worker	One-year dosimetry period	500
	(b) Any other person	One calendar year	50

Czech Republic

100 mSv/5years and 50mSv/y.

Iceland

[no comment]

<p><u>Korea</u></p> <p>For occupational dose: 100mSv for 5 years, 50 mSv in any single year; for public 1 mSv in a year.</p> <p><u>Norway</u></p> <p>20 mSv/year.</p> <p><u>Slovakia</u></p> <p>Annual limits on effective dose: Workers 100 mSv/5 y and 50 mSv/y; public 1 mSv/y.</p> <p><u>Slovenia</u></p> <p>[no comment]</p> <p><u>Spain</u></p> <p>Workers: 100 mSv averaged over 5 years with a maximum of 50 mSv/y. Members of the public: 1 mSv/y.</p> <p><u>Sweden</u></p> <p>Essentially, those of ICRP 60. Initially, in addition to the ICRP limits, there was a lifetime limit on occupational effective dose of 700 mSv, corresponding to 15 mSv per year of occupational exposure, but this was discarded after a few years.</p> <p><u>UK</u></p> <p>As per the 1996 Euratom BSS Directive, i.e., limit on effective dose in any calendar year: (a) employees – 20 mSv; (b) trainees aged under 18 yrs – 6 mSv; (c) other persons – 1 mSv.</p>
<p><i>Current limits (2/3)</i></p>
<p>Question A3.3: Was any flexibility built into dose limits, e.g., public limits allowed up to 5 mSv in exceptional circumstances?</p>
<p><u>Summary</u></p> <p>While 5-year averaging of occupational doses is an option in most countries, albeit sometimes only after special application, at least two countries do not at all permit such flexibility for public doses (SK and ES), and no one seems to regard averaging of public doses as important (though CA reports a 5 mSv limit for caregivers)..</p> <p><i>Range of responses:</i></p> <p><u>Australia</u></p> <p>Yes, averaging is permitted with essentially the same wording as in ICRP 60.</p> <p><u>Canada</u></p> <p>There was no specified flexibility in the legislation, but the Commission (the tribunal that decides on licensing issues) has the authority to grant exemptions to the regulations. <i>[This refers to flexibility for public doses; the Canadian A.3.2 reply above confirms that the flexibility of 5-year averaging does apply to occupational doses. In the medical sector, caregivers have a 5 mSv limit].</i></p> <p><u>Czech Republic</u></p> <p>Yes, but in fact it is not used in practice.</p>

<p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>Yes (in special circumstances, a higher value could be allowed in a single year, provided the average over 5 years does not exceed 1 mSv per year).</p> <p><u>Norway</u></p> <p>For workers : 50 mSv in a single year provided that 100 mSv was not exceeded during a 5 year period (permission must be applied for).</p> <p><u>Slovakia</u></p> <p>It is not allowed to expose any member of the public to 5 mSv/y according to our legislation.</p> <p><u>Slovenia</u></p> <p>[no comment]</p> <p><u>Spain</u></p> <p>No, this is not permitted.</p> <p><u>Sweden</u></p> <p>Yes, as in ICRP 60, i.e., workers 100 mSv in 5 years with max 50 mSv in a year; public exceptionally up to 5 mSv in 5 years. However, nobody has ever requested the flexibility for public exposures.</p> <p><u>UK</u></p> <p>Flexibility for 100 mSv in any period of 5 consecutive years, max 50 mSv in any single calendar year, for employees, subject to conditions.</p>
<i>Current limits (3/3)</i>
<p>Question A3.4: If 5-year averaging was chosen for occupational doses, what is your experience? Were there any difficulties?</p>
<p><u>Summary</u></p> <p>There is a very wide range of experiences, from SE where averaging is seen as useful and easily implemented to ES where averaging is regarded as unnecessary and cumbersome (and we encountered a corresponding wide range of different opinions about 5-y averaging in various fora). Most countries report few or no difficulties, but also that the flexibility is rarely used.</p> <p><i>Range of responses:</i></p> <p><u>Australia</u></p> <p>Although averaging of occupational doses is a formal possibility, we do not believe that it has been used in practice.</p> <p><u>Canada</u></p> <p>There were no great difficulties, but a number of growing pains. Computer codes had to be changed in our National Dose Registry as well those of the operators and licensees. Some licensees and some jurisdictions used a rolling five year period whereas the CNSC adopted a five year block. Some of the smaller licensees, such as radiographers, initially did not realize there was a five year limit. In the</p>

healthcare sector the main challenge is the turnover of staff and students.

Czech Republic

No difficulties, because of our national register of doses we are able to control the sum of doses.

Iceland

[no comment]

Korea

No, there aren't any difficulties.

Norway

No. In the few such cases, we require that a good work plan is prepared with dose budgets.

Slovakia

No difficulties, since individual doses are very low and it is still possible to expose the worker to 50 mSv in a single year (assuming that the limit of 100mSv / 5y will not be exceeded).

Slovenia

[no comment]

Spain

Our experience has been that the 5-year average limit in addition to the annual limit caused a lot of work with tracking and follow-up of occupational doses. Few cases of exceeding the five-year limit have been reported where the limit (100 mSv) had not been exceeded for the current year. On the other hand most practices in Spain have annual doses well below 20 mSv. Thus from a practical point of view we find it interesting (as many European countries did) to use a single dose limit of 20 mSv/y.

Sweden

Nuclear operators claim that the flexibility for occupational exposure is important, not because workers need to exceed 20 mSv, but because it permits operators to plan work in the 15-20 mSv bracket without fearing a direct infraction in case somebody gets 21 mSv. No real problems were encountered. Itinerant workers got high doses in the first few years, but operators quickly learned to 'budget' their doses to be able to use staff adequately through entire 5-y periods. Much of the optimisation was very cheap and simple, like proper planning of jobs, bringing the right tools, etc. Furthermore, reduced dose rates led to reductions of other costs.

UK

No experience – flexibility never used.

Transition experience (1/3)

Question A3.5: What was your experience of establishing these lower dose limits?

Summary

Information well before the formal implementation of ICRP 60, with guidance as required and permitting operators to adapt to the new limits before they became mandatory, contributed to a smooth transition. Five-year averaging was regarded as important by CA and SE operators; SE nuclear operators also came to consider the lower limits as investments that paid off in the longer term. Workers in the investigated countries are considered to wear their dosimeters as prescribed (i.e., they do not try to evade high recorded doses). In UK radiotherapy, dose rates were and are an issue (see also A.3.6).

Range of responses:

Australia

There were no significant problems, doses were already mostly below the new limits due to optimisation of protection.

Canada

The original RP Regulations proposed an annual dose limit of 20 mSv/y with no five-year averaging. There was considerable opposition to this, notably from uranium mines, who did not believe they could meet that limit. Also, the NPPs indicated that they would have difficulties meeting the limits when the reactors underwent refurbishment. Five-year averaging was added in the final version. Also, there was objection to reducing the pregnant dose limit as discussed under A.4.1-3. The hospital sector reported no problems with the lower limits, but some reclassification of workers.

Czech Republic

[no comment]

Iceland

[no comment]

Korea

The most important thing was that the stakeholders had an understanding and their preparation to implement ICRP 60.

Norway

No problems with this.

Slovakia

The individual doses were low, well below the limits; transition to new limits was not a significant problem.

Slovenia

[no comment]

Spain

Good; in practice the new limits were applied before the new regulations were released. Annual doses at Spanish practices were well below the new limits long before they entered into force.

Sweden

The new limits reduced doses considerably; annual doses around 20 mSv are now rare exceptions. The new limits forced new technology, better planning, and reduced source terms and dose rates. Also, different operators are now balancing low collective dose vs low individual doses more similarly. There were some initial complaints about technology and training costs, but the lower doses permitted the use of fewer, more experienced workers, and senior management realised that the costs were trivial compared to continuous investments in safety and modernisation. Thus, the RP investment paid off rapidly and led to savings in the long run. People do wear their dosimeters, at least in Sweden.

NPP operator: The lowered dose limit was not a problem. However, the flexibility of averaging over 5 years is very important. The central dose registry for all nuclear workers provides a clear overview of the 5-y averages. We advise contractors to try to keep below 20 mSv at all times, but occasionally a dose closer to 50 mSv to a particular specialist is optimal, even though that worker may then have to do non-radiation work for a year or more. Our workers always use their dosimeters as prescribed.

Large hospital (physicist): One cardiologist needed some convincing, but now everybody uses their dosimeters as prescribed. **(Clinic director):** The 20 (100/5) limit was rarely a problem; we had more difficulties with skin and eye lens doses.

Non-destructive testing outfit: We were already below the new dose limits so we had no problems.

UK

No significant problem - because of the Como Statement employers were generally already working within the revised dose limits and the primacy of ALARP had been established in the 1985 Regulations. Public doses were already well below 1 mSv.

The main problem in the medical sector was the instantaneous dose rate of 7.5 uSv/h for radiotherapy units (intended to ensure <0.3 mSv/y for members of the public), which remains an issue today. In at least some parts the nuclear industry a dose reduction programme was implemented, involving managers and workforce. Regular meetings examined the reduction programme. The programme involved changes in practices as well as introduction of additional shielding. Prior to this glove box workers received 50mSv per year external dose.

Transition experience (2/3)

Question A3.6: Did any installation need significant rebuilding to comply with added shielding requirements? If no, how was this avoided?

Summary

No significant rebuilding requirements were reported. However, in a few countries, more realistic occupancy modelling and/or amended access/occupancy control were used to avoid the need for additional shielding, and one medical operator (SE) felt that much effort went into the calculations needed to convince the regulator that added shielding was unnecessary. Several operators said that they introduced additional shielding not because of new limits but as a part of their optimisation of protection.

Range of responses:**Australia**

We are not aware of any case where shielding had to be amended due to the implementation of ICRP 60. The highest doses in the Australian context are to miners, and are due to intake of dust.

Canada

Not that CNSC is aware. Many of the operations were already ALARA and had taken dose savings where they could. In the medical sector, minimal shielding changes were needed, reflecting the frequent application of AECB Guide AG-5 [Ref. Ca9] with design dose limits more stringent than the dose limits following from implementation of ICRP 60.

<p><u>Czech Republic</u></p> <p>Not as we remember it.</p> <p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>No, this could be solved by access control and occupancy control.</p> <p><u>Norway</u></p> <p>No.</p> <p><u>Slovakia</u></p> <p>No.</p> <p><u>Slovenia</u></p> <p>[no comment]</p> <p><u>Spain</u></p> <p>No. Doses were already below the new limits, so only minor shielding rearrangements were required.</p> <p><u>Sweden</u></p> <p>Improved modelling, e.g., more realistic occupancy factors, meant that usually, no significant rebuilding was necessary, but calculations to verify this are mandatory. Note that there are new and better materials for temporary shielding purposes.</p> <p><i>NPP operator:</i> We did add some more permanent shielding at some locations, but we regard this as an ALARA action rather than a compliance necessity.</p> <p><i>Large hospital (physicist):</i> No actual rebuilding was required but the mandatory calculations or measurements are difficult - see also A.4.5 below.</p> <p><i>Non-destructive testing outfit:</i> We don't rebuild our customers' installations, but we have improved the mobile shielding equipment that we are using. However, this is done as part of our optimisation of RP, not in response to any new requirement.</p> <p><u>UK</u></p> <p>In the medical sector some additional areas became controlled or supervised.</p>
<i>Transition experience (3/3)</i>
<p>Question A3.7: Were there any other difficulties? If so, what were they and how were they resolved?</p>
<p><u>Summary</u></p> <p>No other difficulties are mentioned; UK reports that shielding at medical installations was upgraded in connection with rebuilding for other reasons.</p> <p><i>Range of responses:</i></p> <p><u>Australia</u></p> <p>[no comment]</p>

Canada

Don't recall any.

Czech Republic

Difficult to say; the regulatory staff at the time are no longer employed.

Iceland

[no comment]

Korea

[no comment]

Norway

No.

Slovakia

[no comment]

Slovenia

[no comment]

Spain

No.

Sweden

No.

UK

In the medical sector, shielding was upgraded when new developments took place.

Resulting doses (1/3)

Question A3.8: What analyses of dose distributions are available for your country, over what period?

Summary

Comprehensive reports are usually available concerning nuclear worker doses, at least after ICRP 60. Several countries also have reports on other sectors. In addition to national reports, there are also dose reports from UNSCEAR and, for nuclear workers, ISOE.

Range of responses:**Australia**

Since we are only now organising a national dose registry, we do not have comprehensive information.

Canada

Health Canada's National Dose Registry publishes summaries and trends of all worker doses, see www.hc-sc.gc.ca/ewh-semt/pubs/occup-travail/index-eng.php#expose

CNSC also published a review of 'Occupational Dose Data for Major Canadian Nuclear Facilities

2001–07', see www.nuclearsafety.gc.ca/pubs_catalogue/uploads/INFO_0775_e.pdf

Czech Republic

We have dose distributions from 1997 – i.e., only after our new legislation entered into force.

Iceland

[no comment]

Korea

We have collected occupational exposure data for the employees of NPPs and radiation source utilities and reported to ISOE since 1996 and to UNSCEAR.

Norway

Annual national dose reports.

Slovakia

[no comment]

Slovenia

[no comment]

Spain

Since a long time, the Spanish regulatory body carries out yearly analyses of dose results by sectors of practices.

Sweden

There is a Central Dose Registry common to all nuclear installations and distributions are provided in annual reports on nuclear issues that can be obtained from SSM. There are several suppliers of dose meters for health care and while the regulator has reasonable access to information about doses and dose distribution, this is not systematically organised or published.

UK

Central Index of Dose (CID) Information contains annual summaries of dose for classified persons (category A workers). Reports for 1990 – 96 and for each year 1997 – 2004 are available at <http://www.hse.gov.uk/radiation/ionising/doses/cidi.htm>

'Ionising Radiation Exposure of the UK Population' reviews of public exposures were carried out by the UK National Radiological Protection Board (NRPB; now the Health Protection Agency, HPA) since 1974. For the most recent = 2005 review, see <http://www.hpa.org.uk/Publications/Radiation/HPARPDSeriesReports/HpaRpd001/>

For reports on radioactivity in food and the environment entitled (1967 – 1994) Radioactivity in Surface and Coastal Waters of the British Isles and, post 1994, Radioactivity in Food and the Environment, see <http://www.cefas.defra.gov.uk/publications/scientific-series/aquatic-environment-reports.aspx>.

Resulting doses (2/3)

Question A3.9: Have these dose distributions changed? How?

Summary

In general, doses are reported to be much lower, but with several variations: Reduced doses to miners and to medical staff in AU, an increase in the collective dose in CA, *increasing* doses to medical staff in NO, planned investments in dose at SE NPPs to achieve later reductions, and increasing doses to NDT staff visiting SE NPPs.

Range of responses:**Australia**

We know that improved ventilation in mines led to significant dose reductions over the last 20 years, and that doses in connection with medical procedures have also gone down significantly.

Canada

Generally speaking, there has been a rise in the collective dose. The overall trend in medical occupational exposure has been a decrease since ICRP 60, though some increases were seen in radiology and radiopharmacy.

Czech Republic

[no comment]

Iceland

[no comment]

Korea

Yes. The occupational dose distributions have been reduced year by year.

Norway

In recent years: increasing doses to medical staff (interventional procedures).

Slovakia

Dose distributions have changed considerably, individual doses are lower now and the number of persons in higher dose intervals decreased significantly.

Slovenia

[no comment]

Spain

Some of them experienced additional reductions. Mainly, practices that before the new regulations had doses over 10 mSv/y reduced them to values under 10 mSv/y.

Sweden

Since 1990, there has been a major shift downwards in average dose as well as a significant reduction of the number of doses close to the dose limits. However, the trend is not a simple linear reduction. Several major refurbishments at nuclear installations were planned investments in dose as well as money, where high collective and individual doses were accepted in a particular year in order to reduce longer-term doses.

Non-destructive testing outfit: For those of our staff working outside the nuclear sector, doses are decreasing. However, in recent years dose trends are increasing for those who are working inside NPPs. This is because of the large refurbishments and increased effects at the plants.

UK

CIDI information showed a dramatic reduction (more than 10-fold) over the first 6-year period, in the proportion of classified persons who had a reported annual dose in excess of 15 mSv (the principal investigation level). The number reported as having doses over 20 mSv in a year also fell by the same factor. There was a definite and sustained downward trend in both mean and effective dose for classified persons over the whole period, even taking account of uncertainties in dose assessment.

For more detail see the actual reports.
Resulting doses (3/3)
Question A3.10: If yes, what was (were) the main factor(s) influencing these changes?
<p><u>Summary</u></p> <p>The general trend towards lower doses is attributed to more rigorous optimisation of RP, the discussion, training, and attention to RP generated by the implementation of ICRP 60, and (in UK) the introduction of new mandatory investigation levels of dose. The closure of the last UK tin mine also led to lower average doses. The increasing collective dose in CA is attributed to more frequent inspections of and refurbishment of older NPPs. The increasing doses to medical staff in NO are attributed to an increasing use of radiological rather than surgical procedures and to increasing use of sophisticated equipment (such as CT).</p> <p>Range of responses:</p> <p><u>Australia</u></p> <p>The reduced doses to miners and to medical staff are a result of optimisation, not of limitation.</p> <p><u>Canada</u></p> <p>The increasing collective dose is due to two major reasons, one being more frequent inspections at aging NPPs and two, the refurbishment of older reactors. In the medical sector, the increases were largely due to an increase in fluoroscopy cases (with no significant increase in staff) and an increased demand for PET-isotopes.</p> <p><u>Czech Republic</u></p> <p>[no comment]</p> <p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>The main factor behind the dose reductions would be the implementation of the optimization principle. The ALARA provision was added in the national regulation in 1995.</p> <p><u>Norway</u></p> <p>The higher doses to medical staff are due to more patients treated with radiological procedures rather than surgical, and to more use of sophisticated equipment.</p> <p><u>Slovakia</u></p> <p>Probably more rigorous implementation of optimisation.</p> <p><u>Slovenia</u></p> <p>[no comment]</p> <p><u>Spain</u></p> <p>Regulatory control (pressure) to take advantage of optimisation opportunities.</p>

Sweden

The introduction of the 20 (100/5) mSv limit was important. The most important factor was not the limit as such but the added attention to RP that resulted from all the discussions, training, etc. because of the new ICRP rec/s and the Euratom BSS Directive.

Large hospital (clinic director): While the 20 (100/5) limit was not in itself a problem, the discussions helped us focus on RP issues and improve. We also track patient doses much more conscientiously than in the past. RP does need constant attention, otherwise it's easily forgotten.

Non-destructive testing outfit: A new generation has arisen within our profession, the older people who did not always know much about RP are gone and the new employees are well educated. They were influenced by the spirit of ICRP 60, even though their doses were already below the new limits. We want the regulator to demand more RP training for our staff; this would help us to improve further.

UK

The main influence was the introduction, in the Ionising Radiations Regulations 1985 (IRR85), of a mandatory investigation by the employer if an employee had a recorded whole body dose of more than 15 mSv for the first time in any calendar year, to determine whether exposure was being kept as low as reasonably practicable. In 1991 a 4th Part of the ACOP supporting IRR85 introduced an investigation, centred on the past and future work of the individual, triggered if an employee had a recorded dose of more than 75 mSv or more in any period of five calendar years starting 1988. Closure of the last remaining tin mine in 1998 had a significant effect.

A4. Experience with specific technical aspects***Pregnant workers (1/3)***

Question A4.1: What happens when an occupationally exposed worker becomes pregnant?

Summary

Most countries adhere to ICRP 60 (2 mSv to the abdomen) or to the Euratom BSS Directive (1 mSv to the fetus); the exception is CA where 4 mSv to the fetus is tolerated. Monitoring, modified working conditions, and/or restrictions on entering controlled areas are used as appropriate in all countries to ensure compliance with dose limits. Restrictions for breast-feeding women are mentioned by CZ and SE.

Range of responses:**Australia**

It depends on the industry. Medical staff will usually continue to work but not with screening equipment or similar. If required, the person is moved temporarily to an alternative position within the organisation. Currently, ARPANSA is discussing with airlines how to handle pregnant staff, because earlier industry limits on hours worked have been revoked.

Canada

The regulations restrict the dose to 4 mSv for the balance of pregnancy. This usually requires increased monitoring and in some instances, restrictions on occupational duties.

Czech Republic

The exposure to the foetus should be reduced by a modification of working conditions so that the sum of effective doses from external exposure and committed effective doses from internal exposure of the foetus shall not exceed 1 mSv over the remaining period of pregnancy. This is entirely the responsibility of the employer. After notification that a female radiation worker is breastfeeding, the exposure of an infant by intake of radionuclides from milk shall be immediately reduced by a modification of working conditions or her suspension from work in the controlled area.

Iceland

[no comment]

Korea

When pregnancy of a female employee has been declared, her exposure should be controlled not to exceed 2 mSv to the surface of her abdomen and to limit intakes of radionuclides to about 1/20 of the ALI.

Norway

Tasks may be changed locally. Only a few staff are affected.

Slovakia

The work organisation should ensure that the dose of the fetus will be lower than 1 mSv. Pregnant workers must not work in controlled areas.

Slovenia

[no comment]

Spain

She may (voluntarily) declare her pregnancy to the service in charge of RP. If she does, she receives a new dosimeter to be placed on her abdomen to survey monthly doses to the fetus with a limit of 1 mSv at the time of birth (2 mSv at the dosimeter is assumed to equal 1 mSv to the fetus).

Information for women, practitioners and RP staff has been developed by CSN on implications and how to manage pregnancy of exposed workers.

Sweden

The worker is expected to declare her pregnancy to the employer. Then, the employer must provide an appropriate analysis. The worker has a right to be moved to non-radiation tasks during pregnancy, if there is any chance at all of exceeding the embryo/fetus dose limit.

UK

IRR99 would expect a risk assessment and ALARA-based approach subject to the requirements that:
...a radiation employer shall ensure, that -

(a) in relation to an employee who is pregnant, the conditions of exposure are such that, after her employer has been notified of the pregnancy, the equivalent dose to the foetus is unlikely to exceed 1 mSv during the remainder of the pregnancy; and

(b) in relation to an employee who is breastfeeding, the conditions of exposure are restricted so as to prevent significant bodily contamination of that employee.

Comprehensive guidance on the application of this Regulation is available

In at least some parts of the nuclear industry pregnant workers tended to be removed from controlled areas where there was a risk of internal exposure. In other areas risk assessments were carried out and their exposure carefully monitored. So no problems, as exposure above the limit could not occur.

Pregnant workers (2/3)

Question A4.2: Did the introduction of the 2 mSv limit for the abdomen (ICRP 60) or the 1 mSv limit for the embryo / fetus (Euratom Directive) cause any problems or costs?

Summary

All countries except CA state that there are no major problems. However, small employers in SE mention extra costs because it is difficult to find alternative tasks for those concerned.

Range of responses:**Australia**

No, employers where doses could be high usually understand the concerns.

Canada

Yes (*limit* not adopted, though Health Canada's Safety Code 20A contains a *recommendation* of 2 mSv to the surface of the abdomen for the balance of pregnancy).

Czech Republic

The introduction of the limit (1 mSv for the embryo/fetus) did not cause any problems.

Iceland

[no comment]

Korea

No.

Norway

Not really.

Slovakia

No.

Slovenia

[no comment]

Spain

No problems. There is an additional cost for a new dosimeter during pregnancy.

Sweden

Similar arrangements were in place already and the new limits did not cause any major problems or costs. Some operators have had additional, more stringent internal rules, and occasionally those rules caused problems when a pregnant worker refused to be removed from work with radiation.

NPP operator: We have no problems, our organisation is large enough that it is usually easy to arrange alternative work and the costs are trivial. It could be a bit more difficult for contractors and in rare cases, the pregnant worker is unwilling to do non-radiation work.

Large hospital (physicist): We comply with the rules and labour relations are fine, but sometimes it does cause costs because it is difficult to find suitable alternative work.

Non-destructive testing outfit: So far, we have never had a pregnant tester among our 120 testing staff, so we have no experience of any problems.

UK

No.

Pregnant workers (3/3)

Question A4.3: If yes, what were they and how were they resolved?

Summary

The one country with significant problems, CA, adopted a 4 mSv abdomen limit, rather than the 2 mSv abdomen (or 1 mSv fetus) limit. The reason given is that female radiation workers protested in view of possible discrimination against them if the ICRP 60 level of protection of the fetus were adopted. The limit was supplemented with a recommendation to keep abdomen doses below 2 mSv, and apparently the medical sector usually manages to follow the recommendation. A hospital in SE mentions costs because it is sometimes difficult to find alternative work for pregnant females.

Range of responses:**Australia**

[n/a]

Canada

The original draft regulations included a dose limit of 2 mSv to the abdomen for the balance of pregnancy. During the consultation process, there was considerable objection to the proposal from women working with radiation who felt that a dose limit of 2 mSv could lead to discrimination against women, because some employers might conclude that the only effective method of compliance with this low limit would be to remove a pregnant worker from work with radiation, or not hire women at all. As a result, CNSC selected a higher dose limit, 4 mSv for the balance of pregnancy. Health Canada, Canada's Dept of National Defense and many of the provinces have also adopted the 4 mSv limit. This is supplemented by a recommendation that abdomen doses be kept below 2 mSv. The medical sector reports that adhering to the recommendation does not cause any problems.

Czech Republic

[n/a]

Iceland

[no comment]

Korea

[n/a]

Norway

[n/a]

Slovakia

[n/a]

Slovenia

[no comment]

Spain

Additional dosimetry required during pregnancy.

Sweden

Large hospital (physicist; clinic director). Sometimes it is difficult to find a suitable non-radiation task for a pregnant worker, leading to extra costs.

<u>UK</u> [n/a]
Constraints (1/3)
Question A4.4: What is your experience of the introduction and use of dose constraints for occupational and public exposures?
<p><u>Summary</u></p> <p>Regulators in several countries (CA, CZ, ES) state that they are not using constraints for occupational exposure (although it is not clear if operators are using constraints internally). In countries where constraints are definitely used, understanding, explaining, and implementing them took some time. However, once correctly established, constraints are regarded as useful, both by regulators and by operators.</p> <p>Range of responses:</p> <p><u>Australia</u></p> <p>Constraints are used to good effect in the industrial context (mining, ANSTO...) and in many but not all medical contexts. ARPANSA strongly encourages licensees to set and use dose constraints. Thus, in line with ICRP recommendations, occupational dose constraints are not normally mandated but set by the operators.</p> <p><u>Canada</u></p> <p>The CNSC does not have any constraints as defined by ICRP. Where applicable, CNSC regulations require Action Levels where an Action Level is a monitored level of some type, typically dose or effluent release, which if exceeded, may indicate a loss of control. In these instances, an investigation must be initiated by the Licensee, the CNSC must be notified and corrective actions taken if necessary. At least one hospital has Investigation Levels and Action Levels for occupational exposure, the numerical values being specific to the role of the healthcare worker. Modified work duties are triggered when such levels are reached.</p> <p><u>Czech Republic</u></p> <p>We do not actually have dose constraints for occupational exposures.</p> <p>For public exposure, the dose constraint is an upper bound of the annual dose that members of the critical group of the public could receive from a discharge of radioactive substances. The dose constraint for a total discharge from a workplace is an average effective dose of 250 μSv per year for a member of a critical group, for NPPs 200 μSv for airborne discharges and 50 μSv for watercourse discharges. NPPs perform an optimization process and on the base of its results the SUJB sets down site-specific authorized discharge limits for the NPP. The authorized limits are: for NPP Dukovany 40 μSv for airborne discharges and 6 μSv for watercourse discharges and for NPP Temelín 40 μSv for airborne discharges and 3 μSv for watercourse discharges.</p> <p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>The regulatory authority provided dose constraints in terms of design targets for occupational and public exposure and annual dose standards for gaseous effluents and liquid effluents for public exposure. For NPP operation, some operational targets such as occupational exposure targets were selected by the management.</p> <p><u>Norway</u></p> <p>A good planning instrument.</p>

Slovakia

In the beginning, there were some problems with the understanding of constraints. Some clarification was necessary.

Slovenia

[no comment]

Spain

We did not introduce or use dose constraints for occupational exposures.

A constraint for dose to population from a single nuclear facility was used (100 µSv/y). It is set up by regulatory authorities in the conditions for operating permits; no problem were identified for its implementation.

Sweden

Very positive, dose constraints are used frequently (albeit sometimes with other names) and the effect is excellent. The regulator has been keen not to set occupational dose constraints but to require operators to set (and report) such constraints.

NPP operator: Our experience over the last 10-15 y is very positive. Our electronic dosimeters have area-specific alarm trigger levels which help staff to keep below constraints. Monthly follow-up analyses show that problems are almost always due to workers deviating from instructions and help us to improve training and work discipline. We do not report formally individual deviations to the regulator, but annual statistics are provided and we discuss interesting cases in our day-to-day contacts with the inspectors.

UK

It took a long time before the constraint philosophy was accepted as a useful concept. Dose constraints for occupational exposures were useful in the dose reduction programme. Direct shine from Magnox stations was an issue for a while as potentially the 300 µSv constraint could be breached – but measurements confirmed that this did not occur.

Regulatory guidance indicates that dose constraints for occupational exposures are only likely to be appropriate where doses will be a significant fraction of a dose limit. Dose constraints for public exposure are most commonly associated with environmental discharges of radioactive materials and used within the permitting system.

Constraints (2/3)

Question A4.5: Were there any difficulties? If yes, what were they and how were they resolved?

Summary

One regulator (in KR) is still trying to get operators to understand the concept and not mistake it for a limit. The ES regulator is not using constraints but achieves some of the effect by using reference levels proposed by operators and then authorised by the regulator. A hospital (in SE) mentions difficulties in assessing or measuring whether existing shielding is sufficient to comply with pertinent constraints.

Range of responses:**Australia**

[no comment]

Canada

The medical sector found that determining the actual values for their Investigation and Action Levels was perhaps the most challenging aspect, though CNSC guidance was followed.

<p><u>Czech Republic</u></p> <p>[n/a]</p> <p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>Yes. The utilities considered the dose constraint provided by the regulatory authority as a limit and the final goal, not a step of the optimization process. This couldn't be resolved [however, see B.2.3].</p> <p><u>Norway</u></p> <p>Not really.</p> <p><u>Slovakia</u></p> <p>No.</p> <p><u>Slovenia</u></p> <p>[no comment]</p> <p><u>Spain</u></p> <p>Traditionally in Spain we use reference levels, proposed by licensees and accepted by regulatory authorities.</p> <p><u>Sweden</u></p> <p>At first, there was a learning curve, particularly for an older generation of RP experts, to avoid confusion with limits. However, mostly staff at operators are well educated and in touch with developments at ICRP = well prepared. There is no adversarial tradition, rather a spirit of operators and regulators collaborating towards a common goal.</p> <p><i>Large hospital (physicist):</i> It is difficult to assess (or measure) whether our shielding is sufficient to achieve compliance with the 0.1 mSv in a year constraint on public exposure.</p> <p><i>Non-destructive testing outfit:</i> Usually, constraints is not an issue, but occasionally, special testing tasks at NPPs required us to think through the optimisation and apply constraints that affected the way the job was performed. Again, this is due to the radiation environment at the plant, not our own equipment.</p> <p><u>UK</u></p> <p>The difficulty was deciding on what to use as a constraint.</p>
Constraints (3/3)
Question A4.6: Have you at all used risk constraints? If yes, what is your experience?
<p><u>Summary</u></p> <p>Most countries have not applied formal risk constraints. Two countries (NO, UK) report that they can be useful; informal application is reported from SE while CA tries to achieve similar results using dose indicators.</p> <p>Range of responses:</p> <p><u>Australia</u></p> <p>[no comment]</p>

<p><u>Canada</u></p> <p>We have used regulatory tools [<i>restricting dose</i>] similar to constraints. The CNSC has also included secondary release limits in some licences that could be viewed as a constraint.</p> <p><u>Czech Republic</u></p> <p>[no comment]</p> <p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>[no comment]</p> <p><u>Norway</u></p> <p>More or less, yes. The experience is OK.</p> <p><u>Slovakia</u></p> <p>No.</p> <p><u>Slovenia</u></p> <p>[no comment]</p> <p><u>Spain</u></p> <p>[no comment]</p> <p><u>Sweden</u></p> <p>Hardly ever in a formal sense, although calculations performed at some irradiator installations and a few other similar establishment could be interpreted as setting risk constraints.</p> <p><i>Large hospital (clinic director):</i> Not formally, but in reality we've done the calculations for radiotherapy equipment and in nuclear medicine.</p> <p><u>UK</u></p> <p>Useful in design and risk assessments.</p>
<p style="text-align: center;"><i>Radiation dosimetry (1/3)</i></p> <p>Question A4.7: Please describe briefly the organisation and regulatory framework for dosimetry in your country.</p>
<p><u>Summary</u></p> <p>All responding countries require employers to provide workers in controlled areas with personal dosimetry from an approved dosimetry service.</p> <p><i>Range of responses:</i></p> <p><u>Australia</u></p> <p>[no comment]</p>

Canada

The CNSC Act and RP regulations require that licensees ascertain and record the dose of any persons with duties in respect to the licensed activities. If there is a possibility that the person may receive an effective dose of >5 mSv, then that licensee must use a licensed dosimetry service to measure and monitor that worker's dose. Dosimetry services are licensed under the CNSC regulations and regulatory criteria. The dose records are reported by the dosimetry service to Health Canada's National Dose Registry (NDR). The NDR will notify the CNSC, licensees and provincial authorities (where applicable) of dose transgressions and provide dose records to workers and licensees according to Privacy regulations.

Czech Republic

Personal dosimetry services must be licensed and are subject to annual metrological control.

Iceland

[no comment]

Korea

In accordance with the Atomic Energy Act, personal dosimetry services must be approved by the Ministry of Education, Science and Technology (MEST). As approval conditions, they must pass a technical proficiency assessment of personal dosimetry through performance test provided by KINS and follow a Quality Assurance Plan (QAP) composed of a quality manual, procedures, and directions including management and technical requirements.

Norway

We operate a SSDL at NRPA and have the national norm for dosimetric quantities. *[While not explicitly mentioned here, NRPA regulates the use of personal dosimetry].*

Slovakia

Personal doses should be monitored in controlled areas. Personal dosimetry is carried out by approved dosimetry services.

Slovenia

[no comment]

Spain

There are up to 22 private companies providing external dosimetry for practices. They must be authorised by CSN. Similarly, for internal dosimetry there are nine companies authorised with body counters and two companies authorised for excreta dosimetry.

Four labs are capable of providing biological dosimetry, but there is no authorisation of these labs.

Sweden

Employers are required to provide dosimetry from an approved supplier. The Euratom Directive prescribes this for Cat. A workers only, but at nuclear installations they are used for everybody ever entering controlled areas. Health care establishments have been more cost conscious and focused on Cat. A only, not least because many dosimeters never registered any dose.

UK

Employers are required to use one or more approved dosimetry service for systematically assessing doses to classified persons and making and maintaining dose records for such individuals. Approval is carried out by HSE on a five-year cycle (assessing services) and a seven-year cycle (record-keeping services). A statement made under IRR99 specifies how services are recognised and HSE publishes

detailed standards and performance tests for dosimetry services to meet.
Radiation dosimetry (2/3)
Question A4.8: Did the introduction of ICRP 60 radiation and tissue weighting factors lead to any difficulties? If yes, what were they and how were they resolved?
<p><u>Summary</u></p> <p>Most countries do not report any significant problems. The inclusion of internal doses in effective dose is mentioned by CA and UK (although this was recommended already in ICRP 26). Several licensees in SE and UK confirm that they were able to fit upgrading into their normal calibration/replacement programmes and therefore had no extra costs. However, there are also operator comments from UK that they had to wait for new dose-per-intake data [<i>a similar problem applies to ICRP 103</i>], and that many published papers used old tissue weighting factors in the absence of comprehensive new data.</p> <p>Range of responses:</p> <p><u>Australia</u> No.</p> <p><u>Canada</u> Yes. The new regulations required the calculation and reporting of the effective dose. While internal doses were monitored previously, they were not reported as an effective dose. This required significant modifications to the National Dose Registry and the licensing of dosimetry services.</p> <p><u>Czech Republic</u> No.</p> <p><u>Iceland</u> [no comment]</p> <p><u>Korea</u> [no comment]</p> <p><u>Norway</u> No.</p> <p><u>Slovakia</u> No significant problems.</p> <p><u>Slovenia</u> [no comment]</p> <p><u>Spain</u> No problems were reported. Procedures and authorization for all services were updated.</p> <p><u>Sweden</u> Problems predicted by some metrology boffins never materialised. Survey meters as well as personal dose meters were re-calibrated over a few years in the normal process of recurrent calibration.</p>

NPP operator: Recalibrations and, when required, new instrumentation were all fitted into the normal running calibration and replacement programme, so there were no real extra costs.

Large hospital (clinic director): We had to obtain some new types of personal dosimeters for finger and eye lens doses - the problem was to find equipment that worked in practical contexts; once we had identified them their use was financed within existing budgets.

UK

Comments included: (a) We had to wait for new dose/intake data; (b) No difficulties except there are many published papers using the old w_T factors as they have not been fully transformed; (c) The site already had arrangements for dosimetry, modelling and calibration. So impact was not significant.

Greatest impact was including internal exposure in the annual dose limit.

Radiation dosimetry (3/3)

Question A4.9: Were there any costs associated with the implementation of the ICRP 60 dosimetric approach (e.g. dose coefficients, modelling, instrument calibration, etc.), if so, how much and borne by whom?

Summary

Just one country, CA, reports any significant costs, viz., 100k CAD for amendments to the National Dose Registry plus various attendant costs, and initially 5k CAD annually per dosimetry service and some attendant costs. Part of the cost was not 'recoverable' [*i.e.*, *must have been paid by tax- and/or rate payers*].

Range of responses:

Australia

[no comment]

Canada

Yes there were significant costs to modify the NDR as well as licence dosimetry services. The direct cost of the NDR modifications was about \$100,000 Can. The licensing of dosimetry services was partially cost recoverable, initially at about \$5k per year per dosimetry service although this does not reflect the full regulatory cost. In addition, the dosimetry service requires participation in blind intercomparisons which are run cost-free to the licensee by Health Canada.

Czech Republic

Not that we know of.

Iceland

[no comment]

Korea

[no comment]

Norway

No, we had this ever since the 1950ies.

Slovakia

The cost of implementation has not been assessed and reported.

Slovenia

[no comment]

Spain

Some joint development (services and regulatory body together) was necessary to introduce the new modelling in ICRP 66 for internal dosimetry (measurement, dose calculation and calibration).

Sweden

Large hospital (clinic director): We did not really need to do anything beyond our normal calibration programme, so no problem, no extra cost.

Non-destructive testing outfit: The requirements on dosimetry and on dose statistics have become more stringent, but this does not seem to be because of ICRP 60.

UK

Any such costs were met by dosimetry services and employers.

Radon (1/2)

Question A4.10: Please describe briefly the current arrangements with respect to radon, in dwellings and at the workplace.

Summary

There is a wide range of rules and recommendations, from a recommended level of 148 Bq/m³ in public buildings and no other recommendation (KR) to a mandatory level of 200 Bq/m³ in all buildings (NO). In most cases, workplaces are treated differently than dwellings; requirements on landlords may also be stricter than those on home-owners. At least in one case (CZ), state subsidies are available for remediation of unusually high radon levels.

Range of responses:**Australia**

[no comment]

Canada

CNSC licensees are required to monitor and report exposures to radon progeny where applicable, but presently this only occurs in uranium mines. Health Canada and the provinces have a radon guideline of 200 Bq/m³ for residences and work areas not under the jurisdiction of the CNSC, although federally owned buildings are required to become compliant with that limit.

Czech Republic

Dwellings: There is a guidance level of 400 Bq/m³ for existing dwellings and of 200 Bq/m³ for new dwellings. In the Radon Program of the Czech Republic, detectors for radon concentration measurement are provided free of charge, methods and technologies for remediation are available. If the radon concentration in a flat is higher than 1000 Bq/m³, there is a possibility of state financial subsidy up to 6000 Eur.

Workplaces: In the decree on RP there is a list of workplaces with increased possibility of exposure to radon. The owners must ensure radon concentration measurements in such workplaces. If the radon concentration is higher than 400 Bq/m³, other investigations must be done to evaluate if the annual effective dose can be higher than 6 mSv. In that case appropriate measures must be taken to lower the radon concentration; or the workers must be protected in the same way as in controlled areas.

Iceland

[no comment]

Korea

According to the law of controlling indoor air quality to public buildings, radon is one of the 10 contaminants that should be controlled in indoor air, and the recommendation value is 148 Bq/m³. However, there is no action level or recommendation level for dwellings and workplaces.

Norway

In schools, daycare/nurseries, and dwellings for hire (not the owner) the action level is 100 Bq/m³ for taking countermeasures.

The new absolute limit is 200 Bq/m³.

Slovakia

Workplaces: Individual monitoring is preferred, but assessment of dose on the basis of workplace is allowed.

Dwellings: Radon measurements are recommended but not mandatory. The measurement could be provided by approved services.

Slovenia

[no comment]

Spain

Dwellings: a lot of measurements were performed by the regulatory body. Recommendations for building were released.

Workplaces: a technical regulation (binding) is about to be released by the regulatory body, with concentration levels above which measures must be taken and defining the specific measures for remediation and protection to be taken.

Sweden

The maximum concentration of radon in dwellings is 200 Bq/m³ (mandatory for new houses, recommended for existing houses). At workplaces above ground, the mandatory maximum concentration is 400 Bq/m³; in mines and other underground workplaces, it is 2.5 MBq/m³ per year. There are also regulations and recommendations concerning radon in drinking water.

UK

The 1999 Regulations apply to any work (other than a practice) carried out in an atmosphere containing radon 222 gas at a concentration in air, averaged over any 24 hour period, exceeding 400 Bq m⁻³ except where the concentration of the short-lived daughters of radon 222 in air averaged over any 8 hour working period does not exceed $6.24 \times 10^{-7} \text{Jm}^{-3}$. Similar requirements were contained in IRR85, so were not new to employers.

HPA has recently published new radon advice (see HPA website). Radon surveys are carried out in conjunction with local authorities on a periodic basis, focusing on areas with higher radon concentrations.

Radon (2/2)

Question A4.10: Did the implementation of ICRP 60 cause any new efforts or costs? If yes, what were they and how were they resolved?

Summary

One country (ES) mentions a lot of work with measurements and development of remediation methods. Most other respondents, including a Canadian operator, do not think that there were significant efforts or costs – at least not due to ICRP 60 (SK and SE mention some efforts but also that these are not directly connected to ICRP 60).

Range of responses:

Australia

[no comment]

Canada

Other than the issues discussed above with respect to dosimetry licensing (there is one licensed radon progeny dosimetry service), there were no additional efforts in regards to radon (although the forthcoming increase in the radon risk by ICRP will impact the uranium mine industry).

Czech Republic

Since 1991 exposure to radon has been regulated. There was state financial support mainly for measurement of radon concentration and for development of technologies for remediation. The Radon Program of the Czech Republic continues up to now.

Iceland

[no comment]

Korea

No.

Norway

A large market for radon measurements has emerged.

Slovakia

ICRP 60 itself does not cause new efforts except limiting the exposure. Regulation and control of exposures has been necessary.

Slovenia

[no comment]

Spain

A lot of work was carried out for radon measurements and to develop building techniques and materials.

Sweden

The rules and regulations concerning radon have been tightened successively over a long period, not necessarily connected directly to ICRP 60. There have been several campaigns of government-subsidised favourable loans to home-owners for radon mitigation projects.

UK

[n/a]

A5. Training implications

Regulators' staff (1/4)

Question A5.1: What methods did you use to ensure that relevant members of staff were aware of and understood the revised legislation?

Summary

All respondents describe extensive internal training programmes, using people with first-hand experience of ICRP and Euratom discussions if possible. A stratified approach in SE included a brief and simple introduction for support staff.

Range of responses:

Australia

People were already well aware of what went on in ICRP so ICRP 60 was not 'a great shock of horror'.

Canada

The CNSC has a comprehensive training program for employees, which includes training on the intent and interpretation of all the regulations.

Czech Republic

[no comment]

Iceland

[no comment]

Korea

By the periodic re-education program at KINS, all of the regulators were made aware of the revised legislation.

Norway

Internal working groups.

Slovakia

There were courses for RP officers.

Slovenia

[no comment]

Spain

Internal training was provided by those staff members who had active roles in the development of new European and national regulations.

Sweden

At the time, recurrent training was regarded as a priority (also apart from ICRP 60) and significant resources were devoted to provide staff with what they needed. There was a basic 2 h lecture on ICRP 60 with a compendium for every employee, including all support staff. For professionals, this

was followed by a 2-day course to start them reading their ICRP 60 copies. Then, there were seminars, discussions, national and international meetings, and 'table-top exercises' in handling regulatory issues with ICRP 60 at hand. Also, there were informal discussions about ICRP 60 all the time, at coffee breaks, over lunch, etc.

UK

Guidance to inspectors was prepared, also short training courses. Inspectors are well experienced with acquainting themselves with new legislation. They also attended and/or took part in familiarisation workshops and courses for employers.

Regulators' staff (2/4)

Question A5.2: Were there any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?

Summary

Not many problems are reported. The use of non-SI units in some CA installations caused and still causes confusion; the contribution of skin dose to effective dose was a source of UK discussion.

Range of responses:

Australia

[no comment]

Canada

Not too many as most were already using dose coefficients. Some licensees still use the older units (Ci and rem) which still causes some confusion.

Czech Republic

[no comment]

Iceland

[no comment]

Korea

No.

Norway

Probably.

Slovakia

Some explanation and discussions were necessary but no special problem could be reported.

Slovenia

[no comment]

Spain

No.

<p><u>Sweden</u></p> <p>Nothing that can be recalled now.</p> <p><u>UK</u></p> <p>There were some reported issues with dose coefficients. One was that skin dose contributed to effective dose.</p>
<p><i>Regulators' staff (3/4)</i></p>
<p>Question A5.3: Were you involved in ensuring that stakeholders were aware of and understood the revised legislation?</p>
<p><u>Summary</u></p> <p>All responding regulatory bodies participated in training and information of licensees; many also mention open meetings and other activities aimed at the general public. The SE NPP operator also provided information to the public.</p> <p><i>Range of responses:</i></p> <p><u>Australia</u></p> <p>[no comment]</p> <p><u>Canada</u></p> <p>The CNSC offered training on the Act and regulations to licensees and others that were interested.</p> <p><u>Czech Republic</u></p> <p>The verification of special professional competence of RP Officers is carried out before the examining commission of the regulator (SONS). The requirements for an RPO are education, 1 year experience in RP, 4 days course on RP (if working in the controlled area). Training facilities providing these courses are accredited by SONS, SONS inspectors participate as lecturers.</p> <p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>Yes.</p> <p><u>Norway</u></p> <p>Yes.</p> <p><u>Slovakia</u></p> <p>The authorities organized some seminars and courses for stakeholders and their RP officers.</p> <p><u>Slovenia</u></p> <p>[no comment]</p> <p><u>Spain</u></p> <p>Yes we, as the regulatory body, were involved.</p>

<p><u>Sweden</u></p> <p>Yes, this was an important task.</p> <p><i>NPP operator:</i> We are always providing information to the local community and to our visitors, and at the time we included some material about ICRP 60 and the Euratom Directive.</p> <p><u>UK</u></p> <p>NRPB (now HPA) provided advice to clients of RPA services and offered training courses to RP professionals and radiation users.</p> <p><i>[Medical applications]</i> The Regulator undertook regular meetings with the professional bodies during the negotiation of EC Directive 97/43/Euratom and held stakeholder meetings around the UK to explain the implementing regulations - IR(ME)R 2000</p>
<i>Regulators' staff (4/4)</i>
<p><i>Question A5.4:</i> If so, how did you do this?</p>
<p><u>Summary</u></p> <p>Written guidance material was produced, there were joint meetings with large licensees and with professional bodies representing smaller licensees, regulator staff gave lectures, etc.</p> <p><i>Range of responses:</i></p> <p><u>Australia</u></p> <p>[no comment]</p> <p><u>Canada</u></p> <p>[no comment]</p> <p><u>Czech Republic</u></p> <p>[no comment]</p> <p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>Experts in KINS participated frequently in re-training towards awareness of the revised legislation.</p> <p><u>Norway</u></p> <p>We prepared guidance documents/information material.</p> <p><u>Slovakia</u></p> <p>[no comment]</p> <p><u>Slovenia</u></p> <p>[no comment]</p> <p><u>Spain</u></p> <p>Joint (regulator + licensees) working groups were created for large facilities (nuclear fuel cycle facilities, NPPs) to develop new RP manuals and procedures.</p>

For small practices, joint working groups were created with professional societies. Formal RP manuals and procedures were written and released for free use. Other deliverables, formats, and templates were also produced. Specific guidance and instructions were released by the regulatory body when required or found of interest. Reference to regulations and guidance developed by international organisations was also used.

Sweden

There were few formal guidance documents. Primarily, guidance was developed by the regulatory authority, SSI/SSM: leaflets, reports, and information material. Professional societies arranged seminars, courses, etc., encouraged by the SSI/SSM.

UK

HSE went to considerable lengths to arrange (open) meetings with stakeholders where we could explain what the regulations really meant, and remove any misconceptions. Other regulators were involved with local liaison committees.

Stakeholders (primarily licensees, users, and employers)

Question A5.5: What was the extent of training and information required? Was this an entirely new effort, or could it be integrated into existing schedules of recurring training? What were the costs of training?

Summary

Several respondents describe extensive training programmes. Most of this was integrated into operators' existing training and information schedules, but the SE hospital interviewed had to spend additional efforts.

Range of responses:

Australia

[no comment]

Canada

NPP operator: Update and Refresher training already existed as part of the overall RP Training Program.

Czech Republic

Each licensee shall appoint at least one person in charge of RP matters = a RP officer (RPO) and a corresponding number of persons with direct responsibility for RP. These persons shall have a special professional competence taking into account the ionising radiation sources and job profile. RPOs are responsible for annual on-the-job training of radiation workers. A medical physicist (MP) shall be involved in any medical unit using X-ray practice. He/she shall be responsible for the accuracy and safety of ionizing radiation applications in clinical practice, and for managing the testing of ionizing radiation sources. The MP is a health profession according to legislation of the Ministry of Health. Due to different competence requirements on MP and RPO, the legislation of the nuclear regulator, SONS, will not be in full agreement with legislation of the Ministry of Health.

Iceland

[no comment]

Korea

ICRP 60, The Basic Safety Standards of IAEA, and the revised legislation were introduced to the stakeholders. This could be integrated into the existing training schedule. The cost of training was provided by the employers, because the training program was requested by regulation.

Norway

[no comment]

Slovakia

Mainly, only basic information was offered, but some approved services provided more detailed education. The courses organised by the authorities were cost-free. Commercial companies offered the training and courses at common prices.

Slovenia

[no comment]

Spain

In Spain all radiation workers need a personal license from CSN. To get a license, a training program must be followed provided by training companies approved by CSN. Training programs and materials were updated to the new regulations under requirement of the regulatory body. Continuous training and on the job training were used to train people at existing practices.

Cost are difficult to calculate. By the time the new regulations were released in Spain there were around 80.000 exposed workers. Not all the people required the same training, for example people working on dosimetry needed more training (hours) than others.

Sweden

NPP operator: There is a significant and mandatory programme of recurrent training of staff and contractors, and ICRP 60 and the subsequent new regulations were fitted into this programme. Thus, we did not regard this as an extra cost.

Large hospital (physicist): We planned to integrate it into our normal recurring training programme, but in reality the ICRP 60 component took much more time.

Non-destructive testing outfit: The training was integrated into our normal programme. Actually, we would welcome regulations on more training; the cost would be acceptable.

UK

Costs difficult to quantify since they involved conferences, meetings etc. Additional training was implemented to ensure operators were aware of new requirements. This was built into the current training. New Regulations required some additional training beyond the routine need for refresher/update but not believed to be excessive.

Part B: incorporating ICRP 103: Anticipated key impacts/provisions**B1. General****Legislation (1/2)**

Question B1.1: Do you expect to have to change your ionising radiation protection legislation/rules if/when ICRP 103 is incorporated?

Summary

Most respondents expect to make minor amendments only, and (as was usually the case with ICRP 60) to do these in connection with 'regular' reviews. Whether this includes changes to Acts of parliaments, or only to government/agency regulations, probably depends more on the national legal system than on the nature of the actual amendments. The federal structure in AU will lead to varying time frames between jurisdictions. UK points out that for European countries, the extent of the amendments required can hardly be determined before the new Euratom BSS Directive is published.

Range of responses:**Australia**

Yes, we are currently updating RPS1 (cf. A 1.1 above) to incorporate ICRP 103 and the international BSS. The amended RPS1 will be part of the NDRP (see A 1.1 above) and effectively become law in all jurisdictions. However, the process of implementing RPS1 into local legislation varies between jurisdictions and because of the considerable variety, this may take quite a while.

Canada

We are currently initiating a review of our radiation protection regulations and will take the opportunity to update them to the applicable ICRP recommendations, although this was not the sole reason for the review.

Czech Republic

Yes. But revision of the atomic law and related regulations are planned anyway due to changes in European law, expected construction of new nuclear installations and experience collected during the validity of current law.

Iceland

[no comment]

Korea

Yes, probably 2013-2014.

Norway

Probably not.

Slovakia

Yes.

Slovenia

We have not yet started to implement ICRP 103.

<p><u>Spain</u></p> <p>Yes.</p> <p><u>Sweden</u></p> <p>The Act is under review for other reasons but changes due to ICRP 103 are not expected to be necessary (protection of the environment is already an aim of the current Act). Minor revision of some SSM regulations will be made in the process of continuous review.</p> <p><u>UK</u></p> <p>Without a final BSS Directive it is difficult to ascertain the required changes to UK legislation/rules. On current knowledge of what the revised BSS Directive may contain, there are several new requirements, including those relating to building materials and environmental protection.</p>
<i>Legislation (2/2)</i>
<p>Question B1.2: If appropriate, please briefly describe the anticipated changes.</p>
<p><u>Summary</u></p> <p>Respondents frequently mention exposure situations, weighting factors, and optimisation and the use of constraints and reference levels. Several respondents mention new limits on dose to the lens of the eye (technically not a part of ICRP 103, but new limits were predicted there). Protection of the environment is mentioned only by ES. SK reminds us again that the extent of the amendments will depend on the European and international Basic Safety Standards.</p> <p><i>Range of responses:</i></p> <p><u>Australia</u></p> <p>With environmental protection in mind, there is a substantial amount of work going on to obtain transfer factors etc relevant for Australia.</p> <p><u>Canada</u></p> <p>The main topics that will be considered are the new radon and eye dose limits, constraints and weighting factors.</p> <p><u>Czech Republic</u></p> <p>Some changes of terminology and values, incorporation of the 'exposure situation' concept, changes in the approach to optimisation etc.</p> <p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>Anticipated changes: implementation of dose constraints and reference levels, weighting factors, evaluation of effective dose.</p> <p><u>Norway</u></p> <p>[n/a]</p> <p><u>Slovakia</u></p> <p>It depends on the final version of BSS issued by the IAEA and particularly by EU.</p>

Slovenia

[no comment]

Spain

The new dose limits for eye lenses, new categories of expositions and new approach for emergency and existing exposures, change from intervention levels to reference levels, radiation protection of the environment.

Sweden

[no comment]

UK

Reduction of the eye dose limit could have a significant effect on the number and distribution of classified workers and on the need for emergency plans under REPPIR.

Organisation (1/2)

Question B1.3: Do you expect that the incorporation of ICRP 103 will lead to any changes to the organisation and/or resources of the radiation protection regulators, compared with that reported in Section A?

Summary

Most respondents expect no change, or only minor changes.

Range of responses:**Australia**

[no comment]

Canada

No major changes are anticipated.

Czech Republic

No.

Iceland

[no comment]

Korea

No.

Norway

No.

Slovakia

Changes will be necessary, but are not expected to require considerable resources.

Slovenia

[no comment]

<p><u>Spain</u></p> <p>We don't expect big changes but small ones.</p> <p><u>Sweden</u></p> <p>Not as a consequence of ICRP 103 (but regulatory agencies are re-organised from time to time for other reasons).</p> <p><u>UK</u></p> <p>Too early to say.</p>
<i>Organisation (2/2)</i>
<p>Question B1.4: If appropriate, please briefly describe how consistency of approach between regulatory organisations is to be achieved?</p>
<p><u>Summary</u></p> <p>Where co-ordination is required, it will be achieved by continued contacts along existing mechanisms.</p> <p><i>Range of responses:</i></p> <p><u>Australia</u></p> <p>[no comment]</p> <p><u>Canada</u></p> <p>By communication, principally the Canadian Federal/Provincial/Territorial Radiation Protection Committee as discussed above.</p> <p><u>Czech Republic</u></p> <p>[no comment]</p> <p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>[n/a]</p> <p><u>Norway</u></p> <p>[n/a]</p> <p><u>Slovakia</u></p> <p>[n/a]</p> <p><u>Slovenia</u></p> <p>[no comment]</p> <p><u>Spain</u></p> <p>The same way as now.</p>

<p><u>Sweden</u></p> <p>Through continued collaboration.</p> <p><u>UK</u></p> <p>Good liaison, as before.</p>
<p><i>Burdens and benefits</i></p>
<p>Question B1.5: Does your regulatory authority expect to perform a cost-benefit analysis of the implications of any new regulations (regulatory analysis) and if so, when might a report become available (where)?</p>
<p><u>Summary</u></p> <p>In 7 of the 10 countries that responded to this question, an analysis of the costs and benefits is a mandatory part of any new rule-making. KR, SK, and ES state that they do not plan or expect to provide such an analysis.</p> <p><i>Range of responses:</i></p> <p><u>Australia</u></p> <p>Yes, a Regulatory Impact Statement including a CBA at the national level will be required.</p> <p><u>Canada</u></p> <p>Yes, Canadian Law requires that a Regulatory Impact Analysis Statement be submitted to our governing body with the draft regulations. This will not be available for until the draft regulations are ready and that will not be for 3 to 4 years. <i>[Annex B is the RIAS from the 2000 Regulations]</i>.</p> <p><u>Czech Republic</u></p> <p>Yes, it is an obligatory part of the legislation process. The final report will be available after adoption of the law or regulation.</p> <p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>No.</p> <p><u>Norway</u></p> <p>Generally - If regulations are proposed to be changed – a cost analysis must be done also.</p> <p><u>Slovakia</u></p> <p>We do not at present expect to do so.</p> <p><u>Slovenia</u></p> <p>[no comment]</p> <p><u>Spain</u></p> <p>No.</p>

<p><u>Sweden</u></p> <p>Yes, this is a formal requirement for any new regulation, and will be part of the consultative document that precedes every new regulation.</p> <p><u>UK</u></p> <p>Yes, with an input from stakeholders – already in hand. Likely to be published, as before, as an annex to the Consultative Document and thus open to comment.</p>
<p style="text-align: center;"><i>Cost of not acting</i></p> <p>Question B1.6: Will the costs / savings / implications of not implementing Publication 103 be assessed? If so, when?</p>
<p><u>Summary</u></p> <p>In a few European countries, such analyses are regarded in principle as part of a regulatory impact assessment, but there will be little or no analysis of the cost of not implementing ICRP 103 since the updated Euratom BSS Directive will make ICRP 103 mandatory in member countries.</p> <p><i>Range of responses:</i></p> <p><u>Australia</u></p> <p>[no comment]</p> <p><u>Canada</u></p> <p>Not directly, but we would not imagine it being any different than the current status quo.</p> <p><u>Czech Republic</u></p> <p>Yes, it is an obligatory part of the legislation process. The final report will be available after adoption of the law or regulation.</p> <p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>No.</p> <p><u>Norway</u></p> <p>Probably not.</p> <p><u>Slovakia</u></p> <p>There is no requirement, nor any capacity, to assess such costs.</p> <p><u>Slovenia</u></p> <p>[no comment]</p> <p><u>Spain</u></p> <p>No.</p>

<p><u>Sweden</u></p> <p>This is a mandatory part of the cost assessment, but is likely to be very cursory since the Euratom Directive will also be mandatory.</p> <p><u>UK</u></p> <p>N/a (implementation of the revised BSS Directive is an imperative).</p>
<p><i>Anticipated costs (1/2)</i></p>
<p>ICRP 103 and the new Euratom Directive will entail, e.g., amended w_R and w_T; and added emphasis on dose constraints.</p> <p>Question B1.7: How do you expect these new requirements arising from ICRP 103 to impact on operations?</p>
<p><u>Summary</u></p> <p>The impact will be limited and less than that of ICRP 60.</p> <p><i>Range of responses:</i></p> <p><u>Australia</u></p> <p>[no comment]</p> <p><u>Canada</u></p> <p>The medical sector envisages significant health physics resources being required to determine projected effective doses from each individual source in the hospital and to validate those projections. Health physics resources would also be required to re-work biokinetic models for uptake of radiopharmaceuticals used in estimation of patient doses, which is performed routinely for volunteers participating in human studies and on a case-by-case basis for patients under special circumstances (e.g., pregnancy discovered after procedure). Waste disposal may also involve additional costs, depending on any new requirements for protection of the environment.</p> <p><u>Czech Republic</u></p> <p>We are unable to estimate this now.</p> <p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>The amended w_R and w_T are expected to require significant/additional resources and time for the licensees to update their current system of dose assessment. We are going to provide them with as much assistance as we can.</p> <p>The dose constraints concept is already implemented at for NPP sites, so no new / extra significant burden is expected. However, the current system should be carefully reviewed in due course.</p> <p><u>Norway</u></p> <p>Not much.</p> <p><u>Slovakia</u></p> <p>The implementation of new weighting factors will not be a problem for the operators. The operators will probably apply dose constraints more frequently.</p>

<p><u>Slovenia</u> [no comment]</p> <p><u>Spain</u> The impact is going to be very limited. Costs are expected to be far below those for ICRP 60. Some cost may come from the incorporation and development of dose constraints.</p> <p><u>Sweden</u> <i>NPP operator:</i> ICRP 103 involves fewer changes than ICRP 60, so any costs will be smaller. As always, we will be consulted on all new regulations and the anticipated cost. We will need to consider the new weighting factors and the new phantoms for internal dosimetry. We may also have to review our emergency plans in view of ICRP 103. Mostly, this will fit into the normal work programme. <i>Large hospital (physicist):</i> The only problem we anticipate is that we will now need to clarify how we measured or assessed that our shielding is sufficient, but this is really an effect of ICRP 60, not ICRP 103. (<i>Clinic director</i>): There will be no change at all, really. <i>Non-destructive testing outfit:</i> No change that will affect us, so no new costs.</p> <p><u>UK</u> Will depend how it is implemented in UK via Euratom Directive. Not expected to be particularly significant, but still need to incorporate new dose/intakes etc.</p>
<i>Anticipated costs (2/2)</i>
<p>Question B1.8: Do you anticipate that the incorporation of ICRP 103 may lead to any reduction of any kind of cost or effort?</p>
<p><u>Summary</u></p> <p>As yet, little is known about possible cost reductions. SK points out that possible dose reductions can also be regarded as cost reductions. ES considers that elimination of 5-y dose averaging may lead to lower costs.</p> <p>Range of responses:</p> <p><u>Australia</u> [no comment]</p> <p><u>Canada</u> [no comment]</p> <p><u>Czech Republic</u> [no comment]</p> <p><u>Iceland</u> [no comment]</p> <p><u>Korea</u> No.</p> <p><u>Norway</u> Maybe stricter radon requirement will imply more costs – no real overview of this.</p>

<p><u>Slovakia</u></p> <p>It is possible that the implementation may lead to a dose reduction, but we do not expect that the reduction will be significant.</p> <p><u>Slovenia</u></p> <p>[no comment]</p> <p><u>Spain</u></p> <p>Some cost reduction is possible if the 5-yr averaging of dose limits is abolished.</p> <p><u>Sweden</u></p> <p>Not yet known.</p> <p><u>UK</u></p> <p>Not yet known.</p>

B2. Experience with specific technical aspects

Pregnant workers (1/2)

Question B2.1: Do you envisage that the introduction of the 1 mSv limit for the embryo / fetus (ICRP 103) will cause any problems or costs? (*Note: this question does not apply to EU member countries since the current Euratom BSS Directive already prescribes such a limit.*)

Summary

None is expected in any of the four responding countries that are not EU member states (which are already subject to the limit in question – see Note above). CA does not expect to change its current higher limit, which is supplemented by a recommendation to adhere to the ICRP 60 level.

Range of responses:

Australia

[no comment]

Canada

While the current dose limit for pregnant workers would be open to change during the review, it has undergone two major consultation processes and so we don't anticipate changing it.

Czech Republic

[n/a]

Iceland

[n/a]

Korea

No.

<p><u>Norway</u> No.</p> <p><u>Slovakia</u> [n/a]</p> <p><u>Slovenia</u> [n/a]</p> <p><u>Spain</u> [n/a]</p> <p><u>Sweden</u> [n/a]</p> <p><u>UK</u> [n/a]</p>
<i>Pregnant workers (2/2)</i>
Question B2.2: If yes, what might they be, and how do you plan to resolve them?
<p><u>Summary</u></p> <p>Since no country expects any problems, no respondent provided any reply to this question.</p>
<i>Constraints (1/2)</i>
Question B2.3: Is the added emphasis on dose constraints in ICRP 103 expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?
<p><u>Summary</u></p> <p>Difficulties are expected in CA and ES where constraints have been little used so far. In KR, where operators tend to mistake constraints for limits (cf. A.4.5), the regulator resolved difficulties by recommending constraints in a non-mandatory guide. In countries already using constraints (CZ, NO, SK, SE, UK) no or only limited difficulties are expected (UK cites waste disposal), and the SE NPP operator is outright enthusiastic.</p> <p><i>Range of responses:</i></p> <p><u>Australia</u> [no comment]</p> <p><u>Canada</u> Yes, there is already wide opposition to the use of dose constraints, both inside and outside of the CNSC. Nevertheless they will be put forward for discussion. NPP operators believe firm dose constraints could cause difficulties if they're implemented as <i>de facto</i> source-specific (meaning from their NPP operations) dose limits set at values lower than existing dose limits. Depending on the dose levels chosen or imposed, operations and refurbishment projects could be impacted. The impacts are likely to be restricted to occupational exposure. The medical sector foresees significant resources being needed to determine the projected effective dose from each of the many sources in a hospital. However, much is already standard practice and restricting efforts to identified roles would be one possible solution.</p>

<p><u>Czech Republic</u></p> <p>No.</p> <p><u>Iceland</u></p> <p>[no comment]</p> <p><u>Korea</u></p> <p>Yes. But we resolved it by recommending the use of constraints in non-mandatory regulatory guides rather than as legal requirements.</p> <p><u>Norway</u></p> <p>No.</p> <p><u>Slovakia</u></p> <p>No.</p> <p><u>Slovenia</u></p> <p>[no comment]</p> <p><u>Spain</u></p> <p>Yes. The use of dose constraints has been very limited in Spain so far. We need to introduce dose constraints for occupational, emergency and existing situations and to develop approaches to implement them and control their use.</p> <p><u>Sweden</u></p> <p>No difficulties expected, but in theory this will require some new approaches by operators. In reality, they have already moved in this direction - they read ICRP reports, and such developments follow naturally from the continuous dialogue between operators and regulators.</p> <p><i>NPP operator</i>: No problem, we are very pleased with the experience of working with constraints.</p> <p><i>Large hospital (physicist)</i>: No problems envisaged.</p> <p><u>UK</u></p> <p>Yes, waste disposal – but constraints are there already as part of policy.</p>
Constraints (2/2)
Question B2.4: Are risk constraints likely to be introduced with the implementation of ICRP 103?
<p><u>Summary</u></p> <p>No country is firmly committed to introducing risk constraints.</p> <p>Range of responses:</p> <p><u>Australia</u></p> <p>[no comment]</p> <p><u>Canada</u></p> <p>The medical sector sees a possible use in emergency preparedness and response, though the concept fits well with the current guidance/best practice in these areas.</p>

<p><u>Czech Republic</u> Maybe.</p> <p><u>Iceland</u> [no comment]</p> <p><u>Korea</u> No.</p> <p><u>Norway</u> [no comment]</p> <p><u>Slovakia</u> This depends on the coming Euratom Directive.</p> <p><u>Slovenia</u> [no comment]</p> <p><u>Spain</u> Probably not.</p> <p><u>Sweden</u> Possibly by encouraging operators to set risk constraints more often.</p> <p><u>UK</u> [n/a]</p>
<i>Dosimetry</i>
<p>Question B2.5: Are the new ICRP 103 radiation and tissue weighting factors expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p>
<p><u>Summary</u></p> <p>No country seems to expect serious difficulties. However, KR and UK mention technical computation problems which may take some time to resolve, and UK adds that publications will continue to use old weighting factors for some time.</p> <p>Range of responses:</p> <p><u>Australia</u> [no comment]</p> <p><u>Canada</u> No, they should not cause any undue difficulties.</p> <p><u>Czech Republic</u> No.</p>

<p><u>Iceland</u> [no comment]</p> <p><u>Korea</u> Difficulties come from the new added tissues. But, we have developed new phantoms which incorporate the new added tissues and are in the process of resolving the difficulties.</p> <p><u>Norway</u> No.</p> <p><u>Slovakia</u> No serious difficulty expected.</p> <p><u>Slovenia</u> [no comment]</p> <p><u>Spain</u> No they are not. The same difficulties as for ICRP 60 are expected.</p> <p><u>Sweden</u> Given that ICRP 60 caused few problems in this respect, and ICRP 103 involves less dramatic changes, no difficulties are expected.</p> <p><u>UK</u> Published papers will use old factors and these will be in use until replaced. Work is in progress to calculate new ICRP dose coefficients using the revised radiation and tissue weighting factors, but at the same time update methodology more generally using, for example, new phantoms of the human body and updated nuclear decay data. ICRP intend in the short-term to provide a compilation of pre-103 dose coefficients for external and internal exposures to be used in the revised BSS until new coefficients are published. Effective doses from some exposures are likely to increase due to the changes, e.g., those involving breast doses, and others will decrease. The overall effects are complex and will not be known until calculations are complete.</p>
<p><i>Radon</i></p> <p>Question B2.6: Is the implementation of ICRP 103 expected to cause any new efforts or costs with respect to radon? If yes, what are they and how do you plan to resolve them?</p>
<p><u>Summary</u></p> <p>Replies range from 'no efforts/costs' (CA, CZ) via 'not yet known' (KR, SK, UK), 'miners want new dose coefficients but have expertise in-house' (AU), and 'there will be costs, but not due to ICRP 103' (SE) to 'yes, there will be significant efforts and costs' (NO, ES).</p> <p><i>Range of responses:</i></p> <p><u>Australia</u></p> <p>The main problem is that relevant dose coefficients are not yet available. We follow the ICRP advice to use existing coefficients until new information is provided. Miners would like this information, but they have good expertise in house.</p>

Canada

No, n/a

Czech Republic

No special new effort or costs are expected.

Iceland

[no comment]

Korea

Radon is a difficult and hot remaining issue. A lot of discussions are underway; no national consensus is reached yet. The conclusion is expected soon with a new Living Environment Radioactivity Act.

Norway

Yes, this will affect many public buildings and houses. National action plans will be prepared. The cost is difficult to foresee at this stage.

Slovakia

This depends on how it will be implemented in Euratom directives.

Slovenia

[no comment]

Spain

Yes. As radon concentrations must now be lower, the scope of activities and facilities will grow. The approach will probably be very similar to that introduced after ICRP 60.

Sweden

No, there may well be further developments and costs with respect to radon, but not as a result of ICRP 103.

UK

Not yet known.

B3. Training implications

Regulators' staff (1/3)

Question B3.1: What methods do you plan to use to ensure that relevant members of staff were aware of and understood the revised legislation?

Summary

Most respondents expect much the same kind of training programme as with ICRP 60.

Range of responses:

Australia

[no comment]

Canada

There will be a formal training program for the new regulations.

Czech Republic

[no comment]

Iceland

[no comment]

Korea

Open seminar, workshop and specific training courses.

Norway

Internal working groups.

Slovakia

We will prepare some workshops and training for the regulatory body staff.

Slovenia

[no comment]

Spain

Internal training provided by those who took part in development of the new IAEA BSS and Euratom Directive.

Sweden

In principle, the same methods that were applied when ICRP 60 was implemented (cf. A.6.1). For a number of reasons, e.g., scarcity of resources, it is feared that in reality the training this time will be less complete, but the intention is to do the same thing.

UK

Written instructions, seminars and government and regulator guidance.

Regulators' staff (2/3)

Question B3.2: Do you anticipate any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?

Summary

No significant problems are expected (UK mentions some terms that will need explaining).

Range of responses:

Australia

[no comment]

Canada

No, no issues anticipated.

Czech Republic

[no comment]

Iceland

[no comment]

Korea

No.

Norway

Not really.

Slovakia

No.

Slovenia

[no comment]

Spain

No. We anticipate only operational difficulties to be sorted out based on knowledge and experience.

Sweden

No.

UK

'Critical Groups' are out, 'representative persons' are in, this will need explaining. And that a rep. person is purely notional.

Regulators' staff (3/3)

Question B3.3: Do you expect to be involved in ensuring that stakeholders are aware of and understood the revised legislation? If so, how do you anticipate doing this?

Summary

All respondents expect to participate in stakeholder involvement. Basically, the same procedures as with ICRP 60 are envisaged, but some countries mention that internet technology (not available at the time of ICRP 60) will facilitate this significantly.

Range of responses:**Australia**

[no comment]

Canada

Yes, stakeholders will be widely informed and consulted during the entire regulation amendment process. This will be done by bulletins, web postings and public meetings.

Czech Republic

[no comment]

Iceland

[no comment]

Korea

Stakeholders will be involved in the implementation of ICRP 103 in accordance with the existing rules.

Norway

Yes, revision of guidance documents.

Slovakia

We expect that the regulatory staff will be involved and a few seminars or workshops for the stakeholders will be organised after the BSS of IAEA and EU are issued.

Slovenia

[no comment]

Spain

As we did for the ICRP 60 implementation, we will involve them in regulations development and work with them for the implementation.

Sweden

Yes, as with ICRP 60. Thus: consultations, meetings, FAQ documents, lectures... E-mail and web sites will facilitate this work.

UK

Yes, as previously, including local site stakeholder groups.

Stakeholders (primarily licensees, users, and employers)

Question B3.4: What do you expect will be the extent of training and information required? Will this be an entirely new effort, or could it be integrated into existing schedules of recurring training? What

may be the anticipated costs of training?

Summary

Respondents, including operators, expect to be able to fit the training into existing programmes (also at the SE hospital where training for ICRP 60 required more effort). The caveat that the imminent Euratom Directive may change conditions is added by UK.

Range of responses:

Australia

[no comment]

Canada

Generally, integration into existing training programs and schedules.

Czech Republic

[no comment]

Iceland

[no comment]

Korea

The training is expected to be integrated into existing schedules of recurring training. Not much cost.

Norway

[no comment]

Slovakia

[no comment]

Slovenia

[no comment]

Spain

As the system has not been entirely changed but explained in a different (more clear and friendly) way, we think training efforts will be less than those made to introduce ICRP 60. The main uncertainty is that related to dose constraints as this tool has had very limited use in the past.

Sweden

NPP operator: General information will be provided within the normal recurrent training programme. Some specialists will need much more detailed information, but this is a small group. Thus, the extra costs will be trivial.

Large hospital (clinic director): We will have training of course, but expect to be able to fit this into our normal training programme by focusing specifically on ICRP 103 during one or two years,

UK

Depends on the Euratom Directive. HPA/CRCE has provided update training for RP professionals and will provide user training when UK situation is known.

Additional comments provided

Australia

Even in cases where ARPANSA is not the direct regulator, our presence is strong and operators regard our documents as binding for them. However, we try to use professional bodies when possible, particularly in the medical area. This is time-consuming, but works well so it's worth the effort.

Canada

Medical sector: The impact of ICRP 103 to medical facilities will ultimately depend on how federal and provincial regulatory bodies incorporate these concepts into regulation. The outreach to stakeholders analogous to the issuance of C-122 for stakeholders comment in 1991 addressing ICRP 60 recommendations has not yet happened for ICRP 103. That being said, the impact of ICRP 103 is anticipated to be minimal on current medical practice, as many of the changes do not apply/significantly impact our operations.

With doses to patients from medical procedures not currently addressed in Canadian legislation, such standards (i.e. Dose Reference Levels, concepts of justification and optimization) provide guidance for practitioners but do not fit into the current regulatory framework. Should the regulatory framework in Canada change to encompass oversight of doses to patients, this would have large implications in the practice of Radiation Safety/Health Physics at medical installations. Currently our mandate is limited to occupational exposures, unless a malfunction of a radiation-emitting device is involved.

Czech Republic

Concerning the retrospective estimation of the costs, the implementation of ICRP 60 and BSS 1994 happened just after political changes in our country and the whole legislative system went through dramatic changes – so nobody really cared about the costs – particularly in our 'small' field. Now it is obligatory to do some kind of regulatory impact assessment as it is popular everywhere and we do it 'somehow' but for the implementation of ICRP 103 it is too early for us. We are now in the stage of preparation of an entirely new Atomic Law and all related legislation where we intend to implement also some aspects of ICRP103 and of course to be prepared also for new European legislation already but we are really in the beginning. We have prepared some 'objectives' for new legislation where major changes are identified (but the real major changes are, e.g., the complete change of financing of our office, a quite new organizational structure, or some specific problems of nuclear safety – so in this light our 'RP problems' are at this stage too small for more detailed specification of possible impacts.

Slovakia

The Public Health Authority carries out all activities in the RP area (legislation, supervision, licensing...). The financial support is given from the Ministry of Health.

Sweden

Nuclear operators are usually prepared to accept sensible proposals. If we can convince them that something will increase safety and/or reduce doses, they will accept the costs. There is a clear tradition of constant improvement in collaboration with the regulator. The health care sector is also keen on collaboration in principle, but in health care, cost does become an issue more often.

Canada Gazette



Gazette du Canada

Part II

Partie II

OTTAWA, WEDNESDAY, JUNE 21, 2000

OTTAWA, LE MERCREDI 21 JUIN 2000

Statutory Instruments 2000

Textes réglementaires 2000

SOR/2000-200 to 239 and SI/2000-43 to 50

DORS/2000-200 à 239 et TR/2000-43 à 50

Pages 1122 to 1555

Pages 1122 à 1555

NOTE: Irrelevant pages below deleted; only the pages comprising the regulatory impact statement for new rad.prot. rules are retained

NOTICE TO READERS

The *Canada Gazette* Part II is published under authority of the *Statutory Instruments Act* on January 5, 2000 and at least every second Wednesday thereafter.

Part II of the *Canada Gazette* contains all "regulations" as defined in the *Statutory Instruments Act* and certain other classes of statutory instruments and documents required to be published therein. However, certain regulations and classes of regulations are exempted from publication by section 15 of the *Statutory Instruments Regulations* made pursuant to section 20 of the *Statutory Instruments Act*.

Each regulation or statutory instrument published in this number may be obtained as a separate reprint from Canadian Government Publishing, Public Works and Government Services Canada. Rates will be quoted on request.

The *Canada Gazette* Part II is available in most libraries for consultation.

For residents of Canada, the cost of an annual subscription to the *Canada Gazette* Part II is \$67.50, and single issues, \$3.50. For residents of other countries, the cost of a subscription is US\$67.50 and single issues, US\$3.50. Orders should be addressed to: Canadian Government Publishing, Public Works and Government Services Canada, Ottawa, Canada K1A 0S9.

Copies of Statutory Instruments that have been registered with the Clerk of the Privy Council are available, in both official languages, for inspection and sale at Room 418, Blackburn Building, 85 Sparks Street, Ottawa, Canada.

AVIS AU LECTEUR

La *Gazette du Canada* Partie II est publiée en vertu de la *Loi sur les textes réglementaires* le 5 janvier 2000 et au moins tous les deux mercredis par la suite.

La Partie II de la *Gazette du Canada* est le recueil des « règlements » définis comme tels dans la loi précitée et de certaines autres catégories de textes réglementaires et de documents qu'il est prescrit d'y publier. Cependant, certains règlements et catégories de règlements sont soustraits à la publication par l'article 15 du *Règlement sur les textes réglementaires*, établi en vertu de l'article 20 de la *Loi sur les textes réglementaires*.

Il est possible d'obtenir un tiré à part de tout règlement ou de tout texte réglementaire publié dans le présent numéro en s'adressant aux Éditions du gouvernement du Canada, Travaux publics et Services gouvernementaux Canada. Le tarif sera indiqué sur demande.

On peut consulter la *Gazette du Canada* Partie II dans la plupart des bibliothèques.

Pour les résidents du Canada, le prix de l'abonnement annuel à la *Gazette du Canada* Partie II est de 67,50 \$ et le prix d'un exemplaire, de 3,50 \$. Pour les résidents d'autres pays, le prix de l'abonnement est de 67,50 \$US et le prix d'un exemplaire, de 3,50 \$US. Veuillez adresser les commandes à : Les Éditions du gouvernement du Canada, Travaux publics et Services gouvernementaux Canada, Ottawa, Canada K1A 0S9.

Des exemplaires des textes réglementaires enregistrés par le greffier du Conseil privé sont à la disposition du public, dans les deux langues officielles, pour examen et vente à la pièce 418, édifice Blackburn, 85, rue Sparks, Ottawa, Canada.

REPEAL

36. The *Atomic Energy Control Regulations*¹ are repealed.

37. The *Transport Packaging of Radioactive Materials Regulations*² are repealed.

38. The *Uranium and Thorium Mining Regulations*³ are repealed.



39. The *Physical Security Regulations*⁴ are repealed.

COMING INTO FORCE

40. These Regulations come into force on the day on which they are approved by the Governor in Council.

SCHEDULE
(Section 33)

CERTIFICATE OF INSPECTOR

	<p>This is to certify that Le présent certificat atteste que</p> <p>employed by employé de</p> <p>is designated as an inspector by the Canadian Nuclear Safety Commission pursuant to section 29 of the <i>Nuclear Safety and Control Act</i>.</p> <p>est un inspecteur désigné par la Commission canadienne de sûreté nucléaire conformément à l'article 29 de la <i>Loi sur la sûreté et la réglementation nucléaires</i>.</p> <p>This certificate expires on Ce certificat expire le</p>	
	<p>Inspector / Inspecteur</p> <p>Secretary, CNSC / Secrétaire, CCSN</p>	
<p> Canadian Nuclear Safety Commission Commission canadienne de sûreté nucléaire</p>		<p></p>

ABROGATIONS

36. Le *Règlement sur le contrôle de l'énergie atomique*¹ est abrogé.

37. Le *Règlement sur l'emballage des matières radioactives destinées au transport*² est abrogé.

38. Le *Règlement sur les mines d'uranium et de thorium*³ est abrogé.

39. Le *Règlement sur la sécurité matérielle*⁴ est abrogé.

ENTRÉE EN VIGUEUR

40. Le présent règlement entre en vigueur à la date de son agrément par le gouverneur en conseil.

ANNEXE
(article 33)

CERTIFICAT DE L'INSPECTEUR

<p>The person identified on this certificate may exercise the powers granted to an inspector under the <i>Nuclear Safety and Control Act</i> in respect of the following places or vehicles:</p>	<p>La personne identifiée sur ce certificat peut exercer les pouvoirs d'un inspecteur prévus à la <i>Loi sur la sûreté et la réglementation nucléaires</i> dans les lieux ou véhicules suivants :</p>
<p>This certificate is not transferable and is to be surrendered on the termination of this designation.</p>	<p>Le certificat est incessible et doit être remis lorsque la désignation prend fin.</p>

REGULATORY IMPACT
ANALYSIS STATEMENT

(This statement is not part of the Regulations nor the Rules.)

1. Description

This Regulatory Impact Analysis Statement (RIAS) pertains to the regulations and rules made under the *Nuclear Safety and Control Act* (NSC Act). A draft version of nine technical regulations was published for comment in the *Canada Gazette*, Part I on October 10, 1998, and the *Canadian Nuclear Safety Commission Rules of Procedure* were similarly published on February 13, 1999. Changes have been made to the draft version of the RIAS, regulations and rules based on comments received during the consultation phase.

¹ C.R.C., c. 365
² SOR/83-740
³ SOR/88-243
⁴ SOR/83-77

RÉSUMÉ DE L'ÉTUDE D'IMPACT
DE LA RÉGLEMENTATION

(Ce résumé ne fait pas partie des règlements ni des règles.)

1. Description

Le présent Résumé de l'étude d'impact de la réglementation (RÉIR) se rapporte aux règlements et aux règles pris aux termes de la *Loi sur la sûreté et la réglementation nucléaires*. Une version provisoire de neuf règlements techniques a été publiée aux fins de commentaires dans la *Gazette du Canada* Partie I le 10 octobre 1998, tout comme les *Règles de procédures de la Commission canadienne de sûreté nucléaire*, qui ont paru le 13 février 1999. La version provisoire du RÉIR, les règles et les règlements ont été modifiés à partir des commentaires recueillis au cours de la période de consultation.

¹ C.R.C., ch. 365
² DORS/83-740
³ DORS/88-243
⁴ DORS/83-77

Nuclear activities in Canada are regulated by the Atomic Energy Control Board (AECB) under the *Atomic Energy Control Act* (AEC Act) of 1946. These activities are carried out by approximately 3,700 licensees and occur, for example, in power and research reactors, uranium mines and mills, accelerators, waste management facilities, nuclear medicine, packaging and transport of radioactive materials, industrial gauges and research involving radioisotopes. The AEC Act is out of date in many significant areas and to correct the situation, Parliament passed the NSC Act on March 20, 1997. This new legislation is intended to come into force when new regulations, based on the powers set out in the NSC Act, have been finalized. This will allow continuation of the regulatory system administered by the AECB. Under the provisions of the NSC Act, the AECB will be replaced by the Canadian Nuclear Safety Commission (CNSC) and, with the exception of the ex officio position on the Board, the members and staff of the AECB will become the members and staff of the CNSC.

In order to simplify the transition to the new regulatory system under the NSC Act, the AECB has minimized the number of substantive changes in the new regulations. For the most part, the new regulations consist of the requirements in the AEC Act, AEC Regulations and licence conditions, but in a format compatible with the NSC Act. These unchanged requirements are not discussed in this document. Some new regulatory requirements have been added and these are discussed in detail below.

Under the AEC Act, the technical requirements are specified in the *Atomic Energy Control Regulations*, the *Transport Packaging of Radioactive Materials Regulations* and the *Uranium and Thorium Mining Regulations*. Under the NSC Act, these requirements are specified in nine regulations, each of which is described separately in section 3 below. Where significant changes are made, the alternatives, costs and benefits of the changes are described under the specific regulation. Consultation and compliance issues that are common to all of the new regulations are addressed in sections 5 and 6, rather than under each separate regulation. Consultations on a specific issue however, are described in the section dealing with the issue.

The regulations continue the practice of allowing licensees considerable flexibility in how they comply with the requirements. With some exceptions, such as the dose limits, transport packaging and licence exemption criteria for certain devices, the regulations do not specify in detail the criteria that will be used in assessing a licence application or judging compliance. The regulations provide licence applicants with general performance criteria and lists of information that they must supply. If the information is acceptable, it may be referenced in the licence, thus making it a legal requirement for the licensee in question. This approach to nuclear regulation is consistent with the practice followed to date in Canada.

The CNSC intends to continue the use of regulatory documents to inform applicants of its regulatory expectations. Not all documents have been completed but those with an immediate or significant impact on licensees' operations have been identified. High priority has been given to their completion and many have been approved or have been published in draft form for comments. Those that are unavailable are expected in the near future and where necessary, their lack is addressed in the CNSC's plan for transition to the new regulatory regime. During development

La Commission de contrôle de l'énergie atomique (CCEA) réglemente toutes les activités nucléaires au Canada aux termes de la *Loi sur le contrôle de l'énergie atomique* (LCEA) de 1946. Environ 3 700 titulaires de permis exercent ces activités dans les domaines suivants : réacteurs de puissance ou de recherche, mines ou installations de concentration d'uranium, accélérateurs, installations de gestion des déchets, médecine nucléaire, emballage et transport de matières radioactives, utilisation d'instruments industriels calibrés et recherche impliquant des radioisotopes. La LCEA étant périmée dans nombre de domaines importants, le Parlement a adopté le 20 mars 1997 la *Loi sur la sûreté et la réglementation nucléaires* (LSRN). La nouvelle loi entrera en vigueur lorsque ses règlements d'application seront complétés, assurant ainsi la continuité du régime de réglementation administré par la CCEA. Aux termes de la LSRN, la CCEA sera remplacée par la Commission canadienne de sûreté nucléaire (CCSN) et, à l'exception du poste de membre d'office de la Commission, les commissaires et le personnel de la CCEA passeront au service de la CCSN.

Afin de simplifier la transition au nouveau régime de réglementation de la LSRN, la CCEA a réduit au minimum le nombre de changements réglementaires significatifs apportés à la nouvelle réglementation, qui reprend essentiellement les exigences, les règlements et les conditions de permis stipulées dans la LCEA, et les rend compatibles avec la LSRN. Nous n'aborderons pas ici les exigences réglementaires qui demeurent inchangées, mais nous expliquerons en détail celles qui viennent s'ajouter.

Aux termes de la LCEA, les exigences techniques étaient énoncées dans le *Règlement sur le contrôle de l'énergie atomique*, le *Règlement sur l'emballage des matières radioactives destinées au transport* et le *Règlement sur les mines d'uranium et de thorium*. Aux termes de la LSRN, ces exigences figurent dans neuf règlements, décrits plus loin à la rubrique 3. Lorsque des modifications importantes ont été apportées, les coûts et les avantages qui en découlent ainsi que les solutions de rechange qui ont été envisagées sont décrites. Les questions de consultation et de conformité communes à tous les nouveaux règlements sont traitées aux rubriques 5 et 6. Par contre, les consultations entreprises sur une question particulière sont rapportées dans la rubrique qui s'y rattache.

Les règlements continuent de laisser aux titulaires de permis une souplesse considérable quant à la façon de satisfaire aux exigences. Mises à part quelques exceptions comme les limites de dose, l'emballage destiné au transport et les critères d'exemption de permis pour certains appareils, ils ne précisent pas en détail les critères qui serviront à l'évaluation d'une demande de permis ou de la conformité au règlement. Ils indiquent aux demandeurs de permis les critères généraux de rendement et les renseignements qu'ils doivent fournir. Si les renseignements fournis sont jugés acceptables, ils pourront être cités au permis, devenant ainsi exigence légale pour ce titulaire de permis. Cette approche de la réglementation nucléaire est conforme aux pratiques courantes au Canada.

La CCSN souhaite continuer d'utiliser les documents d'application de la réglementation pour informer les demandeurs de permis de ses attentes en matière de réglementation. Ces documents ne sont pas entièrement achevés, mais tous ceux qui ont une incidence directe ou importante sur les activités des titulaires de permis ont été cernés. Plusieurs documents, qui font l'objet d'une attention prioritaire, ont déjà été soit approuvés, soit publiés en version provisoire aux fins de commentaires. Les documents qui ne sont pas achevés sont attendus dans un proche avenir et,

of each regulatory document, the CNSC is committed to extensive consultation on all aspects of the document and the Act provides an opportunity for those affected by CNSC actions to be heard by the Commission.

2. Alternatives to New Regulations

Since the nuclear regulatory control system must function after the transition from the AEC Act to the NSC Act, new compatible regulations must be issued simultaneously with the introduction of the new NSC Act to allow the scheme to operate. Therefore, there are no alternatives to passage of new regulations.

3. Regulatory Initiatives

This section describes the significant new requirements of the regulations together with their impact on licensees and the significant changes that were made to the regulations as a result of comments received following publication in the *Canada Gazette*, Part I. Many changes were also made to improve clarity but these are not described in this document unless they had a significant effect on the requirements.

3.1 General Nuclear Safety and Control Regulations

The *General Nuclear Safety and Control Regulations* contain the general requirements that apply to all licensees. They consist primarily of the regulatory requirements contained in the AEC Regulations and licence conditions. They also continue the exemption for naturally occurring radioactive materials that have not been associated with the development, production or use of nuclear energy. As authorized by the NSC Act, a requirement to provide information on any proposed financial guarantees has been added. Except for section 12 as described below, there were no major changes to these Regulations as a result of comments received following publication in the *Canada Gazette*, Part I.

3.1.1 Financial Guarantees

Under the AEC Act and Regulations, only a few licensees were required to provide financial assurances for decommissioning and waste management. A possible consequence of this was the costs associated with these activities would fall on the taxpayer if the licensee had not set aside sufficient funds for their completion. To address this, subsection 24(5) of the NSC Act provides the CNSC with the authority to include a licence condition requiring financial guarantees in a form that is acceptable to the Commission. The financial guarantees section of the NSC Act is being implemented by regulations requiring licence applicants to provide information on proposed financial guarantees and to describe their plans for decommissioning and waste management at the end of the life of the nuclear facility. The estimated costs of these plans and the financial guarantees proposed to cover these costs will be reviewed by the Commission. The resulting requirements would be imposed by licence condition.

The regulations permit substantial flexibility in the ways that licensees can meet the financial requirements. Options acceptable to the Commission are described in a draft regulatory document.

s'il y a lieu, leur absence sera compensée dans le plan de transition au nouveau régime de réglementation de la CCSN. L'élaboration de chacun des documents d'application de la réglementation continuera d'être le résultat de vastes consultations effectuées par la CCSN, et la LSRN permet aux personnes touchées par les mesures envisagées d'être entendues par la Commission.

2. Solutions envisagées

Puisque le régime de réglementation nucléaire doit être mis en application après la transition de la LCEA à la LSRN, les règlements d'application de la LSRN doivent être prêts au moment de l'entrée en vigueur de la LSRN. Il n'y a donc pas d'autre solution que d'adopter les nouveaux règlements.

3. Initiatives en matière de réglementation

Cette section fait état des exigences significatives contenues dans les nouveaux règlements, de leurs conséquences pour les titulaires de permis ainsi que des changements notables apportés aux règlements à partir des commentaires qui ont suivi la publication des projets de règlement dans la *Gazette du Canada* Partie I. Plusieurs modifications ont aussi été apportées par souci de clarté, mais elles ne sont pas mentionnées ici si elles n'ont pas de conséquences notables sur les exigences.

3.1 Règlement général sur la sûreté et la réglementation nucléaires

Le *Règlement général sur la sûreté et la réglementation nucléaires* renferme les exigences générales qui s'appliquent à tous les titulaires de permis. Il contient principalement les exigences actuellement prévues au *Règlement sur le contrôle de l'énergie atomique* et aux conditions de permis. Il maintient aussi l'exemption accordée relativement aux matières radioactives naturelles qui ne sont pas associées au développement, à la production ou à l'utilisation d'énergie nucléaire. En conformité avec la LSRN, il est dorénavant requis de fournir des renseignements sur toute garantie financière proposée. À l'exception de l'article 12 (explications ci-dessous), le règlement n'a subi aucune modification importante à la suite de commentaires reçus après sa publication dans la *Gazette du Canada* Partie I.

3.1.1 Garanties financières

Aux termes de la LCEA et de ses règlements, seuls quelques-uns des titulaires de permis étaient tenus de fournir des assurances financières en prévision du déclassement de leurs installations et de la gestion de leurs déchets. Or, il pourrait en résulter que ce fardeau financier retombe sur les épaules des contribuables dans le cas où les titulaires de permis n'auraient pas réservé les sommes suffisantes pour achever ces travaux. Pour régler ce problème, le paragraphe 24(5) de la LSRN stipule que la CCSN peut assortir un permis d'une condition exigeant une garantie financière sous une forme qu'elle juge acceptable. L'article relatif aux garanties financières de la LSRN est mis en application par le biais du règlement selon lequel le demandeur de permis doit décrire ses garanties financières et ses plans de déclassement et de gestion des déchets à la fin de la vie utile de l'installation nucléaire. La CCSN examinera les coûts estimés de ces plans et les garanties financières proposées. Les exigences découlant de cette analyse seraient imposées comme conditions du permis.

Le règlement est très souple quant à la façon dont le titulaire de permis peut satisfaire aux exigences financières. Les options que la CCSN juge acceptables sont décrites

(a) Alternatives to Financial Guarantees

It was clearly the intent of Parliament to authorize the CNSC to require financial guarantees, and consequently, the consideration of alternatives does not apply.

(b) Costs

Licensees have always been responsible for the costs associated with decommissioning their facilities. Therefore, the cost resulting from the application of subsection 24(5) of the NSC Act is limited to the incremental cost of providing a financial guarantee. Financial guarantees are already required under the *Uranium and Thorium Mining Regulations* so for these licensees, there are no incremental costs. There will be several types of mechanisms that a licensee may use to satisfy the CNSC requirement for a financial guarantee, but there are factors outside the control of the CNSC that can significantly affect the cost of providing a financial guarantee. The most important of these factors is the willingness of governments (federal and provincial) to underwrite the decommissioning costs of facilities they own or that operate within the province. Depending on these decisions, the cost of financial guarantees could range from zero if there is a commitment from government to millions of dollars in the case of major facilities with high decommissioning costs. It is therefore difficult to estimate the actual financial impact of this requirement.

The AECB is currently reviewing the comments received on the draft regulatory document on financial guarantees. Until this document is finalized and until other decisions are made, in particular those referred to above, it will not be possible to estimate with any degree of accuracy, the total cost resulting from implementing subsection 24(5) of the NSC Act. For this reason, no costs are included in this document.

(c) Benefits

Requiring financial guarantees will reduce the risk that taxpayers will eventually have to pay the decommissioning costs.

3.1.2 Obligations of Licensees

In the version of the regulations published in the *Canada Gazette*, Part I, subsection 12(2) required licensees to take certain actions, such as conducting a test or modifying equipment, when requested to do so by the Commission. It was pointed out that these requests were in effect the same as orders under section 35 of the NSC Act, without the appeal mechanisms provided by the Act. Subsection 12(2) of the regulations has been changed to require only that licensees provide a response to a request from the Commission within the time period specified. A request will therefore not have the effect of an order.

3.2 Radiation Protection Regulations

These Regulations contain the radiation protection requirements and as such, they apply to all licensees and others who fall within the mandate of the Commission. Medical doses, doses to caregivers who do not do this as a profession and doses to

dans une version provisoire d'un document d'application de la réglementation.

a) Solutions de rechange aux garanties financières

Le Parlement avait clairement l'intention d'autoriser la CCSN à exiger des garanties financières. Aucune solution de rechange n'a donc été envisagée.

b) Coûts

Le titulaire de permis a toujours été responsable des coûts relatifs au déclassement de ses installations. Le coût résultant de l'application du paragraphe 24(5) de la LSRN est donc limité au coût additionnel de la garantie financière. Des garanties financières déjà exigées aux termes du *Règlement sur les mines d'uranium et de thorium*. Par conséquent, les titulaires de permis concernés n'auront pas à engager de coûts additionnels. Un titulaire de permis aura le choix parmi plusieurs mécanismes pour satisfaire aux exigences de garantie financière de la CCSN. Il existe cependant des facteurs hors du contrôle de la CCSN qui peuvent affecter le coût d'une garantie financière, le principal étant le consentement des pouvoirs publics (fédéraux et provinciaux) de soutenir financièrement les coûts de déclassement des installations qu'ils possèdent ou qui sont exploitées dans leur province. Selon ces décisions, le coût des garanties financières pourrait varier entre zéro, s'il y a un engagement gouvernemental, et plusieurs millions de dollars dans le cas d'installations importantes dont les coûts de déclassement sont élevés. Il est donc difficile d'estimer l'ampleur des répercussions financières de cette exigence.

La CCEA étudie actuellement les commentaires recueillis sur la version provisoire d'un document d'application de la réglementation traitant des garanties financières. Il sera impossible d'estimer avec précision le coût total que représente la mise en application du paragraphe 24(5) de la LSRN tant que ce document ne sera pas achevé et que d'autres décisions n'auront pas été prises, notamment celles qui sont mentionnées plus haut. C'est pour cette raison que les coûts ne figurent pas ici.

c) Avantages

En imposant des garanties financières, on réduit considérablement le risque pour les contribuables d'avoir à payer les coûts de déclassement.

3.1.2 Obligations du titulaire de permis

Le paragraphe 12(2) de la version du règlement publiée dans la *Gazette du Canada* Partie I stipulait que, sur demande de la Commission, le titulaire de permis est tenu de prendre certaines mesures comme la mise à l'essai ou la modification d'équipement. Il est apparu qu'une telle demande est, en fait, identique à l'ordre mentionné à l'article 35 de la LSRN, sans les mécanismes d'appel que prévoit la loi. On a donc modifié le paragraphe 12(2) du règlement de façon à exiger du titulaire de permis uniquement une réponse à la demande de la Commission dans le délai donné. Une demande n'aura donc plus l'effet d'un ordre.

3.2 Règlement sur la radioprotection

Ce règlement stipule les exigences en matière de radioprotection et, à ce titre, il s'applique à tous les titulaires de permis et autres organismes assujettis à la réglementation de la CCSN. Les doses médicales, les doses reçues par les bénévoles qui dispensent

volunteers in biomedical research are specifically excluded from the regulations.

As a result of comments received following publication in the *Canada Gazette*, Part I, changes were made to the definitions in sections 1 and 12 and to the application of ALARA (as low as reasonably achievable) in paragraph 4(a) to improve clarity and make these Canadian requirements consistent with international practice.

The *Radiation Protection Regulations* represent regulatory requirements under the AEC Act with revised dose limits and the addition of action levels.

3.2.1 New Dose Limits

The dose limits in most countries are based on the recommendations of the International Commission on Radiation Protection (ICRP). Using the most recent data on the effects of radiation, the ICRP recommended lowering the dose limits in 1991 as follows:

- for nuclear energy workers, from 50 millisievert* (mSv)/year to 100 mSv for five years (i.e., an average of 20 mSv/year);
- for pregnant nuclear energy workers, from 10 mSv/year to 2 mSv/year; and
- for members of the public, from 5 mSv/year to 1 mSv/year.

Except for pregnant workers as described below, the new regulations reflect these recommendations.

* A millisievert is the unit used to measure the dose equivalents from different types of radiation. Typically, Canadians receive between 2 and 3 mSv per year from background radiation.

In July 1991, the AECB published consultative document C-122, which contained the basic proposal for reduction of the dose limits. Based on the comments received, it was clear that the dose limit for pregnant workers required special consideration since it was a significant decrease from existing practice and could affect employment opportunities for women in the nuclear industry. In 1992, a series of eight workshops was held across Canada specifically on the topic of dose limits for pregnant workers. A total of 338 persons attended the meetings and based on these consultations and a thorough review of the risks of radiation, the maximum effective dose to the worker during the period of the pregnancy was set at 4 mSv in the new regulations. The new regulations also require licensees to take any measure that does not constitute undue hardship to the licensee, to continue to employ the pregnant worker and meet the dose limit. In 1997, the ICRP also recognized the possibility of employment discrimination and as a result, stated that its recommended dose limit for pregnant workers should not be interpreted too rigidly.

Since 1992, the AECB has consulted extensively with the nuclear industry and the Canadian public on the issue of implementing ICRP 60 recommendations as the standard for the Canadian dose limits. The AECB has also been working closely with workers and the industry to lower exposures and thus make introduction of the proposed dose limits less of a burden.

des soins et les doses administrées aux volontaires qui collaborent à la recherche biomédicale sont expressément exclues du règlement.

Les définitions des articles 1 et 12 et l'application du principe ALARA (le niveau le plus faible qu'il soit raisonnablement possible d'atteindre) du paragraphe 4a) ont été modifiées en fonction des commentaires qui ont suivi la publication du règlement dans la *Gazette du Canada* Partie I afin de les rendre plus claires et d'harmoniser les exigences canadiennes avec les pratiques internationales.

À l'exception des nouvelles limites de dose et des nouveaux seuils d'intervention, le *Règlement sur la radioprotection* reprend les exigences réglementaires de la LCEA.

3.2.1 Nouvelles limites de dose

Dans la plupart des pays, les limites de dose sont fondées sur les recommandations de la Commission internationale de protection radiologique (CIPR). D'après les données les plus récentes sur les effets des rayonnements, la CIPR a recommandé en 1991 que ces limites soient réduites et passent :

- pour le travailleur du secteur nucléaire, de 50 mSv* par année à 100 mSv pour cinq ans (soit une moyenne de 20 mSv par année);
- pour la travailleuse enceinte du secteur nucléaire, de 10 à 2 mSv;
- pour le public, de 5 à 1 mSv par année.

Les nouveaux règlements reflètent ces recommandations, sauf en ce qui concerne la travailleuse enceinte.

* Un millisievert est l'unité de mesure la plus communément utilisée pour évaluer les doses équivalentes des différents types de rayonnement. En général, un Canadien reçoit entre 2 et 3 mSv par année de rayonnement naturel.

En juillet 1991, la CCEA publiait le document de consultation C-122, qui contenait la proposition de base pour la réduction des limites de doses. À la lumière des commentaires reçus, il était clair qu'il fallait accorder une attention particulière à la limite de dose pour la travailleuse enceinte puisqu'il s'agissait d'une diminution importante par rapport à la pratique existante et que cette mesure pouvait avoir des répercussions sur les perspectives d'emploi des femmes dans l'industrie nucléaire. En 1992, 338 personnes ont participé à huit ateliers organisés partout au Canada sur ce sujet particulier de la limite de dose pour la travailleuse enceinte. À la suite de ces consultations et d'un examen complet des risques du rayonnement, la dose maximale efficace pour la travailleuse enceinte a été fixée dans le nouveau règlement à 4 mSv. Le nouveau règlement exige aussi du titulaire de permis qu'il prenne toutes les mesures qui ne présentent pas pour lui des contraintes excessives afin de garder la travailleuse enceinte comme employée tout en respectant la limite de dose fixée. En 1997, ayant également reconnu la possibilité de discrimination dans l'emploi, la CIPR a par la suite déclaré que la limite de dose recommandée pour la travailleuse enceinte ne devrait pas être interprétée de façon trop rigoureuse.

Depuis 1992, la CCEA mène de vastes consultations auprès des représentants de l'industrie nucléaire et du public canadien au sujet de l'adoption des recommandations de la CIPR (Publication 60) à titre de norme visant les limites de

(a) Alternatives to New Dose Limits

The ICRP recommendations are becoming the world standard for radiation exposure. These values represent a risk level that is recognized as “acceptably low” by the international scientific community, and there is no sound rationale to adopt different limits, with the exception of the pregnant worker dose limit described above.

(b) Costs

The proposal to reduce the dose limits for workers has been under discussion since the publication of AECB consultative document C-122 in 1991. To avoid problems associated with dose averaging, this document proposed a dose limit of 20 mSv/year for workers in the nuclear energy industries. In the same year, an AECB-funded study by Price-Waterhouse concluded the costs associated with this lower limit would be very significant, increasing overall costs by approximately 17% for reactor operations and 4% for mining operations. Since then, a number of changes have occurred that have convinced the AECB that the flexibility of the ICRP's five-year limit should be introduced in Canada. These changes include modification of the National Dose Registry to accommodate averaging and reductions in the average exposure of Canadian workers.

In 1997, Health Canada reported that for the five-year period ending in 1995, no nuclear worker at a reactor site received a dose that exceeded 100 mSv. Therefore, the new dose limit should have no significant effect on reactor operations or costs. For the uranium mining industry during the same five-year period, 72 underground miners and support workers from a total of 1,485 in these categories exceeded 100 mSv by an average of 22%. During the 10-year period ending in 1995, the average dose for these categories decreased by approximately 4% per year and if this trend continues, the excess should be eliminated within several years. A preliminary analysis by Health Canada of the dosimetry data for 1998 indicates that no reactor or mining worker received a dose that exceeded 20 mSv/year as compared with 9 reactor workers and 37 mining workers who exceeded that limit in 1997.

For both reactor and mining licensees, some new costs will be associated with increased surveillance caused by the new dose limits and averaging. Some greater attention will need to be paid to work scheduling and dose monitoring to reduce exposures. The incremental cost is estimated to be less than \$200,000 annually for all reactor licensees. Based on information from the mining industry, the annual incremental costs will be approximately \$100,000 per mining facility for a total industry cost estimated to be \$600,000 per year.

Thirty-seven from a total of 3,444 industrial radiographers received a dose that exceeded 100 mSv during the five-year period ending in 1995. The average dose for the 37 workers must be decreased by 40% using a combination of retraining, better supervision, rearranged workloads, and better use of time, distance and shielding. Reducing by an average of 40% the dose received by 1% of the workers in this industry is estimated to cost \$200,000 per year.

The new public dose limits will result in a number of licensees' staff being designated as nuclear energy workers who were not considered atomic radiation workers under the AEC Act. Data from the National Dose Registry shows that, approximately 6,000 workers received doses between

dose au Canada. La CCEA a également collaboré étroitement avec les travailleurs et l'industrie afin de diminuer les expositions pour ainsi faciliter l'instauration des limites de dose proposées.

a) Solutions de rechange aux nouvelles limites de dose

Les recommandations de la CIPR sont en train de s'imposer comme norme mondiale en matière d'exposition aux rayonnements. Ces valeurs représentent ce que la communauté scientifique internationale considère comme un niveau de risque « assez faible pour être acceptable » et, sauf en ce qui concerne la travailleuse enceinte tel qu'expliqué plus haut, il n'y a aucune raison valable d'adopter des limites différentes.

b) Coûts

La proposition visant à abaisser la limite de dose des travailleurs a fait l'objet de discussions depuis la publication en 1991 du document de consultation C-122 de la CCEA. Pour éviter les problèmes liés à l'utilisation d'une dose moyenne, ce document préconisait un maximum de 20 mSv par année pour le travailleur des industries utilisant l'énergie nucléaire. Au cours de la même année, à la suite d'une étude financée par la CCEA, Price-Waterhouse a conclu que les coûts de cette réduction de la limite de dose seraient très élevés puisqu'ils se traduiraient par une augmentation des coûts globaux d'environ 17 % pour les centrales nucléaires et de 4 % pour les mines d'uranium. Depuis, un certain nombre de changements, comme les modifications apportées au Fichier dosimétrique national pour permettre l'utilisation de doses moyennes et incorporer la réduction de l'exposition moyenne du travailleur canadien, ont convaincu la CCEA que la souplesse de la limite de cinq ans de la CIPR méritait d'être introduite au Canada.

En 1997, Santé Canada a rapporté que, pour la période de cinq ans se terminant en 1995, aucun travailleur de centrale nucléaire n'avait été soumis à un rayonnement de plus de 100 mSv. La nouvelle limite ne devrait donc pas affecter les opérations ou les coûts des centrales de façon notable. Pour la même période dans l'industrie minière de l'uranium, 72 mineurs de fond et travailleurs auxiliaires sur un total de 1 485 ont reçu plus de 100 mSv dans 22 % des cas. Pendant la période de dix ans se terminant en 1995, la dose moyenne pour ces catégories a diminué d'environ 4 % par année et, si cette tendance se maintient, le dépassement devrait être éliminé d'ici à plusieurs années. Une analyse préliminaire des données dosimétriques réalisée par Santé Canada pour 1998 indique qu'aucun travailleur de centrale ou de mine n'a reçu de dose supérieure à 20 mSv par an alors qu'en 1997, cette limite avait été dépassée dans le cas de neuf travailleurs de centrale et de 37 mineurs.

Les titulaires de permis de centrales et de mines devront exercer une surveillance accrue quant aux nouvelles limites de dose et au calcul de la moyenne et porter plus d'attention à l'établissement des horaires de travail et à la surveillance des doses afin de réduire les expositions. On estime à moins de 200 000 \$ par année pour l'ensemble des titulaires de permis de centrales le coût additionnel qui sera associé à ces mesures. Des renseignements recueillis auprès des industries minières indiquent qu'elles devront pour leur part envisager des coûts d'environ 100 000 \$ pour chacune des installations, pour un coût total estimé à 600 000 \$ par année.

1 mSv and 5 mSv during 1997. People occupying these positions will have to be notified that they are nuclear energy workers and provided with information about the risks of radiation. This information can be obtained from sources such as the CNSC and the International Atomic Energy Agency (IAEA). The majority of affected licensees are involved with power reactors or uranium mining, and in such cases, programs and procedures already exist for their atomic radiation workers. Incremental costs therefore should be minimal. Approximately 1,000 licensees primarily involved with medical or research uses will have to establish a notification program. The average cost per licensee is estimated to be \$1,000. The one-time cost to the industry is therefore estimated to be \$1 million.

(c) Benefits

The basic benefit from lower dose limits is the reduced risk to workers and members of the public from radiation resulting from the nuclear industry. This will make Canada's dose limits consistent with international standards. Providing nuclear energy workers with information about radiation protection and risks will tend to reduce exposures.

Chez les opérateurs de gammagraphie, 37 travailleurs sur un total de 3 444 ont reçu des doses dépassant 100 mSv pendant cette même période de cinq ans se terminant en 1995. La dose moyenne pour ces travailleurs devrait donc diminuer de 40 % grâce à l'effet combiné des mesures suivantes : perfectionnement des connaissances, amélioration de la supervision, réaménagement des horaires et utilisation efficace du temps, de la distance et du blindage. La hausse des coûts correspondant à une réduction en moyenne de 40 % de la dose pour 1 % des travailleurs de cette industrie ne devrait pas se chiffrer à plus de 200 000 \$.

En raison des nouvelles limites de dose pour le public, un grand nombre de personnes employées par des titulaires de permis seront désignées comme travailleurs de l'industrie nucléaire alors qu'aux termes de la LCEA ces personnes n'étaient pas considérées comme travailleurs sous rayonnements. Les données du Fichier dosimétrique national montrent qu'environ 6 000 travailleurs ont reçu en 1997 des doses variant entre 1 mSv et 5 mSv. Les personnes qui occupaient ces postes devront être informées qu'elles sont dorénavant considérées comme des travailleurs de l'industrie nucléaire et devront recevoir de l'information sur les risques de l'exposition aux rayonnements. On peut obtenir cette information à la CCSN et à l'Agence internationale de l'énergie atomique (AIEA). Comme la majorité des titulaires de permis concernés appartiennent au secteur des centrales nucléaires ou à celui des mines d'uranium, ils possèdent déjà des programmes et des procédures visant leurs travailleurs sous rayonnements. Les coûts supplémentaires associés à cette mesure devraient donc être mineurs. Environ 1 000 titulaires de permis, notamment dans les secteurs de la médecine et de la recherche, devront mettre sur pied un programme de notification dont le coût moyen est estimé à 1 000 \$ par titulaire de permis. On prévoit donc que l'industrie aura à assumer un coût ponctuel d'environ 1 million de dollars.

c) Avantages

Le principal avantage des nouvelles limites de dose est de réduire les risques d'exposition aux rayonnements pour les travailleurs et les membres du public provenant de l'industrie nucléaire. Les limites de dose en vigueur au Canada seront dorénavant conformes aux normes internationales. De plus, les expositions devraient être diminuées grâce à l'information qui sera distribuée aux travailleurs du secteur de l'énergie nucléaire au sujet de la radioprotection et des risques reliés aux rayonnements.

3.2.2 Action Levels

An action level is a specific dose or other parameter which, if reached, may indicate a partial loss of control of the radiation protection program. The *General Nuclear Safety and Control Regulations* require applicants to submit information on any action level they use or propose to use. If an action level is referred to in a licence, the *Radiation Protection Regulations* require the licensee to investigate, take appropriate actions and notify the Commission when an action level is exceeded.

The establishment of action levels is consistent with the recommendations of the ICRP. Most major licensees have action levels, but they may be identified as reference levels, investigation levels, etc. Reporting when one of these levels is exceeded was not a regulatory requirement under the AEC Act or Regulations.

3.2.2 Seuils d'intervention

Un seuil d'intervention peut être une dose particulière ou un autre paramètre qui, une fois atteint, pourrait indiquer la perte de contrôle d'une partie du programme de radioprotection. Le *Règlement général sur la sûreté et la réglementation nucléaires* exige que le demandeur présente des renseignements sur les seuils d'intervention qu'il utilise ou se propose d'utiliser; si un seuil d'intervention indiqué dans un permis est dépassé, le *Règlement sur la radioprotection* exige que le titulaire de permis fasse enquête, prenne les mesures voulues et avise la Commission.

L'établissement de seuils d'intervention correspond aux recommandations de la CIPR. La plupart des titulaires de permis importants possèdent déjà des seuils d'intervention, parfois désignés sous le nom de seuils de référence,

(a) Alternatives to Action Levels

One alternative to action levels is to allow licensees to delay any response to an anomaly until a regulatory limit is reached, thus increasing the risk that a person may be exposed to doses in excess of the limits before the problem is identified and corrected. This is not considered acceptable in protecting persons and the environment.

Allowing licensees complete flexibility in the establishment of action levels and in notification to the CNSC has been effective for some licensees but such flexibility is not considered acceptable for the industry as a whole.

(b) Costs

Most licensees already have established levels and take actions before regulatory limits are reached, so no major costs are anticipated. Some additional documentation and reporting may be necessary, but the associated incremental costs per licensee are not considered to be significant (i.e., approximately \$100,000 per year for all licensees).

(c) Benefits

By taking action before regulatory limits are reached, the frequency and severity of noncompliance with regulatory limits will be minimized.

niveaux d'investigation, etc. La LCEA et ses règlements ne prévoient pas que le titulaire de permis soit tenu de signaler le dépassement de ces seuils.

a) Solutions de rechange aux seuils d'intervention

Une solution de rechange serait de permettre au titulaire de permis de reporter tout rapport d'anomalie tant que la limite réglementaire n'est pas atteinte. Or, cette solution augmente le risque qu'une personne soit exposée à des doses supérieures aux limites avant que le problème ne soit identifié et corrigé, ce qui n'est pas jugé acceptable lorsqu'il s'agit d'assurer la protection des personnes et de l'environnement.

Une entière flexibilité dans l'établissement des seuils d'intervention et des rapports à communiquer à la CCSN convient à certains titulaires de permis, mais n'est pas jugée acceptable pour l'industrie dans son ensemble.

b) Coûts

La plupart des titulaires de permis établissent déjà des seuils d'intervention et prennent des mesures avant que les limites réglementaires ne soient atteintes. Cette initiative ne devrait donc pas entraîner de coûts importants. Il pourrait être pertinent d'ajouter de la documentation et des rapports, mais le coût supplémentaire par titulaire de permis ne sera pas élevé (ex. : environ 100 000 \$ par année pour l'ensemble des titulaires de permis.)

c) Avantages

Lorsque des mesures sont prises avant que les limites réglementaires ne soient atteintes, les cas de non-conformité sont moins fréquents et moins graves.

3.3 Class I Nuclear Facilities Regulations

The *Atomic Energy Control Regulations* include reactors, particle accelerators, uranium processing plants and waste management facilities in the definition of "nuclear facilities." Under the NSC Act, the definition has been expanded to include those plants that possess, process or use large quantities of radioactive material because their level of risk falls within the range of other nuclear facilities. Since the licensing criteria vary significantly for this expanded list of nuclear facilities, it was decided to separate the group of licensees into two classes of facilities that better reflect their operations and the risks associated with them. Class II nuclear facilities therefore consist of low-energy particle accelerators and equipment containing only sealed sources because of the lower risk these types of facilities represent.

The requirements specified in the *Class I Nuclear Facilities Regulations* for major facilities such as reactors, high-energy accelerators and uranium processing facilities are essentially the same as those under the AEC Act, regulations and licence conditions. The impact of the new regulations on operator recertification and uranium or large radioisotope processing plants that are included as class I nuclear facilities, are discussed below.

The only major change to these Regulations resulting from the comments received following publication in the *Canada Gazette*, Part I concerned the subdivision of the class I nuclear facilities into class IA and class IB. The rationale for this change is explained as part of section 3.3.2.

3.3 Règlement sur les installations nucléaires de catégorie I

La définition d'« installation nucléaire » figurant dans le *Règlement sur le contrôle de l'énergie atomique* désigne les réacteurs, les accélérateurs de particules, les usines de traitement d'uranium et les installations de gestion des déchets. Aux termes de la LSRN, cette définition a été élargie pour inclure les usines qui possèdent, traitent ou utilisent de grandes quantités de matière radioactive, car leur seuil de risque est semblable à celui d'autres installations nucléaires. Puisque les critères menant à l'obtention du permis varient considérablement entre les installations nucléaires apparaissant sur cette nouvelle liste élargie, ces installations ont été regroupées en deux catégories, qui reflètent mieux leurs activités et les risques qu'elles représentent. Dans la catégorie II se trouvent réunis les accélérateurs de particules à faible énergie et les équipements n'utilisant que des sources scellées, vu le moindre risque que représente ce type d'installation.

Le *Règlement sur les installations nucléaires* de catégorie I, qui précise les exigences applicables aux grandes installations comme les centrales, les accélérateurs à haute énergie et les usines de traitement d'uranium, reprend essentiellement les termes de la LCEA, de ses règlements et des conditions de permis. Nous décrivons plus loin l'effet du nouveau règlement, en ce qui a trait au renouvellement de l'accréditation des opérateurs et aux usines de traitement d'uranium ou aux grandes usines de traitement des radio-isotopes, qui font partie des installations nucléaires de catégorie I.

La seule modification importante apportée à ce règlement à la lumière des commentaires reçus à la suite de la publication dans la *Gazette du Canada* Partie I a trait à la subdivision des installations nucléaires de catégorie I en catégories IA et IB. Les motifs de ce changement sont expliqués à la section 3.3.2.

3.3.1 Operator Certification

The AECB required the senior control room staff of nuclear power reactors to pass examinations administered by the AECB that tested their competence to operate nuclear reactors safely. Only examinations for initial certification were required, but licensees were expected to maintain the competence of their staff through regular training. For some time, the AECB has considered that a mechanism for verifying continuing competence is necessary and under the AEC Act, it began the process by adding an expiry date to all existing certifications.

Under the *Class I Nuclear Facilities Regulations*, certifications issued by the CNSC expire after five years, and in order to be recertified, senior control room staff will be required to successfully complete a continuing training program and requalification tests administered by the licensee to demonstrate continuing competence. The licensee's continuing training program and tests will be evaluated regularly by Commission staff.

A recertification process, which has been under discussion with the industry for more than five years, was started under the AEC Act and Regulations. A series of meetings was held with the power reactor operators on implementation of a five-year recertification program. The power utilities made presentations to the Board at its August 12, 1999, meeting in which they expressed concern about the proposed recertification program. The Board concluded that further consultation was necessary, and at its November 4, 1999, meeting, it received five presentations from union and other groups representing affected workers at the three power generation licensees. The Board confirmed the decision to implement a five-year recertification process.

(a) Alternatives to Operator Recertification

There are no alternatives to recertification to provide the regulator with adequate assurance of continuing competency. High standards of performance are expected and as with safety-critical jobs in other industries, a formal demonstration that those standards continue to be met is considered essential. Periodic renewal of certification is consistent with the practices in many other countries where nuclear power plants operate.

(b) Costs

It is estimated that reactor licensees will need to invest about \$500,000 in total to develop recertification training programs for their nuclear operators. The continued management and conduct of this training are expected to require additional staff for a total cost of \$350,000 per year. Additional staff will be required at the Commission to monitor these requalification programs conducted by the licensees. This cost, which is estimated to be approximately \$200,000 per year, is expected to be reflected in licensing fees charged to the affected licensees. The incremental operating cost to the industry for this new regulatory requirement is therefore estimated to be \$550,000 per year.

(c) Benefits

The safe operation of nuclear power plants in Canada is dependent upon highly trained and competent staff. The initial training and examination programs for senior control room operators are comprehensive to allow the regulator to be satisfied that staff can meet the high standards required to perform their duties. The continuing training programs

3.3.1 Accréditation des opérateurs

La CCEA a exigé que les membres supérieurs du personnel de la salle de commande d'une centrale nucléaire passent des examens administrés par la CCEA et ce, pour permettre d'évaluer leur compétence à exploiter des réacteurs nucléaires en toute sûreté. Jusqu'à présent, les examens n'étaient exigés que pour l'accréditation initiale, et il incombe au titulaire de permis de maintenir la compétence de son personnel grâce à une formation régulière. Depuis un certain temps, la CCEA est d'avis qu'il faut implanter un mécanisme visant à vérifier le maintien du niveau de compétence; ce processus a été amorcé avec la LCEA puisque toutes les accréditations existantes sont limitées par une date d'expiration.

Le *Règlement sur les installations nucléaires de catégorie I* stipule que l'accréditation accordée par la CCSN expire après une période de cinq ans et que, pour obtenir le renouvellement de leur accréditation, les membres supérieurs du personnel de la salle de commande doivent suivre et réussir un programme de formation et des examens de requalification administrés par le titulaire de permis afin de démontrer que leurs compétences sont maintenues à niveau. La CCSN évaluera régulièrement les programmes de formation continue et les examens utilisés par les titulaires de permis.

Un processus de renouvellement de l'accréditation, à l'étude avec les représentants de l'industrie depuis plus de cinq ans, a débuté sous le régime de la LCEA et de ses règlements. La mise sur pied d'un programme de renouvellement de l'accréditation de cinq ans a été l'objet d'une série de réunions tenues avec des exploitants de centrales. Lors de la réunion de l'actuelle Commission du 12 août 1999, les services publics d'électricité ont fait des présentations dans lesquelles ils exprimaient leurs inquiétudes par rapport au programme proposé de renouvellement de l'accréditation. La CCSN a conclu que des consultations supplémentaires s'imposaient et a entendu les présentations des syndicats et d'autres groupes qui représentaient les travailleurs concernés chez les trois titulaires de permis centrales nucléaires. La CCSN a confirmé par la suite sa décision d'implanter un processus de réaccréditation de cinq ans.

a) Solutions de rechange au renouvellement de l'accréditation

Aucune solution de rechange au renouvellement de l'accréditation ne permettrait d'assurer un maintien adéquat des compétences. On s'attend à ce que le rendement d'un exploitant d'installation nucléaire satisfasse à des normes élevées et, à l'instar d'autres industries où certains emplois ont une grande incidence sur la sûreté, on juge essentiel qu'il soit formellement démontré que ces normes sont respectées en permanence. Le renouvellement périodique de l'accréditation fait partie des pratiques en vigueur dans de nombreux pays où sont exploitées des centrales nucléaires.

b) Coûts

On estime que les titulaires de permis de centrales nucléaires devront investir environ 500 000 \$ pour mettre sur pied des cours et des programmes pour assurer le renouvellement de l'accréditation de leurs opérateurs. La gestion de la formation et la formation elle-même pourraient exiger du personnel supplémentaire, ce qui représente un coût de 350 000 \$ par année. En outre, la CCSN aura besoin de personnel supplémentaire pour assurer la surveillance des

and periodic requalification tests by this new initiative will provide confidence that operators will maintain the competence required for safe reactor operation.

3.3.2 Reclassification

Based on the definition of a class I nuclear facility, the large processors of radioactive material will become class I nuclear facilities. They have expressed concerns that because of this new categorization, they would be subjected to the same standards as applied to reactors which are also class I facilities and that these standards are not commensurate with the level of risk associated with the operation of their facilities. The AECB has provided assurances that this will not be the case. The regulatory requirements will reflect the risk and not the classification of the facility. Alternatives to and the impact of reclassification have been discussed at a series of meetings with industry.

The uranium processing facilities have suggested that it would be more appropriate if they were included in the *Uranium Mines and Mills Regulations* rather than the *Class I Nuclear Facilities Regulations*. As discussed below, the AECB does not believe that such a change is appropriate.

The same processors of radioactive material have also commented that these Regulations were not as clear as they could be with respect to the application of operator certification to their facilities. To clarify the AECB's intentions on this matter, the definition of class I nuclear facilities has been modified. Class I nuclear facilities have been subdivided into class IA and class IB and the text of section 9 has been modified to state that sections 9-13, which deal with certification of persons, do not apply to class IB nuclear facilities.

(a) Alternatives to Reclassification

The AECB has undertaken an initiative to promote greater consistency in the application of regulatory tools to all licensees, and in particular, to adjust AECB activities to relate more closely to the risk associated with each facility. This initiative is consistent with the 1994 recommendations of the Office of the Auditor General concerning the need for a clearly documented regulatory strategy and formal program evaluation. A review indicated that the risks associated with three large processors of radioactive material and the uranium processing facilities more closely match those of class I nuclear facilities than those associated with radioisotope licences, uranium mines or class II nuclear facilities. Therefore, in the interest of a consistent risk-based

programmes de renouvellement de l'accréditation des titulaires de permis, entraînant des frais supplémentaires d'environ 200 000 \$ par année, qui se refléteront dans les droits de permis des titulaires concernés. Cette nouvelle exigence réglementaire représentera donc pour l'industrie des coûts supplémentaires de 550 000 \$ par année.

c) Avantages

L'exploitation sûre des centrales nucléaires au Canada dépend étroitement de la compétence et de la bonne formation de leur personnel. La formation initiale et les programmes d'examen des membres supérieurs du personnel des salles de commande sont exhaustifs, et la CCSN peut ainsi être convaincue que le personnel peut satisfaire à la norme élevée de compétence nécessaire pour effectuer ses tâches. La formation continue et les examens périodiques de renouvellement de l'accréditation apporteront l'assurance que les opérateurs maintiennent le niveau de compétence exigé pour une exploitation sûre des centrales nucléaires.

3.3.2 Reclassification

La définition d'une installation nucléaire de catégorie I entraînera la reclassification des grandes installations de transformation des matières radioactives dans cette catégorie. Ces industries ont des réserves, car ces nouvelles classifications les assujettissent aux mêmes normes que les centrales nucléaires, qui sont aussi classées dans la catégorie I, alors que leur seuil de risque n'est pas comparable. À cet égard, elles ont reçu l'assurance de la CCEA que ce ne serait pas le cas. Les exigences réglementaires correspondront au seuil de risque de chacun et non à la classification des installations. Les solutions de rechange à la reclassification et les répercussions de la reclassification ont fait l'objet de discussions au cours d'une série de réunions tenues avec les représentants de l'industrie.

Les représentants des installations de traitement de l'uranium estiment qu'il serait plus approprié de les régir par l'application du *Règlement sur les mines et les usines de concentration d'uranium* plutôt que du *Règlement sur les installations nucléaires de catégorie I*. Or, comme il a été expliqué plus haut, la CCEA ne croit pas qu'un tel changement est approprié.

Les mêmes installations de transformation de matières radioactives ont aussi fait observer que le règlement pourrait mieux préciser si les dispositions visant l'accréditation du personnel s'appliquent également à leurs installations. Pour clarifier son intention à ce sujet, la CCEA a modifié la définition des installations nucléaires de catégorie I. Ces installations ont été subdivisées en deux catégories, soit la catégorie IA et la catégorie IB. De plus, l'énoncé de l'article 9 a été modifié pour indiquer que les articles 9 à 13 inclusivement, portant sur l'accréditation des personnes, ne s'appliquent pas aux installations nucléaires de catégorie IB.

a) Solutions de rechange à la reclassification

La CCEA a entrepris une initiative visant à promouvoir une plus grande uniformité dans l'application des outils de réglementation envers tous les titulaires de permis et surtout à adapter les activités de la CCEA de façon à ce qu'elles correspondent plus étroitement aux risques associés à chacune des installations. Cette initiative s'inscrit dans la perspective des recommandations faites en 1994 par le Bureau du vérificateur général concernant la nécessité d'une stratégie

approach to licensing, the proposed classification scheme is appropriate.

An alternative to classifying the large processors as class I nuclear facilities is to create a separate class of facility regulations to clearly differentiate them from reactors. The AECB has systematically reviewed each section of the *Class I Nuclear Facilities Regulations* with a view to identifying any changes in regulatory requirements that would be appropriate for a new set of regulations. The AECB concluded that a new set of regulations would be identical to the existing draft except for the operator certification requirement. Therefore, from a regulation drafting point of view, another class of nuclear facility would serve no useful purpose. However, the subdivision of class I nuclear facilities into classes IA and IB permits a clearer identification of which facilities are not subject to the requirements relating to the certification of personnel.

The uranium processing facilities have suggested that it would be more appropriate if they were included in the *Uranium Mines and Mills Regulations*. This would be a change from their status under the AEC Act. A similar review of these Regulations also indicates that the uranium processing facilities are more appropriately regulated under the *Class I Nuclear Facilities Regulations*.

(b) Costs

The *Class I Nuclear Facilities Regulations* contain no regulatory requirements other than the list of information to be supplied with a licence application and operator recertification which was discussed previously. Consequently, the incremental cost associated with reclassification itself will not be significant. It is recognized, however, that certain documentation and procedures will require updating to reflect the risk associated with these facilities. Based on data provided by the largest processor, the incremental cost to implement these changes for the three licensees involved is estimated to be \$275,000. Ongoing costs are estimated to be \$110,000 per year.

(c) Benefits

The benefit of the new classification scheme is greater consistency in licensing based on risk.

3.4 *Class II Nuclear Facilities Regulations*

The *Class II Nuclear Facilities Regulations* specify the requirements for nuclear facilities that pose a lower risk than class I facilities. These include low-energy accelerators, irradiators and radiation therapy installations. These Regulations introduce new

de réglementation clairement documentée et d'un mécanisme d'évaluation formelle du programme. Une étude de la question a indiqué qu'en matière de risque, les trois grandes installations de traitement de matières radioactives et les installations de traitement de l'uranium s'apparentent plus aux installations nucléaires de catégorie I qu'aux installations qui sont titulaires de permis de radio-isotopes, aux mines d'uranium ou aux installations nucléaires de catégorie II. Par conséquent, le plan de classification proposé est jugé approprié à une approche axée sur la similarité des seuils de risque.

La classification des grandes installations de traitement de matières radioactives comme celles de catégorie I pourrait être remplacée par la création d'une catégorie distincte qui établit une distinction claire entre ces installations et les réacteurs. Or, la CCEA a examiné systématiquement chaque article du *Règlement sur les installations nucléaires de catégorie I* en tentant d'identifier toute modification des exigences réglementaires qui pourrait constituer un nouveau règlement. La CCEA a conclu que, mis à part l'exigence de renouvellement de l'accréditation des opérateurs, tout nouveau règlement serait identique à la version existante. Vu sous l'angle de la rédaction des règlements, il serait donc inutile de créer une nouvelle catégorie d'installations nucléaires. Toutefois, la subdivision des installations nucléaires de catégorie I en catégories IA et IB permet de bien clarifier les installations nucléaires auxquelles les exigences en matière d'accréditation du personnel ne s'appliquent pas.

Les représentants des installations de traitement de l'uranium estiment qu'il serait plus approprié de les soumettre au *Règlement sur les mines et les usines de concentration d'uranium*, ce qui représenterait un changement par rapport au statut qu'elles avaient en vertu de la LCEA. Un examen similaire de ce règlement démontre que le *Règlement sur les installations nucléaires de catégorie I* est plus approprié pour les installations de traitement de l'uranium.

b) Coûts

Le *Règlement sur les installations nucléaires de catégorie I* ne renferme pas d'exigences autre que la liste des renseignements qui doit accompagner une demande de permis et un renouvellement d'accréditation tel qu'expliqué ci-dessus. Par conséquent, le coût supplémentaire associé à la reclassification proprement dite sera négligeable. Il est cependant reconnu que certains documents et certaines procédures devront être mis à jour afin de refléter le risque associé aux installations. Selon les données communiquées par la plus grosse installation de traitement, la CCEA estime le coût additionnel de ces modifications à 275 000 \$ pour les trois titulaires concernés, et les coûts permanents à 110 000 \$ par année.

c) Avantages

Le nouveau plan de classification a pour avantage de proposer une plus grande uniformité dans l'attribution de permis correspondant aux risques.

3.4 *Règlement sur les installations nucléaires de catégorie II*

Le *Règlement sur les installations nucléaires de catégorie II* prévoit les exigences pour les installations nucléaires dont le seuil de risque est inférieur à celui des installations de catégorie I. Il s'agit notamment des accélérateurs à basse énergie, des

requirements for servicing licences and therapy room interlocks and the impact of these requirements is discussed below.

As a result of comments received following publication in the *Canada Gazette*, Part I, changes were made to clarify that these Regulations do not apply to diagnostic X-ray machines. Changes were also made to the requirements for geographical logging accelerators. Since these changes reflect the requirements under the AEC Act, they have no significant effect on licensees.

3.4.1 Servicing Licences

Many companies provide technical services to class II nuclear facility operators and to holders of nuclear substance licences. Many of these services, such as repairs to safety systems, are essential for the safe operation of the nuclear facility or the safe handling of the radioactive material. The AECB had insufficient information about, and no control over, the work these companies perform, the training and qualification of their staff and their quality assurance programs. This Regulation proposes to licence these service providers where nuclear safety-related services are concerned.

(a) Alternatives to Servicing Licences

The alternative of leaving these essential safety-related services unregulated is not considered acceptable since these services contribute directly to the safe management of nuclear facilities and materials.

Another alternative is to require licensees to develop in-house expertise, but this is considered too restrictive for licensees who do not need these services performed frequently. It is also doubtful that in-house expertise would continue to be current when used infrequently.

(b) Costs

It is estimated that there are five organizations that service class II equipment without a licence from the AECB. Many cancer clinics perform in-house servicing that will require a licence but as health care institutions, they are exempt from the *AECB Cost Recovery Fees Regulations*. The total cost for the five service companies is estimated to be \$20,000 to become licensed plus incremental costs of \$10,000 per year.

(c) Benefits

Safety-related activities that are contracted out to technical service providers will be approved and monitored in the same way as the training and qualification of licensees' staff who perform safety-related activities. This will ensure that equivalent standards of safety are applied to licensees and to contracted technical service providers.

irradiateurs et des appareils de radiothérapie. Ce règlement introduit de nouvelles exigences en matière de permis d'entretien et de verrouillage des commandes des salles de traitement. L'impact de ces exigences est expliqué en détail ci-dessous.

Les commentaires qui ont suivi la publication du règlement dans la *Gazette du Canada* Partie I ont entraîné des modifications pour clarifier que le règlement ne s'applique pas aux appareils de radiographie diagnostiques. Certains changements ont aussi touché les exigences relatives aux accélérateurs de diagraphie. Ils n'auront pas de répercussions importantes pour les titulaires de permis puisqu'ils ne font que refléter les exigences de la LCEA.

3.4.1 Permis d'entretien

Plusieurs compagnies fournissent des services techniques aux exploitants d'installations nucléaires de catégorie II et aux titulaires de permis de substances nucléaires. Plusieurs de ces services, par exemple la réparation des systèmes de sûreté, sont essentiels à une exploitation sûre de l'installation nucléaire ou à une manutention sans danger des matières radioactives. La CCEA ne disposait pas de renseignements suffisants et n'avait aucun contrôle sur les travaux que ces compagnies effectuent, sur la formation et la compétence de leur personnel ou sur leurs programmes d'assurance de la qualité. Ce règlement propose que les fournisseurs de services ayant une incidence sur la sûreté nucléaire soient tenus d'obtenir un permis.

a) Solutions de rechange aux permis d'entretien

La solution de rechange consistant à ne pas réglementer ces services essentiels à la sûreté n'est pas jugée acceptable dans la mesure où ces services contribuent directement à une gestion sûre des installations et des matières nucléaires.

Une autre solution de rechange serait d'exiger du titulaire de permis qu'il développe des compétences techniques internes, mais cette mesure est considérée trop restrictive pour les titulaires de permis qui n'exigent pas fréquemment ces services d'entretien. Il est également peu probable que ces compétences internes demeurent à jour si elle ne sont que rarement utilisées.

b) Coûts

On estime qu'il y a cinq entreprises qui fournissent des services d'entretien à des installations de catégorie II sans détenir de permis de la CCEA. De nombreux centres anti-cancer entretiennent eux-mêmes leurs équipements et devront donc obtenir un permis. Cependant, à titre d'établissements de santé, ils sont exemptés du *Règlement sur les droits pour le recouvrement des coûts de la CCEA*. Le coût total d'acquisition des permis est estimé pour l'ensemble des cinq fournisseurs à 20 000 \$, somme à laquelle s'ajouteront des coûts supplémentaires de 10 000 \$ par année.

c) Avantages

Les activités faites à contrat par des fournisseurs de services techniques externes et qui sont associés à la sûreté devront être approuvées et surveillées de la même manière que la formation et la qualification du personnel du titulaire de permis qui effectue lui-même ces tâches. Ainsi, les fournisseurs de services techniques seront soumis aux mêmes normes de sûreté que les titulaires de permis.

3.4.2 Therapy Room Interlocks

All cancer therapy treatment rooms will be required to have interlocks that prevent the production of a radiation beam unless the operator initiates the start-up sequence inside the treatment room before moving to the external control console within a preset period of time. This minimizes the likelihood that an unauthorized person would be in the room when a treatment is being given. Most treatment rooms have this system.

(a) Alternatives to Therapy Room Interlocks

The risk of accidental exposures is significantly reduced when the operator is forced to initiate the start-up sequence from inside the treatment room. The alternative is to rely on administrative procedures. The AECB is aware of cases where administrative procedures have not been effective, so this alternative is not considered to be acceptable.

(b) Costs

It is estimated that there are 20 treatment rooms in Canada that will require the installation of wiring, a timer and a switch. The incremental cost is not expected to exceed \$1,000 per room, so the total cost to hospitals will be \$20,000.

(c) Benefits

The installation of safety interlocks will reduce the risk of inadvertent exposure of staff or the public to radiation.

3.5 Uranium Mines and Mills Regulations

The *Uranium Mines and Mills Regulations* consist primarily of the requirements contained in the *Uranium and Thorium Mining Regulations* and certain licence conditions. Only minor wording changes were made following publication in the *Canada Gazette*, Part I to improve the clarity of the Regulations.

The mining industry has expressed concern that some information, such as a preliminary safety analysis report, will now be required at an earlier stage in the life-cycle of a mine or mill. The Commission believes this information is necessary at an early stage if it is to be satisfied that the operating mine or mill will be capable of meeting regulatory requirements.

3.6 Nuclear Substances and Radiation Devices Regulations

The *Nuclear Substances and Radiation Devices Regulations* apply to all nuclear substances, sealed sources and radiation devices not covered by other regulations. As such, they apply to almost every licensee and result in the vast majority of AECB licences. They also contain the criteria for consumer products such as smoke detectors and safety signs using tritium. In general, these Regulations reflect international practice but there are some minor variations based upon Canadian policy and circumstances.

3.4.2 Verrouillage des commandes des salles de thérapie

Toutes les salles de traitement du cancer devront être munies de dispositifs de verrouillage des commandes, qui empêchent la production d'un faisceau de rayonnement tant que l'opérateur n'a pas déclenché la séquence de démarrage à l'intérieur de la salle avant de se déplacer au tableau de commande dans un laps de temps préétabli. Cette procédure réduit la possibilité qu'une personne non autorisée se trouve à l'intérieur de la pièce pendant l'administration du traitement. La plupart des salles de thérapie sont déjà munies de ce système.

a) Solutions de rechange au verrouillage des commandes des salles de thérapie

Le risque d'exposition accidentelle est réduit de façon notable lorsque l'opérateur est forcé de lancer la séquence de démarrage de l'intérieur de la pièce. La solution de rechange serait de s'en remettre aux procédures administratives. Or, cette solution de rechange n'est pas jugée acceptable puisque la CCEA est au fait de cas où ces procédures administratives n'ont pas été efficaces.

b) Coûts

On estime qu'il y a 20 salles de thérapie au Canada qui nécessiteront l'installation de câblage, d'une minuterie et d'un interrupteur. On prévoit donc que les coûts supplémentaires n'excéderont pas 1 000 \$ par salle, pour un total de 20 000 \$ pour l'ensemble des hôpitaux.

c) Avantages

L'installation de dispositifs de verrouillage de sécurité réduira le risque d'exposition par inadvertance à la fois pour le personnel et pour le public.

3.5 Règlement sur les mines et les usines de concentration d'uranium

Le *Règlement sur les mines et les usines de concentration d'uranium* reprend principalement les exigences énoncées dans le *Règlement sur les mines d'uranium et de thorium* et dans certaines conditions de permis. Seuls des changements mineurs dans la formulation effectués pour plus de clarté ont suivi la publication du document dans la *Gazette du Canada* Partie I.

L'industrie minière a exprimé ses préoccupations quant au fait que certains renseignements tels que le rapport préliminaire de sûreté sera dorénavant exigé dans les premiers stades de l'existence de la mine ou de l'usine de concentration. La CCSN croit, pour sa part, que cette information est nécessaire dès les débuts de façon à ce qu'une fois en phase d'exploitation, la mine ou l'usine de concentration soit en mesure de satisfaire aux exigences réglementaires.

3.6 Règlement sur les substances nucléaires et les appareils à rayonnement

Le *Règlement sur les substances nucléaires et les appareils à rayonnement* s'applique à toutes les substances nucléaires, sources scellées et appareils à rayonnement qui ne sont pas régis par d'autres règlements. Ainsi, il s'applique à presque tous les titulaires de permis et figure dans la grande majorité des permis de la CCEA. Il contient aussi les critères relatifs à des produits de consommation comme les détecteurs de fumée et les panneaux de sécurité au tritium. Généralement, le règlement reflète les pratiques internationales, mais certaines variations mineures sont fondées sur une politique et des circonstances typiquement canadiennes.

The regulations consist of the requirements under the AEC Regulations and licence conditions, with the addition of servicing licences similar to those described previously in section 3.4.1 for class II nuclear facilities, and audible alarming dosimeters for exposure device operators. The scheduled quantities defined in the AEC Regulations have also been replaced with exemption quantities. This means that the quantities of radioactive material that are exempt from licensing have generally decreased.

Following publication in the *Canada Gazette*, Part I, changes were made to the regulations to clarify the requirements for the use of calibrated survey meters and to remove several sections that upon review were found to be redundant. Other minor changes were made to improve clarity.

3.6.1 Exemption Quantities

The schedule to the *Nuclear Substances and Radiation Devices Regulations* contains a list of the quantities of radioactive material below which no licence is required. The AEC Regulations also contain exemption values called “scheduled quantities”, but the exemption quantities proposed under the NSC Act, which are based on current radiation protection knowledge and the new dose limits, are generally smaller than those found in the AEC Regulations. The AEC Regulations exempt from licensing most materials that contain less than one scheduled quantity per kilogram. This exemption was not included in the Regulations under the NSC Act because of concerns about the risks posed by large volumes of materials that contain low concentrations of radioactive material.

(a) Alternatives to the Schedule of Exemption Quantities

The schedule of exemption quantities is calculated from models based on assumptions about the hazards and uses of small quantities of nuclear material. As knowledge and experience has grown, these models have been refined to reflect current information. One alternative would be to continue to use the 1974 values. This is considered to be unacceptable because it would not recognize the new lower dose limits and recent information on the effects of radiation. Another alternative would be to adopt one of the sets of values used in other countries. These have been considered, but the AECB has concluded that the proposed exemption quantities are more appropriate because they provide better protection for Canadians.

The regulations could also continue the exemption for materials that contain less than one scheduled quantity per kilogram. The AECB believes, however, that the blanket exemption should be removed because of the potential risk posed by large quantities of materials containing small concentrations of radioactive materials. In cases where such materials pose no significant risk, the Commission may use section 7 of the NSC Act to exempt them from the application of the Act and Regulations.

(b) Costs

Most users of small sources already have a licence from the AECB for other activities, so no significant additional costs are anticipated. However, some abandoned nuclear sites will require consideration for licensing under the new

Le règlement reprend les exigences prévues par le *Règlement sur le contrôle de l'énergie atomique* et les conditions de permis actuelles, auxquelles s'ajoute l'exigence de permis d'entretien déjà décrite à la section 3.4.1 pour les installations de catégorie II et les dosimètres munis de dispositif d'alarme sonore pour les opérateurs d'appareil d'exposition. Les quantités réglementaires déterminées dans le *Règlement sur le contrôle de l'énergie atomique* ont également été remplacées par des quantités exemptées. Ainsi les quantités de matière radioactive exemptées ont en général diminué.

À la suite de la publication du règlement dans la *Gazette du Canada* Partie I, certaines modifications ont été apportées au règlement dans le but de préciser les exigences relatives à l'utilisation des radiamètres étalonnés et de retirer certains articles jugés redondants après examen. Des changements mineurs ont aussi été apportés pour plus de clarté.

3.6.1 Quantités exemptées

L'annexe du *Règlement sur les substances nucléaires et les appareils à rayonnement* renferme une liste des quantités de matière radioactive au-dessous desquelles un permis n'est pas nécessaire. Le *Règlement sur le contrôle de l'énergie atomique* contient également des valeurs d'exemption appelées « quantités réglementaires », mais les quantités exemptées proposées dans la LSRN — fondées sur les connaissances actuelles en radioprotection et sur les nouvelles limites de dose — sont en général plus faibles que celles qu'on trouve dans le *Règlement sur le contrôle de l'énergie atomique*.

Le *Règlement sur le contrôle de l'énergie atomique* prévoit une exemption de permis pour la plupart des matières qui contiennent moins qu'une quantité réglementaire par kilogramme. Cette exemption n'a pas été stipulée dans les règlements d'application de la LSRN en raison des inquiétudes suscitées par les gros volumes de produits contenant de faibles concentrations de matières radioactives.

a) Solutions de rechange à l'annexe relativement aux quantités d'exemptions

Les quantités d'exemptions sont calculées d'après des modèles fondés sur les hypothèses qui ont été formulées au sujet des dangers des matières nucléaires et de l'utilisation de petites quantités de ces matières. Les modèles sont affinés à mesure que l'on acquiert de l'expérience et de nouvelles connaissances. Une solution de rechange serait de continuer à utiliser les valeurs adoptées en 1974. Cette solution est cependant jugée inacceptable parce qu'elle ne tiendrait pas compte des nouvelles limites de dose moins élevées, ni des découvertes récentes sur les effets du rayonnement. Une autre solution de rechange serait d'adopter l'un des ensembles de valeurs utilisés dans d'autres pays. Ces solutions ont été envisagées, mais la CCEA juge que les exemptions proposées sont plus aptes à protéger les Canadiens.

Le règlement pourrait aussi poursuivre l'exemption accordée aux matières qui contiennent moins qu'une quantité réglementaire par kilogramme. La CCEA croit cependant que l'exemption générale doit être retirée à cause du risque potentiel que représentent les gros volumes de produits contenant de faibles concentrations de matières radioactives. Dans les cas où ces matières ne constituent pas un risque significatif, la CCSN peut utiliser l'article 7 de la LSRN pour les exempter de l'application de la LSRN et des règlements.

regulations. The AECB is aware of approximately 45 such contaminated sites. Most of these, if they do require licensing, would incur incremental costs estimated at less than \$2,000 per year per site. For five or six of the sites, the incremental costs for licensing and monitoring are estimated to be as much as \$10,000 per year per site.

(c) Benefits

The revised exemption quantities will reflect improved safety standards that are based on current scientific knowledge. Removal of the blanket exemption for materials containing low concentrations of radioactive material allows for regulatory control when justified due to the volume of material involved.

3.6.2 Audible Alarming Dosimeters

The use of radiation sources to radiograph structures such as pipeline welds, aircraft components and pressure vessels for flaws is one of the most hazardous activities licensed by the AECB. The new regulations therefore require all exposure device operators to wear an audible alarming dosimeter to alert them to dangerous levels of radiation before significant exposures occur. Under the AEC Regulations, only trainees were required to have these devices. Audible alarms have been a requirement in the United States for several years.

(a) Alternatives to Audible Alarming Dosimeters

Due to the conditions under which radiography may be performed, operators are often unable to observe the ambient dose rate on a survey meter as frequently as safe practice would require. Therefore, the only way operators can be informed of high radiation levels under such circumstances is with an audible alarm. Audible alarms have been a requirement for trainees since 1983, but they were not made mandatory for everyone at that time because they were judged to lack adequate reliability. Technology has advanced to the point where their reliability is now considered acceptable. The AECB is aware of significant exposures that would have been prevented by an audible alarming dosimeter, so the AECB believes that there is no alternative to making them mandatory.

(b) Costs

Basic audible alarming dosimeters that meet the requirements of the regulations cost approximately \$200, but sophisticated units can cost up to \$1,500 per unit. Many operators already have audible alarms. It is therefore assumed that 500 units will have to be purchased at a cost of \$200 for a total cost to industry of \$100,000. Assuming units last five years on average, the incremental replacement cost for the industry will be \$20,000 per year.

(c) Benefits

Industrial radiography causes the largest number of over-exposures and radiation incidents in Canada. Alerting operators to hazardous dose rates before large exposures occur is one of the most effective measures available to meet the new lower dose limits.

b) Coûts

La plupart des utilisateurs de petites sources ont déjà un permis de la CCEA pour d'autres activités. On ne s'attend donc pas à des coûts supplémentaires. Il faudra cependant analyser le cas des sites nucléaires abandonnés avant de leur accorder des permis qui soient conformes au nouveau règlement. La CCEA connaît l'existence d'environ 45 de ces sites contaminés dont la plupart, s'ils devaient se munir de permis, ne devraient faire face qu'à des coûts supplémentaires de moins de 2 000 \$ par année. Toutefois, pour cinq ou six d'entre eux, les coûts de permis et de surveillance pourraient atteindre jusqu'à 10 000 \$ par année, par site.

c) Avantages

La version révisée des quantités d'exemption reflétera les normes de sûreté améliorées, qui sont fondées sur les connaissances scientifiques courantes. Le retrait de l'exemption générale pour des matières contenant de faibles concentrations de matières radioactives prévoit un contrôle réglementaire lorsque le volume de ces matières le justifie.

3.6.2 Dosimètres sonores

L'utilisation de sources de rayonnement pour détecter des vices cachés dans des structures comme les soudures de pipelines, les pièces d'aéronef et les récipients sous pression est une des activités les plus dangereuses autorisées par la CCEA. Par conséquent, le nouveau règlement exige que tous les opérateurs d'appareils à rayonnement portent un dosimètre sonore pour les avertir avant que l'exposition au rayonnement ne devienne dangereuse. Le *Règlement sur le contrôle de l'énergie atomique* exige seulement que les stagiaires portent ces dosimètres. Aux États-Unis, les alarmes sonores sont obligatoires depuis plusieurs années.

a) Solutions de rechange aux dosimètres sonores

En raison des conditions dans lesquelles les travaux de radiographie doivent être effectués, les opérateurs sont souvent incapables de lire le débit de dose ambiant sur le radiamètre aussi souvent que l'exigent les pratiques de sécurité. Par conséquent, dans ces circonstances, une alarme sonore est la seule façon qu'ils ont de savoir s'ils sont exposés à des niveaux élevés de rayonnement. Les alarmes sonores sont obligatoires pour les stagiaires depuis 1983, mais, à l'époque, elles ne l'étaient pas pour tout le monde puisqu'on ne les considérait pas assez fiables. La technologie a fait de tels progrès que ce n'est maintenant plus le cas. La CCEA n'est pas sans savoir que le port de dosimètres sonores aurait empêché des expositions importantes aux rayonnements. Voilà pourquoi elle croit qu'elle n'a pas d'autre choix que de les rendre obligatoires.

b) Coûts

Les alarmes sonores de base qui satisfont aux exigences du règlement coûtent environ 200 \$, mais des alarmes de type avancé peuvent coûter jusqu'à 1 500 \$ l'unité. De nombreux opérateurs possèdent déjà des alarmes sonores. On présume donc qu'il faudra acheter 500 alarmes de 200 \$ chacune, pour un total de 100 000 \$ pour l'industrie. Si les alarmes durent en moyenne cinq ans, il est à prévoir que le coût de remplacement additionnel pour l'industrie sera de 20 000 \$ par année.

c) Avantages

La radiographie industrielle est à l'origine du plus grand nombre de surexpositions et d'incidents liés au rayonnement

3.7 *Packaging and Transport Regulations*

All industrialized countries use the recommendations of the International Atomic Energy Agency (IAEA) to regulate the transport packaging of radioactive materials. The Canadian requirements in the *Transport Packaging of Radioactive Materials Regulations* are based on the 1973 IAEA recommendations, and the new Regulations are based on the 1985 recommendations, as amended in 1990. Many countries and international organizations have already adopted the latter recommendations, so most Canadian exporters and shippers are already in compliance with the packaging requirements. Therefore, the major changes are the requirement for carriers to have a radiation protection program, the expansion of those activities that require quality assurance programs and the use of Type 2 Industrial Packages (IP-2 packages).

The AECB has been a major participant in the development of the IAEA recommendations on the packaging and transport of nuclear materials. In developing a position on transportation issues, the AECB has communicated regularly with Transport Canada and the major Canadian shippers. Transport Canada is normally represented at the IAEA meetings, and experts from the industry have accompanied AECB staff to IAEA meetings when specific topics have been discussed.

Numerous changes were made to these Regulations as a result of consultation. The major changes consist of the removal of the requirement for a licence to package nuclear substances for most types of shipments, allowing additional methods to demonstrate that packages comply with the performance requirements and acceptance of emergency response plans that comply with the requirements of the *Transportation of Dangerous Goods Regulations* (TDG Regulations). Other changes were made to improve clarity and consistency with the TDG Regulations.

Since the regulations make frequent reference to the IAEA recommendations, the Commission has obtained the approval of the IAEA to reproduce the reference material to respond to a frequent concern expressed during the consultation process. This material will be made available to stakeholders free of charge.

3.7.1 *Radiation Protection Program for Carriers*

The use in Canada of nuclear materials for research, industrial applications, medicine and export is substantial and growing. It is estimated that approximately one million packages containing radioactive material are transported in Canada each year. The safety record of this industry is good because of the continued efforts of licensees, Transport Canada, the transportation industry and the AECB to improve the packaging and safe handling of nuclear materials. However, as the number of shipments has increased, more drivers and handlers have become involved. The AECB is aware that some of these drivers and handlers do not have adequate knowledge of radiation to protect

au Canada. Le fait de prévenir l'opérateur avant qu'il ne soit exposé à un niveau élevé de rayonnement est l'une des mesures les plus efficaces qui soient pour respecter les nouvelles limites de dose moins élevées.

3.7 *Règlement sur l'emballage et le transport des substances nucléaires*

Tous les pays industrialisés suivent les recommandations de l'Agence internationale de l'énergie atomique (AIEA) pour la réglementation de l'emballage des matières radioactives destinées au transport. Au Canada, les exigences du *Règlement sur l'emballage des matières radioactives destinées au transport* sont basées sur les recommandations de l'AIEA de 1973, et le nouveau règlement est basé sur les recommandations de 1985, revues en 1990. Nombre de pays et d'organisations internationales ont adopté les dernières recommandations, de sorte que la plupart des exportateurs et expéditeurs canadiens se conforment déjà aux exigences en matière d'emballage. Par conséquent, les principaux changements concernent la nécessité pour les transporteurs d'avoir un programme de formation en radioprotection, d'élargir les activités qui nécessitent des programmes d'assurance de la qualité et d'utiliser des colis industriels de type 2 (colis CI-2).

La CCEA a participé activement à l'élaboration des recommandations de l'AIEA sur l'emballage et le transport de matières nucléaires. Lors de l'élaboration de sa position sur les questions relatives au transport, la CCEA a communiqué régulièrement avec Transports Canada et les principaux expéditeurs canadiens. Transports Canada est habituellement représenté aux réunions de l'AIEA, et les spécialistes de l'industrie ont accompagné les employés de la CCEA aux réunions de l'AIEA lorsque des sujets particuliers y étaient discutés.

De nombreux changements ont été apportés à ce règlement à la suite des consultations. Les principaux changements comprennent le retrait de l'obligation de posséder un permis pour l'emballage de substances nucléaires pour la plupart des types d'expédition. On pourra ainsi recourir à d'autres méthodes pour démontrer que les colis sont conformes aux exigences de rendement et pour accepter les plans d'interventions d'urgence qui sont conformes au *Règlement sur le transport des matières dangereuses*. D'autres modifications ont été apportées pour améliorer la clarté ainsi que l'harmonisation avec le *Règlement sur le transport des matières dangereuses*.

Puisque le règlement fait souvent renvoi aux recommandations de l'AIEA, la CCSN a obtenu l'autorisation de celle-ci pour reproduire la documentation de référence afin de répondre à des préoccupations maintes fois exprimées au cours du processus de consultation. Les parties intéressées pourront se procurer cette documentation sans frais.

3.7.1 *Programme de radioprotection des transporteurs*

Les matières nucléaires sont beaucoup utilisées au Canada pour la recherche, les applications industrielles, la médecine et l'exportation, et cette utilisation augmente. On estime qu'environ un million de colis contenant des matières radioactives sont transportés au Canada par année. Le dossier de sécurité de l'industrie du transport est bon parce que les titulaires de permis, Transports Canada, l'industrie du transport et la CCEA s'efforcent constamment d'améliorer l'emballage et la manutention sûres des matières nucléaires. Toutefois, l'augmentation du nombre d'expéditions a aussi entraîné une hausse du nombre de conducteurs et de manutentionnaires. La CCEA sait que certains conducteurs et

themselves, the public and the environment in all transportation situations. In addition, some exposures will have to be reduced to comply with the new dose limits, and training in radiation protection is one of the most effective ways to achieve this.

(a) Alternatives to Radiation Protection Program for Carriers

Given the growing volume and complexity of transportation activities, and the need to maintain high safety standards, the alternative of no regulation is considered unacceptable. Alternatives such as licensing carriers or setting examinations for drivers and handlers are considered to be too costly and too difficult to implement. The best alternative is considered to be requiring carriers to introduce training programs for their staff that can be integrated into the general training program for drivers and handlers. The AECB plans to work closely with Transport Canada, the provinces and industry associations to promote training and monitor compliance with this requirement.

(b) Costs

Most major carriers of radioactive material are already licensed to use radioactive materials and thus have radiation protection programs in place, or they provide staff with training in the transportation of all dangerous goods. For the smaller or infrequent carriers, radiation protection training is lacking, but it is expected that major shippers, consultants or transport associations will develop basic radiation protection programs for implementation by carriers, much as was done to comply with the *Transport of Dangerous Goods Regulations*. The technical requirements are not complex, and it is estimated that the training should not exceed a half day per person for approximately 2,000 drivers and handlers. The estimated initial cost for the transportation industry to meet this new requirement is therefore approximately \$400,000. The incremental costs should not be significant because radiation protection can be incorporated into the training provided to new staff.

Some licensees have commented that the additional requirements may force some carriers out of the business or raise the charges for those who remain in the business. The costs described above will likely be passed on to the shippers but given that there are approximately 800,000 packages of radioactive material shipped in Canada each year, the initial costs per package are not significant. Once staff is trained, ongoing incremental costs should be minimal.

(c) Benefits

Teaching radiation protection to staff directly involved in the transport of radioactive materials will reduce exposures and reduce the number of reports of incidents that upon investigation, are found to be insignificant. Such incidents delay shipments of all types of cargo and cause unnecessary use of resources.

manutentionnaires ne possèdent pas une connaissance suffisante des dangers du rayonnement pour bien se protéger et assurer la protection du public et de l'environnement dans toutes les situations de transport. De plus, il faudra réduire le taux d'exposition pour se conformer aux nouvelles limites de dose; la formation en matière de radioprotection est l'un des moyens les plus efficaces pour y parvenir.

a) Solutions de rechange au programme de radioprotection des transporteurs

Vu le volume croissant et la complexité des activités de transport, et étant donné qu'il est nécessaire de maintenir des normes de sécurité élevées, l'absence de réglementation n'est pas considérée comme une solution de rechange acceptable. Les solutions de rechange telles que forcer les transporteurs à obtenir un permis ou faire passer des examens aux conducteurs et aux manutentionnaires sont jugés trop coûteuses et difficiles à mettre en oeuvre. La meilleure solution consiste à exiger que les transporteurs offrent des programmes de formation en radioprotection à leurs employés. Le programme de formation en radioprotection peut être intégré au programme de formation général des conducteurs et des manutentionnaires. La CCEA prévoit travailler en étroite collaboration avec Transports Canada, les provinces et les associations de l'industrie pour promouvoir la formation et vérifier si cette exigence a été respectée.

b) Coûts

La plupart des grands transporteurs de matières radioactives sont déjà titulaires d'un permis d'utilisation de matières radioactives et ont donc des programmes de radioprotection en place, ou bien ils dispensent à leur personnel une formation sur le transport des marchandises dangereuses. Les transporteurs dont le volume est moins élevé ou moins fréquent ne possèdent pas de formation en radioprotection, mais on s'attend à ce que les grands expéditeurs, les consultants ou les associations de transporteurs élaborent de concert un programme de base en radioprotection destiné à tous les transporteurs. Beaucoup a été fait pour se conformer au *Règlement sur le transport des matières dangereuses*. Les exigences techniques ne sont pas complexes, et on estime que la formation en radioprotection ne devrait pas dépasser une demi-journée par personne et devrait être offerte à environ 2 000 conducteurs et manutentionnaires. Pour l'industrie du transport, le coût initial prévu pour satisfaire à cette nouvelle exigence s'élève à environ 400 000 \$. Les coûts additionnels ne devraient pas être très élevés, car la formation en radioprotection peut être intégrée à la formation offerte aux nouveaux employés.

Certains titulaires de permis ont soutenu que les exigences additionnelles pourraient contraindre certains transporteurs à se retirer des affaires ou augmenter les frais de ceux qui restent. Les coûts ci-dessus seront probablement transmis aux expéditeurs, mais étant donné qu'il y a environ 800 000 colis contenant des matières radioactives expédiés chaque année au Canada, les coûts initiaux par colis ne sont pas élevés. Une fois que les employés auront reçu une formation, les coûts additionnels permanents seront minimes.

c) Avantages

Une meilleure formation pour aider les employés directement impliqués dans le transport de matières radioactives à se protéger contre le rayonnement réduira les expositions et le nombre de rapports d'accidents qui, après enquête, sont jugés peu importants. De tels incidents retardent les

3.7.2 Quality Assurance Programs

In accordance with the recommendations of the IAEA, the new regulations require every person who designs, produces, tests, uses, services or inspects a package containing radioactive material, or special form material, to have a quality assurance program. This expands the types of packages and the licensed activities that require a quality assurance program under the AEC Act and the *Transport Packaging of Radioactive Materials Regulations*. The Commission will expect licensees to implement staff training programs and verify that work is performed according to documented procedures. The requirements, which will vary depending on the risks associated with the given activity, will be explained in guidance documents.

(a) Alternatives to Quality Assurance Programs

Canada is a strong supporter of international harmonization in the requirements for the transport of radioactive materials, because without harmonization, shipments will be delayed, costs will increase and safety will decrease. Through agencies such as the IAEA, international and most domestic regulations already require quality assurance programs for the handling of radioactive materials and other dangerous goods. There is no alternative to adopting this Regulation if we are to protect workers and the public from deficient packages and meet international requirements.

(b) Costs

Since companies that design and produce packages have had to demonstrate compliance with the *Transport Packaging of Radioactive Materials Regulations*, they essentially meet the new quality assurance requirements. Discussions with some major shippers of radioactive material indicate that this requirement will not be a significant burden because they already have corporate quality assurance programs and for several years, they have been required to have a quality assurance program for their international shipments.

A graded approach to quality assurance will be used, based on the risk associated with the shipment. It is estimated that there are 500 infrequent shippers who will have to modify their practices, each at an average cost of \$1,000. The incremental cost to industry is therefore estimated to be \$500,000. Once established, the ongoing costs should not be significant because the program should not require any additional staff. It is expected that Commission staff will inspect quality assurance programs as part of regular compliance activities, so no significant incremental costs are anticipated.

(c) Benefits

A quality assurance program will ensure that all packages are designed, manufactured, used and maintained in accordance with Canadian and international packaging requirements. This will reduce the risk of package failures and high exposures.

expéditions de tous les types de chargement et consomment inutilement les ressources.

3.7.2 Programmes d'assurance de la qualité

Conformément aux recommandations de l'AIEA, le nouveau règlement exige que chaque personne qui conçoit, produit, essaie, utilise, entretient ou inspecte un colis contenant des matières radioactives, ou des matières radioactives sous forme spéciale, possède un programme d'assurance de la qualité. Cela augmente les types de colis et les activités nécessitant un permis exigeant un programme d'assurance de la qualité en vertu de la *Loi sur le contrôle de l'énergie atomique* et du *Règlement sur l'emballage des matières radioactives destinées au transport*. La CCSN s'attend à ce que les titulaires de permis mettent sur pied des programmes de formation pour les employés et vérifient que le travail se déroule conformément aux procédures écrites. Les exigences, qui seront modifiées selon les risques associés à l'activité donnée, seront expliquées dans des guides d'application de la réglementation.

a) Solutions de rechange aux programmes d'assurance de la qualité

Le Canada est un partisan convaincu de l'harmonisation internationale des exigences en matière de transport de matières radioactives, parce que, sans harmonisation, les expéditions seront retardées, les coûts augmenteront et la sécurité diminuera. Par le biais d'agences comme l'AIEA, les règlements internationaux et la plupart des règlements nationaux exigent déjà des programmes d'assurance de la qualité pour la manutention de matières radioactives et d'autres matières dangereuses. Il n'y a aucune solution de rechange à ce règlement si nous voulons protéger les travailleurs et le public contre les colis non sécuritaires ou satisfaire aux exigences internationales.

b) Coûts

Les entreprises qui conçoivent et fabriquent les colis ayant déjà dû se conformer au *Règlement sur l'emballage des matières radioactives destinées au transport* n'ont désormais qu'à satisfaire aux nouvelles exigences sur l'assurance de la qualité. Des discussions avec certains gros expéditeurs de matières radioactives indiquent que les exigences ne seront pas un trop gros fardeau puisqu'ils possèdent déjà des programmes d'assurance de la qualité et que, depuis plusieurs années, ils étaient tenus d'en posséder un pour les expéditions internationales.

L'établissement de programmes d'assurance de la qualité se fera d'une manière progressive, en fonction des risques associés à l'expédition. On estime qu'il y a 500 expéditeurs dont le volume est peu fréquent qui devront modifier leur façon de faire, ce qui coûtera 1 000 \$ en moyenne à chacun d'eux. Les coûts additionnels pour l'industrie sont par conséquent estimés à 500 000 \$. Une fois le programme en place, les coûts permanents ne seront guère élevés, car le programme ne nécessite pas l'embauche d'employés additionnels. On ne prévoit pas d'autres coûts importants puisque l'inspection des programmes d'assurance de la qualité par les employés de la CCSN se fera dans le cadre de leurs activités régulières de surveillance de la conformité.

c) Avantages

Un programme d'assurance de la qualité permettra d'assurer que tous les colis sont conçus, fabriqués, utilisés et entretenus conformément aux exigences canadiennes et

3.7.3 IP-2 Packages for Ore Samples Containing More than 2% Uranium

The properties of high-grade Canadian ores are such that the hazard they pose is consistent with that of type 2 low specific activity (LSA-2) materials, and as such, the use of IP-2 packages is more appropriate. If the IAEA Regulations had been followed, all grades of uranium ores would have been considered as LSA-1 material that could be shipped in IP-1 packages. However, this provision was developed in the 1960s, when the known ore grades were approximately 1% uranium.

(a) Alternatives to IP-2 Packages

The only alternative to this Regulation is to allow ore samples containing more than 2% uranium to be shipped in IP-1 packages that do not have to undergo any performance tests. This is not considered acceptable given the hazard posed by high-grade ore samples. This is also inconsistent with the packaging requirements for medical isotope shipments that pose a risk similar to that of ore samples containing more than 2% uranium.

(b) Costs

The costs associated with this requirement consist of developing, testing and producing an IP-2 package, mainly for small ore samples taken for analytical purposes. This is not considered to be a significant expense because there are many examples of existing IP-3 and Type A packages that must meet slightly higher performance standards than the IP-2 package being proposed. A one-time cost of \$20,000 for the one licensee involved has been estimated based upon the development, testing and production of similar packages.

(c) Benefits

The benefit of using IP-2 packages is the decreased risk that in normal transport situations or in an accident, uranium ore samples will be released into the environment or unacceptably high radiation levels will exist.

3.7.4 IP-2 Packages

Adoption of the IAEA's definition of an (IP-2 package) will require packaging of low specific activity radioactive materials to meet new drop and puncture tests when shipped under exclusive use (i.e., when packages are not combined with cargo from other shippers). This will affect primarily waste and heavy water shipments from the power utilities. It should be noted that for shipments that are not exclusive use, there is no change to the requirements.

(a) Alternatives to IP-2 Packages

To be consistent with the IAEA's recommendations, there is no alternative to adopting this Regulation.

(b) Costs

During the consultation phase, three licensees commented on this requirement. Each of these licensees will have to determine if their packages meet the requirements, and if not, they will have to develop or purchase new packages. If new packages are required, the costs are not expected to

internationales en matière d'emballage. Cela réduira les risques de colis défectueux et d'expositions élevées.

3.7.3 Colis CI-2 pour échantillons de minerai contenant plus de 2 % d'uranium

Les propriétés du minerai à haute teneur du Canada sont telles que les dangers qu'ils présentent correspondent à ceux des matières FAS-2 à faible activité spécifique. Pour cette raison, il vaut mieux utiliser des colis CI-2. Si on avait respecté les règlements de l'AIEA, toutes les teneurs du minerai d'uranium auraient été considérées comme des matières à faible activité spécifique pouvant être expédiées dans des colis CI-1. Toutefois, cette disposition date des années 1960, à l'époque où la teneur en uranium était d'environ 1 %.

a) Solutions de rechange aux colis CI-2

La seule solution de rechange au règlement est de permettre la livraison d'échantillons de minerai contenant plus de 2 % d'uranium dans des colis CI-1 qui n'ont pas à subir d'épreuves de rendement. Cela n'est pas acceptable étant donné les dangers que présentent les échantillons de minerai à haute teneur. Cela est aussi incompatible avec les exigences d'emballage relatives aux expéditions d'isotopes médicaux, qui présentent un risque similaire à celui des échantillons de minerai contenant plus de 2 % d'uranium.

b) Coûts

Les coûts associés à cette exigence concernent le développement, la mise à l'épreuve et la fabrication des colis CI-2 pour le transport des petits échantillons de minerai destinés à l'analyse. Cela n'est pas considéré comme une dépense importante puisqu'il existe déjà de nombreux spécimens de colis CI-3 et de type A qui doivent satisfaire à des normes de rendement légèrement plus élevées que les colis CI-2. Le coût unique de 20 000 \$ pour le seul titulaire de permis concerné a été estimé en fonction du développement, de la mise à l'épreuve et de la fabrication d'un colis semblable.

c) Avantages

L'utilisation de colis CI-2 se traduit par la diminution du risque de rejet dans l'environnement des échantillons de minerai d'uranium ou des niveaux de rayonnement élevés inadmissibles qui pourraient se produire au cours d'un transport régulier ou d'un accident.

3.7.4 Colis CI-2

L'adoption de la définition de l'AIEA d'un colis CI-2 exigera l'emballage de matières radioactives de faible activité spécifique pour satisfaire aux épreuves de chute et de perforation lorsqu'ils sont transportés dans un conteneur à usage exclusif (c.-à-d. lorsque les colis ne sont pas combinés aux marchandises d'autres expéditeurs). Cela touche surtout les expéditions de déchets et d'eau lourde des services publics d'électricité. Les exigences demeurent inchangées en ce qui concerne les expéditions qui ne sont pas dans un conteneur à usage exclusif.

a) Solutions de rechange aux colis CI-2

Afin de respecter les recommandations de l'AIEA, il ne peut y avoir de solutions de rechange à l'adoption de cette exigence.

b) Coûts

Durant la phase de consultation, trois titulaires de permis ont offert des commentaires concernant cette exigence.

exceed \$100,000 for each licensee to meet the minimum requirements of the regulations. Some cost information has been submitted that is higher than the above estimate but the AECB believes the additional costs are not required to meet the requirements. Licensees may decide to spend larger sums for reasons that are not directly related to the regulations; these additional costs are not included in the above estimate. Operating costs are not expected to be affected.

(c) Benefits

The requirement to use an IP-2 package for low specific activity material will reduce the risk of package failure during transit.

3.8 Nuclear Security Regulations

The three new security requirements in the *Nuclear Security Regulations* described below are considered necessary to bring Canadian nuclear facilities up to the internationally accepted recommendations of the IAEA. In developing these new requirements, the Commission has given consideration to the Canadian security context.

Security experts of the AECB have visited the most affected licensees to discuss these proposals directly with their security experts. The figures used in the cost sections below have been obtained primarily from the affected licensees.

As a result of consultation, the requirements for searching those entering or leaving a protected area have been modified. Details can be found in section 3.8.3 below.

3.8.1 Alarm Assessment System for Protected Areas

Major nuclear facilities in Canada have security measures that are intended to protect them from unauthorized entry. These measures include protected areas and alarm systems. At some sites, a guard is dispatched to investigate the alarm and to report on the cause. This can take some time and the delay in investigating the alarm adds to the response time to address the problem if the alarm is genuine. A new provision has therefore been included in the regulations which will require licensees to continuously maintain, and in some cases, install additional assessment equipment in order to provide accurate and timely alarm assessment.

(a) Alternatives to Alarm Assessment Systems for Protected Areas

One alternative to the assessment system is to trigger the emergency response team on each alarm from the protected area. This would be very expensive, since nuisance alarms, caused by environmental conditions or animals, are difficult to eliminate completely. Nuisance alarms reduce the credibility of the overall security system and reduce the capacity of the response team to deal with a real emergency. Costs might also result from the need to improve the quality of systems to minimize nuisance alarms.

Chacun aura à déterminer si ses colis satisfont aux exigences, et dans la négative, il devra développer ou acheter de nouveaux colis. Les coûts d'acquisition de nouveaux colis satisfaisant aux exigences minimales ne devraient pas dépasser 100 000 \$ par titulaire de permis. Certains renseignements présentés concernant les coûts signalent des coûts plus élevés que l'estimation ci-dessus, mais la CCEA croit que ces coûts additionnels ne sont pas nécessaires pour satisfaire aux exigences. Les titulaires de permis peuvent dépenser des sommes plus importantes pour des raisons qui ne sont pas directement liées au règlement. Ces coûts additionnels ne font donc pas partie des estimations susmentionnées. On ne prévoit pas d'augmentation des coûts d'exploitation.

c) Avantages

Les exigences relatives à l'utilisation de colis CI-2 pour les matières à faible activité spécifique réduiront les risques de défaillance du colis pendant le transport.

3.8 Règlement sur la sécurité nucléaire

Les trois nouvelles mesures de sécurité du *Règlement sur la sécurité nucléaire*, décrites ci-dessous, sont nécessaires pour que les installations nucléaires canadiennes soient protégées selon les normes internationales recommandées par l'AIEA. La CCSN a pris en considération le contexte canadien en matière de sécurité.

Les spécialistes de la sécurité de la CCEA ont rendu visite aux titulaires de permis les plus touchés afin de discuter de ces propositions directement avec leurs spécialistes de la sécurité. Les chiffres figurant dans les sections sur les coûts ci-dessous proviennent principalement des titulaires de permis touchés.

À la suite de consultations, les exigences relatives à la recherche de personnes entrant dans une aire protégée, ou en sortant, ont été modifiées. On trouvera les renseignements détaillés sur ce sujet à la section 3.8.3 ci-dessous.

3.8.1 Système d'évaluation des alertes dans les aires protégées

Au Canada, les grandes installations nucléaires ont adopté des mesures de sécurité destinées à empêcher l'entrée non autorisée. Ces mesures comprennent l'établissement des aires protégées et la mise en place des systèmes d'alarme. À certains emplacements, un garde est dépêché sur le lieu de l'alerte pour faire enquête. Cela peut prendre du temps, et le délai s'ajoute au temps nécessaire pour régler le problème s'il s'agit d'une alerte réelle. Par conséquent, une nouvelle disposition a été ajoutée au règlement, qui exigera que le titulaire de permis maintienne en permanence l'équipement de surveillance et, dans certains cas, installe de l'équipement supplémentaire pour pouvoir évaluer avec précision et rapidité la cause de l'alerte.

a) Solutions de rechange aux systèmes d'évaluation des alertes dans les aires protégées

Une solution de rechange serait de faire intervenir une équipe d'intervention d'urgence à chaque alerte dans une aire protégée. Cela serait très coûteux puisque les fausses alertes causées par les conditions environnementales et les animaux sont difficiles à éliminer complètement. Les fausses alertes compromettent la crédibilité de l'ensemble du système de sécurité et la capacité de l'équipe d'intervention de s'occuper d'une urgence réelle. Des coûts

Having a guard investigate the alarm is not acceptable at large sites where the delay in reaching the alarm location could be considerable. This delay would create a serious weakness in the security system since the response team is not normally called into action unless an alarm is confirmed as a real breach of security.

(b) Costs

Since an alarm assessment system is already in place for the affected licensees, and equipment maintenance systems are already established, the initial costs will be limited to the purchase and installation of additional equipment. These costs are estimated to total \$6,000 for the five licensees affected. Based on the figures supplied by the industry, the operating costs for maintenance and for security guards are estimated at \$600,000 per year for all licensees concerned.

(c) Benefits

Maintenance of security at nuclear facilities in Canada is crucial to protect against terrorism and sabotage. Canadian security precautions should provide a standard of protection that is consistent with those of other countries that have facilities with similar levels of risk. The alarm assessment system provides a remote means of assessing the cause of an alarm from the protected area and will provide quick assessment of the nature of the alarm, whether it is a serious problem or a nuisance alarm. If the alarm represents a serious threat, the appropriate response will be initiated more quickly. This assessment system will also reduce the number of times that security staff must investigate nuisance alarms.

3.8.2 Alarm Assessment System for Inner Areas

Only two licensees are authorized to store sensitive nuclear material in a high security installation known as an inner area. When the alarm for these areas is triggered, a security guard is dispatched to investigate the cause. The introduction of a mandatory assessment system in the inner area will facilitate the immediate assessment of the cause of the alarm.

(a) Alternatives to Alarm Assessment System for Inner Areas

The alternatives are identical to those set out for protected areas described in section 3.8.1(a) above. The material under protection by the security system is usable in nuclear weapons and must be protected to the highest degree.

(b) Costs

According to the cost estimates provided by the industry, installation costs will total \$2,000 and annual operating costs will total \$190,000 per year.

(c) Benefits

As noted above, the immediate assessment of an alarm from the inner area will allow instantaneous initiation of response to unlawful activities in the case of a real alarm, and will save resources in the investigation of nuisance alarms.

pourraient également être entraînés par la nécessité d'améliorer la qualité des systèmes pour éviter les fausses alertes.

Dans les grandes installations, il est inacceptable d'envisager de dépêcher un garde sur le lieu de l'alerte chaque fois que l'alarme se déclenche étant donné le temps considérable exigé pour arriver sur les lieux. Ce délai pourrait affaiblir considérablement le système de sécurité puisqu'on ne fait pas habituellement appel à l'équipe d'intervention à moins que l'alerte soit confirmée.

b) Coûts

Parce qu'un système d'évaluation des alertes est déjà en place chez les titulaires de permis touchés, et que des systèmes d'entretien de l'équipement sont déjà établis, les coûts initiaux se limiteront à l'achat et à l'installation de l'équipement additionnel. Au total, ces coûts se chiffrent à 6 000 \$ pour les cinq titulaires de permis touchés. En se basant sur les chiffres fournis par l'industrie, les coûts d'exploitation pour le maintien du système et les gardes de sécurité sont estimés à 600 000 \$ par année pour tous les titulaires de permis touchés.

c) Avantages

Il est essentiel de maintenir une bonne sécurité dans les installations nucléaires du Canada pour les protéger des actes de terrorisme et de sabotage. Les mesures de sécurité au Canada doivent offrir une qualité de protection comparable à celle d'autres pays ayant des niveaux de risque semblables. Un système d'évaluation des alertes fournira un moyen d'évaluer, à distance, la nature et la cause de l'alerte dans une aire protégée, qu'il s'agisse d'un problème grave ou d'une fausse alerte. En cas d'alerte réelle, il permettra de déclencher plus rapidement l'intervention voulue. En cas de fausse alerte, le personnel de sécurité n'aura pas à consacrer inutilement ses ressources à faire enquête.

3.8.2 Système d'évaluation des alertes dans les aires intérieures

Seuls deux titulaires de permis sont autorisés à stocker des matières nucléaires sensibles dans une installation de haute sécurité appelée aire intérieure. Lorsqu'une alarme se déclenche dans une aire intérieure, un garde de sécurité est dépêché sur le lieu de l'alerte pour faire enquête. L'introduction d'un système de surveillance de l'aire intérieure permettrait d'évaluer sans délai la cause de l'alerte.

a) Solutions de rechange au système d'évaluation des alertes dans les aires intérieures

Les solutions de rechange sont identiques à celles qui ont été indiquées à la section 3.8.1(a) ci-dessus pour les aires protégées. Les matières que le système de sécurité doit protéger peuvent être utilisées dans des armes nucléaires et doivent donc être protégées selon les normes les plus élevées.

b) Coûts

Selon l'estimation des coûts présentée par l'industrie, les coûts d'installation s'élèveraient au total à 2 000 \$, et les coûts annuels d'exploitation s'élèveraient au total à 190 000 \$ par année.

c) Avantages

Comme on l'a noté ci-dessus, l'évaluation immédiate d'une alerte dans une aire intérieure permettra de déclencher une intervention et de contrer des activités illicites, s'il s'agit

3.8.3 Searches at the Perimeter of a Protected Area

Nuclear facilities in Canada are protected by security perimeters that limit access to protected areas. A new provision has been included in the regulations which will require licensees to search, or otherwise monitor, persons without a security clearance and their possessions when entering and leaving the protected area. Licensees also have the right to search, on reasonable suspicion, anyone entering or leaving a protected area. The searches can be carried out by technical means and are similar to the standard of security provided at Canadian airports.

The draft regulations published in the *Canada Gazette*, Part I required that everyone entering and leaving the protected area be searched. Licensees pointed out that including staff in the requirement would be expensive to implement and would delay shift changes, with little increase in security. The regulations now limit mandatory searches as described above pending completion of the project to review the overall threat to security at Canadian nuclear facilities.

The search procedure will deter terrorists and others from carrying weapons or explosives into protected areas or removing Category I, II or III nuclear material. The regulation allows the operator to use non-intrusive technical means such as metal detectors and X-ray machines in carrying out searches.

(a) Alternatives to Searches at the Perimeter of Protected Areas

There is no alternative to searches to prevent explosives and weapons from reaching the protected areas of Canadian nuclear facilities. The alternative of not upgrading the controls over the protected areas would leave the security measures at Canadian nuclear facilities below that found in similar facilities around the world.

(b) Costs

The affected licensees have estimated that the new provisions will cost a total of \$2.7 million to implement, and that operating costs will be approximately \$1.7 million per year.

(c) Benefits

There is a continuing worldwide movement to upgrade the security measures at major nuclear facilities. This new initiative is part of the Canadian response to ensure that Canadian nuclear security measures are keeping pace with those of the rest of the world.

3.9 Nuclear Non-Proliferation Import and Export Control Regulations

The new regulations increase the number of items for which import licences are required so that Canada will be in a better position to implement its international obligations with respect to the control of nuclear equipment. Canada imports little of this

d'une alerte réelle, ou d'économiser des ressources en cas de fausse alerte.

3.8.3 Fouilles au périmètre d'une aire protégée

Au Canada, les installations nucléaires sont protégées par un périmètre de sécurité qui restreint l'accès aux aires protégées. Une nouvelle disposition, qui fait maintenant partie du règlement, exigera que les titulaires de permis fouillent ou surveillent les personnes et les choses qui entrent ou sortent d'une aire protégée sans autorisation de sécurité. Les titulaires de permis ont aussi le droit de fouiller, s'ils ont des motifs raisonnables de le faire, quiconque entre dans une aire protégée ou en sort. Les fouilles se feront par des moyens techniques semblables à ceux utilisés dans les aéroports canadiens pour répondre aux normes de sécurité.

Le projet de règlement publié dans la *Gazette du Canada* Partie I exige la fouille de quiconque entre dans une aire protégée ou en sort. Les titulaires de permis ont fait remarquer que le fait d'inclure les employés dans ces exigences serait coûteux à mettre en place et retarderait la relève des équipes, sans pour autant améliorer vraiment la sécurité. Le règlement limite maintenant les fouilles obligatoires, décrites ci-dessous, en attendant l'achèvement du projet de révision de la menace globale à la sécurité dans les installations nucléaires canadiennes.

Les fouilles empêcheraient les terroristes ou d'autres personnes d'apporter des armes ou des explosifs dans une aire protégée ou d'en retirer des substances nucléaires de catégorie I, II ou III. Le règlement permet à l'exploitant d'effectuer des fouilles en utilisant des moyens techniques non intrusifs comme des détecteurs de métal ou de l'équipement radiographique.

a) Solutions de rechange aux fouilles au périmètre des aires protégées

Il n'existe pas de solution de rechange pour éviter que des explosifs ou des armes ne soient introduits dans une aire protégée d'une installation nucléaire canadienne. La solution de rechange consistant à ne pas améliorer les mesures de sécurité pour les aires protégées ferait que les systèmes de sécurité des installations nucléaires canadiennes seraient inférieurs à ceux dont sont munies des installations similaires de par le monde.

b) Coûts

Les titulaires de permis touchés ont estimé que les nouvelles dispositions coûteraient au total 2,7 millions de dollars à mettre en oeuvre et que les coûts d'exploitation seraient d'environ 1,7 million de dollars par année.

c) Avantages

La tendance mondiale actuelle est de rehausser les mesures de sécurité aux grandes installations nucléaires. La nouvelle initiative visant les fouilles est un élément de la réponse canadienne visant à assurer que les mesures de sécurité protégeant les installations nucléaires sont comparables à celles adoptées ailleurs dans le monde.

3.9 Règlement sur le contrôle de l'importation et de l'exportation à des fins de non-prolifération

Le nouveau règlement augmente le nombre d'articles pour lesquels un permis d'importation est exigé; le Canada sera ainsi mieux placé pour respecter ses obligations internationales en matière de contrôle de l'équipement nucléaire. Le Canada importe

equipment, and most companies who would import these items currently have import licences for other reasons, so the overall effect of adding items to the list is not considered to be significant.

As a result of consultations, the list of items requiring import licences has been significantly shortened from that published in the *Canada Gazette*, Part I. Initially, importing any component of a nuclear facility required a licence, but following discussions with the industry, it was concluded that import licences should only be required for major components as identified in Part A.2 of the schedule to the regulations.

3.10 *Canadian Nuclear Safety Commission Rules of Procedure*

The *Canadian Nuclear Safety Commission Rules of Procedure* provide a legal framework for the conduct of public hearings held by the Commission and for opportunities to be heard by the Commission or a designated officer. In the past, under the Atomic Energy Control Board (AECB), the framework for conducting hearings and meetings was contained in "policy" type documents which were approved by the Board, but were not regulations. These rules, while they can be varied or supplemented in order to ensure that a proceeding is dealt with as informally and expeditiously as possible, will streamline the Commission's decision-making procedures for the benefit of all participants.

The AECB has held public meetings for approximately 10 years. The rules represent the accumulated experience the Board has gained during this period. The Board has received numerous comments on Regulatory Policy P-76 since its publication in August 1997. These comments have been considered in the development of the rules.

On February 13, 1999, the draft *Canadian Nuclear Safety Commission Rules of Procedure* were published in the *Canada Gazette*, Part I for comments. The comments from 21 interested parties were reviewed, and appropriate changes were made to the rules. In general, the changes enhance the opportunity for intervenor participation by providing additional time for intervenors to prepare and send information and submissions to the Commission. The main changes, found in sections 2, 17, 18, 19 and 21, relate to notice of hearings, filing and participation requirements, filing supplementary material, and inclusion of officers and employees of the Commission as participants.

Since the question of alternatives, costs and benefits apply to the rules in their entirety, they will be discussed at the end of the section, rather than following each topic.

3.10.1 Confidentiality

Over half of the 21 submissions received on the proposed rules following their February 13, 1999, publication in the *Canada Gazette*, Part I concerned section 12 which deals with confidentiality of information. Some suggested the Commission should not treat any information confidentially, while others thought any information which a person requests to be kept confidential should be so kept. Section 12 recognizes that confidentiality of

peu d'équipement de ce genre, et la plupart des entreprises qui importent de tels articles possèdent actuellement des permis d'importation pour d'autres raisons; ainsi, l'effet général de l'ajout d'articles à cette liste n'est pas considéré comme important.

À la suite de consultations, la liste des articles nécessitant un permis d'importation a été réduite de façon significative par rapport à celle publiée dans la *Gazette du Canada* Partie I. Au départ, un permis était nécessaire pour importer toute composante d'une installation nucléaire, mais, à la suite de discussions avec l'industrie, on est arrivé à la conclusion qu'il faudrait des permis d'importation seulement pour les composantes importantes, comme celles identifiées à la partie A.2 de l'annexe du règlement.

3.10 *Règles de procédure de la Commission canadienne de sûreté nucléaire*

Les *Règles de procédure de la Commission canadienne de sûreté nucléaire* prévoit un cadre juridique pour la tenue d'audiences publiques de la CCSN et pour les possibilités d'être entendu par la CCSN ou par un fonctionnaire désigné. Auparavant, sous la gouverne de la CCSN de contrôle de l'énergie atomique (CCEA), le cadre de travail pour la tenue d'audiences et de réunions faisait partie de documents dans lesquels des politiques approuvées par la CCSN étaient énoncées, mais il ne s'agissait pas de règlements. Ces règles, qui pourront être modifiées ou enrichies afin de garantir qu'une procédure se déroule de façon informelle et rapide, simplifieront les procédures de prise de décision de la CCSN à l'avantage de tous les participants.

La CCEA tient des réunions publiques depuis environ 10 ans. Les règles représentent l'expérience accumulée par la CCSN au cours de cette période. Depuis la publication de la politique d'application de la réglementation P-76 en août 1997, la CCSN a reçu de nombreux commentaires à son sujet. Ces commentaires ont été pris en considération dans l'élaboration des règles.

Le 13 février 1999, le projet de *Règles de procédure de la Commission canadienne de la sûreté nucléaire* ont été publiées dans la *Gazette du Canada* Partie I, aux fins de commentaires. Les commentaires de 21 parties intéressées ont été analysés et des changements appropriés ont été apportés aux règles. En général, les changements améliorent les occasions de participation des intervenants en leur offrant du temps supplémentaire pour la préparation et l'envoi de renseignements et de mémoires à la CCSN. Les principaux changements, qu'on trouvera aux articles 2, 17, 18, 19 et 21, se rapportent à l'avis d'audience, aux exigences de dépôt et d'intervention, au dépôt de documents supplémentaires, et à la participation des agents et des employés de la CCSN dans les procédures.

Puisque la question des solutions de rechange, des coûts et des avantages s'applique aux règles dans leur intégralité, elle sera discutée à la fin de la présente section plutôt qu'à la suite de chaque sujet.

3.10.1 Confidentialité

Après la publication des règles proposées le 13 février 1999 dans la *Gazette du Canada* Partie I, plus de la moitié des 21 mémoires reçus concernaient l'article 12, qui traite de la confidentialité des renseignements. Certains ont suggéré que la CCSN ne devrait pas traiter les renseignements reçus de manière confidentielle, tandis que d'autres considéraient que, si une personne exigeait la confidentialité de certains renseignements, la CCSN

some information may be needed but that the Commission should not compromise the public interest by unduly limiting disclosure to affected participants. As a result of comments received during consultation, section 12 was amended to clarify the need to establish a balance between the public interest and the need to protect certain security and confidential information.

3.10.2 Process and Notice Provisions

Comments were received on the notice provisions proposed in section 17 of the rules indicating that the process would be longer, and therefore costlier than at present. Other comments were to the effect that the process should be longer to allow intervenors more time to prepare. It is not anticipated that the new process will inherently be any longer than the process under the AEC Act.

The process set out in Part 2 respecting public hearings was revised to increase the ability of intervenors to adequately review and respond to the material submitted by applicants and Commission staff. Where hearings are scheduled to take place over two days, major facilities, licence applicants and Commission staff will be required to submit their information within set time frames prior to the hearing (Rule 18), as has been the practice under the AECB. The first day of the hearing will concentrate on this information. Intervenors will not be required to submit their information until a set period prior to the second hearing day (Rule 19). This will provide them with an increased ability to review the information submitted by licence applicants and Commission staff, and focus on the issues which may have been identified at the first day of the hearing. Intervenors will then be able to submit their information at the second hearing day and to pose questions concerning the information submitted by licence applicants and Commission staff. Commission staff, as well as witnesses appearing for licence applicants during the first day of hearings, will be required, unless the Commission directs otherwise, to attend during the second day (Rule 18), to give intervenors an adequate opportunity to ask questions.

3.10.3 Quorum and Role of Commission Staff in Proceedings

Two subsections have been added to the rules as a result of consultations, one dealing with Commission staff and the other pertaining to the quorum of the Commission and panels.

The rules, as they originally appeared, omitted reference to Commission staff and their reports, which are submitted to the Commission for consideration. Some contributors noted that staff are important participants in the process and that their participation should be formally included; this has therefore been added. A subsection on a quorum has also been included.

devait respecter ce choix. L'article 12 reconnaît que certains renseignements doivent être tenus confidentiels, mais que la CCSN ne doit pas compromettre l'intérêt du public en limitant indûment leur divulgation aux participants concernés. À la suite des commentaires présentés pendant les consultations, l'article 12 a été modifié pour clarifier la nécessité de trouver un juste équilibre entre l'intérêt du public et la protection de certains renseignements à caractère confidentiel et en matière de sécurité.

3.10.2 Dispositions relatives au processus et à la convocation

Des commentaires sur les dispositions relatives à la convocation proposées à l'article 17 des règles indiquaient que le processus serait plus long et, par conséquent, plus coûteux qu'il ne l'est actuellement. D'autres commentaires proposaient de prolonger le processus afin que les intervenants aient plus de temps pour se préparer. Il n'est pas prévu que le processus soit plus long en soi que celui suivi en vertu de la LCEA.

Le processus établi dans la partie 2 concernant les audiences publiques a été révisé pour améliorer la capacité des intervenants d'analyser adéquatement les documents soumis par les demandeurs et les employés de la CCSN et d'y répondre. Dans les cas d'audiences d'une durée de plus de deux jours, les grandes installations, les demandeurs de permis et les employés de la CCSN devront présenter leurs renseignements dans le délai précisé avant l'audience (Règle 18), comme c'était la pratique sous la gouverne de la CCEA. La première journée de l'audience sera consacrée à ces renseignements. Les intervenants ne seront pas obligés de déposer leurs renseignements avant le délai précisé avant la deuxième journée de l'audience (Règle 19). Cela leur donnera plus de temps pour analyser les renseignements présentés par les demandeurs de permis et les employés de la CCSN et de se concentrer sur les questions relevées au cours de la première journée d'audience. Les intervenants seront alors en mesure de présenter leurs renseignements au cours de la deuxième journée d'audience et de poser des questions concernant les renseignements présentés par les demandeurs de permis et les employés de la CCSN. Les employés de la CCSN ainsi que les témoins des demandeurs de permis qui se présentent lors de la première journée d'audience seront obligés, à moins que la CCSN en décide autrement, de participer à la deuxième journée d'audience (Règle 18) afin de donner aux intervenants la possibilité de poser des questions.

3.10.3 Quorum et rôle des employés de la CCSN durant les procédures

Deux paragraphes ont été ajoutés aux règles à la suite des consultations. L'un traite des employés de la CCSN, et l'autre se rapporte au quorum de la CCSN et des formations.

À l'origine, les règles ne mentionnaient pas les employés de la CCSN et leurs rapports, qui sont soumis à la CCSN aux fins d'examen. Certains contributeurs ayant fait remarquer que les employés sont des participants importants du processus et que leur participation doit être reconnue de façon officielle, ce qui a donc été ajouté, ainsi qu'un paragraphe relatif au quorum.

The addition of these two subsections will not affect the rights or obligations of participants and are therefore seen as minor changes.

3.10.4 Other Changes

A number of other changes were made to the rules to provide clarification, correct errors and ensure that the English and French versions were the same. None of these changes is major.

(a) Alternatives

The NSC Act requires the Commission to hold public hearings in certain specified situations and to give a reasonable opportunity for affected parties to be heard. The NSC Act also requires that rules of procedure must be established by regulation so that there are no alternatives. In many respects, the proposed rules reflect the AECB's practice as described in its Regulatory Policy P-76, *Policy and Procedures for Making Submissions and Appearances Before the Atomic Energy Control Board*.

(b) Consistency with Regulatory Policy and the Citizens' Code

The rules provide interested parties with a fair opportunity to participate in the Commission's public hearings process and affected parties with an opportunity to be heard, while ensuring that the statutory rights of applicants and licensees are recognized.

(c) Benefits

These Rules will constitute a published standard set of procedures for all participants to follow in proceedings before the Commission. The rules establish the Commission's procedures in accordance with its mandate to resolve matters before it as informally and expeditiously as the circumstances and the considerations of fairness permit. They will benefit licensees, applicants and interested parties by describing the process. As well, the rules will assist the Commission in conducting its proceedings in accordance with the requirements of administrative law and the NSC Act.

Since the NSC Act also provides the authority for decision making by inspectors and designated officers, the rules address these functions and the opportunity for affected parties to be heard.

(d) Costs

The rules are consistent with the Board's practice and therefore cause no significant additional cost to industry, the public or government.

4. Environmental Impact

There are no adverse environmental effects anticipated from the passage of these Regulations. The major positive environmental impacts of these Regulations are the requirements to consider the environment in any licensing action and the regulatory scheme to require financial guarantees for decommissioning and waste management. The AEC Act and Regulations make no mention of the environment, but the AECB has been including appropriate requirements via licence conditions. The NSC Act, on

L'ajout de ces deux paragraphes n'affecte en rien les droits et les obligations des participants et est, par conséquent, considéré comme une modification mineure.

3.10.4 Autres modifications

Un certain nombre d'autres modifications ont été apportées aux règles dans le but de clarifier des choses, de corriger des erreurs et de s'assurer que les versions anglaise et françaises étaient identiques. Aucune de ces modifications n'est capitale.

a) Solutions de rechange

La *Loi sur la sûreté et la réglementation nucléaires* exige que la CCSN tienne des audiences publiques dans certaines situations précises et donne une possibilité raisonnable aux parties touchées de se faire entendre. Elle stipule également que les règles de procédure doivent être établies par règlement; il n'y a donc pas de solutions de rechange. À bien des égards, les règles proposées reflètent la pratique de la CCEA telle qu'elle est décrite dans sa politique d'application de la réglementation P-76, *Politique et règles de procédure sur les mémoires et les interventions à l'adresse de la Commission de contrôle de l'énergie atomique*.

b) Uniformité avec la politique de réglementation et le code du citoyen

Les règles fournissent aux parties intéressées une possibilité juste de participer aux audiences publiques de la CCSN et aux parties touchées une chance de se faire entendre, tout en garantissant la reconnaissance des droits statutaires des demandeurs et des titulaires de permis.

c) Avantages

Ces règles constitueront un ensemble standard de procédures à suivre par tous les participants qui se présentent devant la CCSN. Elles établissent les procédures de la CCSN conformément à son mandat, qui est de résoudre les questions qui lui sont soumises de la façon la plus informelle et rapide que les circonstances et les questions d'équité le permettent. En donnant une description du processus, les règles sont à l'avantage des demandeurs et titulaires de permis ainsi que des parties intéressées. En outre, elles aideront la CCSN à mener les procédures conformément aux exigences du droit administratif et de la LSRN.

Étant donné que la LSRN donne aussi le droit aux inspecteurs et aux fonctionnaires désignés de prendre des décisions, les règles portent sur ces fonctions et sur la possibilité pour les parties touchées de se faire entendre.

d) Coûts

Les règles correspondent aux pratiques de la CCSN et, par conséquent, n'occasionnent pas de coûts additionnels importants à l'industrie, au public ou au gouvernement.

4. Incidences environnementales

L'adoption des nouveaux règlements n'entraînera vraisemblablement pas d'effets négatifs sur l'environnement. Les règlements ont pour principales retombées positives d'obliger à tenir compte de l'environnement dans toute mesure d'autorisation, ainsi qu'à fournir des garanties financières pour le déclassement et la gestion des déchets. La *Loi sur le contrôle de l'énergie atomique* et ses règlements ne font pas mention de l'environnement, mais la CCEA assortit les permis des conditions appropriées. D'autre

the other hand, states that one of the objects of the Commission is to "prevent unreasonable risk to the environment". Protecting the environment is therefore mentioned extensively throughout the new regulations.

5. Consultation

The AECB maintains close contact with its licensees and the public by a variety of means, including open Board meetings, public meetings and sessions with Board members and staff. Regular visits by staff to licensed premises and staff working at the nuclear power sites allow for a continuous exchange of information. In addition to this regular dialogue with licensees and stakeholders, the AECB undertook general consultations on the new regulations and specific consultations on the new dose limits, transportation requirements and enhanced security requirements.

Although it is not required by the government's regulatory process, the AECB made draft regulations available soon after the Act was passed. This provided the public and the nuclear industry with an indication of the AECB's intentions and the AECB with comments at an early stage in the process. The draft regulations were published on the AECB Web site and paper copies were made available to any person who requested them. Notices were placed in the AECB Reporter and a notice was sent out to approximately 5,000 licensees and persons who have expressed interest in nuclear issues. The AECB received 1,588 comments from 42 individuals or organizations. These comments were analyzed, and where appropriate, changes were made to the regulations. A document describing each comment and the AECB's response to the comment is available on the AECB's Web site (www.aecb-ccca.gc.ca), and paper copies can be obtained by contacting the AECB.

On October 10, 1998, the AECB published a draft version of the nine technical regulations in the *Canada Gazette*, Part I for the official comment period required in the federal government's regulatory approval process. During the comment period, eight public meetings were held in major centres across the country to allow stakeholders an opportunity to obtain more information about the regulations. In addition, meetings were held with the reactor licensees. When the comment period closed on December 1, 1998, the AECB had received approximately 800 individual comments from 78 contributors. Again, these comments were reviewed, and where appropriate, changes were made to the draft regulations. As with the earlier round of consultations, a document describing the comments and how they were addressed has been published by the AECB.

Beginning in January 1999, a series of meetings were held with some major licensees and other stakeholders concerning some of the significant issues associated with implementing the new regulations. These included the Canadian Nuclear Association and its members, the Saskatchewan Mining Association and its members, the Canadian Radiation Protection Association, Transport Canada and the Government of Saskatchewan.

6. Compliance and Enforcement

These Regulations will be proclaimed under the NSC Act and will be subject to the Compliance Policy of the CNSC. With the

part, aux termes de la LSRN, la CCSN a pour mission de maintenir à un niveau acceptable le risque pour l'environnement. La protection de l'environnement est donc mentionnée abondamment dans les nouveaux règlements.

5. Consultations

La CCEA maintient un contact étroit avec ses titulaires de permis et le public par divers moyens, notamment les réunions de la CCSN, les rencontres publiques et les séances avec les commissaires et le personnel de la CCSN. Les visites régulières des employés aux installations autorisées et leur interaction avec le personnel des centrales favorisent l'échange continu d'information. Outre ce dialogue constant avec les titulaires de permis et les parties intéressées, la CCEA a mené des consultations générales sur les nouveaux règlements et des consultations particulières sur les nouvelles limites de dose ainsi que sur les exigences en matière de transport et d'amélioration de la sécurité.

Bien que le processus de réglementation gouvernemental ne l'exige pas, la CCEA a produit des projets de règlement, qui sont devenus disponibles peu après l'adoption de la LSRN. Cela lui a permis de faire connaître au public et à l'industrie nucléaire ses intentions et d'obtenir des commentaires tôt au cours du processus. Les projets de règlements ont été publiés sur le site Web de la CCEA, et toutes les personnes intéressées ont pu s'en procurer une copie sur support papier. Des avis ont été placés dans son périodique, le Reporter, et un avis a été envoyé à environ 5 000 titulaires de permis et personnes ayant manifesté de l'intérêt pour les questions nucléaires. La CCEA a reçu 1 588 commentaires de 42 particuliers et organisations. Elle a analysé ces commentaires et, le cas échéant, modifié les règlements en conséquence. Un document décrivant les commentaires individuels et les réponses fournies par la CCEA est disponible sur le site Web de la CCEA (www.aecb-ccca.gc.ca), et une copie sur support papier peut être obtenue en communiquant avec la CCEA.

Le 10 octobre 1998, la CCEA a publié une version provisoire des neuf règlements techniques dans la *Gazette du Canada* Partie I pour respecter les exigences du processus d'approbation du gouvernement fédéral en matière de période de commentaires officielle. Durant la période de commentaires, huit rencontres publiques ont eu lieu dans les grands centres du pays afin de permettre aux partenaires d'obtenir davantage de renseignements sur les règlements. En outre, des rencontres ont eu lieu avec les titulaires de permis de centrales nucléaires. À la fin de la période de commentaires, le 1^{er} décembre 1998, la CCEA avait reçu environ 800 commentaires individuels provenant de 78 participants. Une fois de plus, elle a analysé ces commentaires et, le cas échéant, modifié les projets de règlement en conséquence. Tout comme pour les consultations précédentes, la CCEA a publié un document décrivant les commentaires et les réponses qu'elle a fournies.

À compter de janvier 1999, une série de rencontres a eu lieu avec les titulaires de permis importants et d'autres parties intéressées concernant certaines questions importantes associées à la mise en oeuvre des nouveaux règlements. L'Association nucléaire canadienne et ses membres, la Saskatchewan Mining Association et ses membres, l'Association canadienne de radioprotection, Transports Canada et le gouvernement de la Saskatchewan ont participé à ces rencontres.

6. Respect et exécution

Les règlements seront proclamés aux termes de la LSRN et assujettis à la politique de conformité de la CCSN. Avec l'adoption

introduction of the new initiatives noted above, and the new range of penalties and enforcement powers established in the NSC Act, the new regulatory regime will put greater emphasis on safe operation in the interests of health, safety, security and the environment. In particular, options under the NSC Act that allow the courts to order redress of contamination and other penalties as part of the sanction system, are expected to yield valuable new compliance tools.

The Commission will also continue the policy of the AECB to promote compliance through notices, explanatory material, public meetings and seminars. Priority will be placed on the new initiatives noted above.

Compliance verification will continue to be carried out by trained inspectors who will monitor all nuclear activities on the basis of risk and the historical performance of the licensees. Nuclear power plant licensees will continue to have resident inspectors from the Commission working full time on site at their facilities. The NSC Act will give wider and more explicit powers to inspectors, subject to review by the Commission.

Violations can result in an escalating range of actions, including warnings, orders by inspectors or designated officers, licence suspension and prosecution. Inspectors will also be able to issue orders to address problems where risks to the safety of persons or the environment are discovered.

6.1 Canadian Nuclear Safety Commission Rules of Procedure

Since the rules are procedural, compliance with them is supported by the procedural powers given to the Commission by the NSC Act. In addition to its power to control its proceedings, the Commission will be a court of record. It has, with respect to the appearance, summoning and examination of witnesses, the production and inspection of records, the enforcement of its orders and other matters necessary or proper for the due exercise of its jurisdiction, all powers that are necessary to carry out its duties.

7. Overall Cost

The total cost to implement the new requirements in the regulations is estimated to be \$5.9 million, 46% of which results from new requirements relating to security.

The annual incremental cost associated with the new requirements in the regulations is estimated to be \$4.5 million per year, 56% of which results from additional security requirements and 22% of which results from the new dose limits.

To implement the new Act and regulations, the Commission received no additional resources so training has and will continue to be accomplished by a reallocation of existing resources. The cost to train Commission staff on the new Act and regulations consists of direct costs for items such as contractors, materials and facilities plus the time spent by Commission staff away from their regular duties. The training program will be spread over the three fiscal years beginning on April 1, 1998 and ending on March 31, 2001. The direct costs are estimated to be \$370,000 per year for each of the three fiscal years. This represents approximately 1% of the Commission's annual budget.

des nouvelles initiatives susmentionnées, et compte tenu des amendes et des pouvoirs d'application prévus dans la LSRN, le nouveau régime de réglementation mettra davantage l'accent sur l'exploitation sûre dans l'intérêt de la santé, de la sécurité, de la sûreté et de l'environnement. Les options qui, aux termes de la LSRN, autorisent les tribunaux à ordonner des réparations lors d'une contamination ou d'autres dommages dans le cadre d'un régime de sanctions devraient s'avérer de précieux outils pour assurer la conformité.

La CCSN maintiendra la politique de la CCEA de promouvoir la conformité grâce à des avis, des documents explicatifs, des rencontres publiques et des séminaires. La priorité sera donnée aux nouvelles initiatives susmentionnées.

Des inspecteurs qualifiés continueront d'effectuer la vérification de la conformité en surveillant toutes les activités nucléaires d'après le risque et en tenant compte des antécédents des titulaires de permis. Le titulaire d'un permis de centrale nucléaire continuera d'avoir à demeure des inspecteurs de la CCSN à plein temps. La LSRN confère à l'inspecteur des pouvoirs plus vastes et plus explicites, sous réserve de révision par la CCSN.

Les infractions peuvent entraîner des mesures allant d'un simple avertissement à une poursuite, en passant par un ordre donné par un inspecteur ou un fonctionnaire désigné à la suspension du permis. Un inspecteur pourra aussi émettre les ordres qu'il estime nécessaires pour assurer la sécurité des personnes et protéger l'environnement.

6.1 Règles de procédure de la Commission canadienne de sûreté nucléaire

Puisque les règles sont de nature procédurale, leur respect est soutenu par les pouvoirs procéduraux consentis à la CCSN par la LSRN. En plus de pouvoir contrôler ses procédures, la CCSN sera un tribunal d'archives. Elle possède, en matière de participation, d'assignation et d'interrogation des témoins, de production et d'inspection des dossiers, d'application de ses ordonnances et d'autres questions nécessaires ou appropriées à l'exercice régulier de sa compétence, tous les pouvoirs nécessaires à l'exercice de ses fonctions.

7. Coût d'ensemble

Le coût total de la mise en oeuvre des nouvelles exigences réglementaires est estimé à 5,9 millions de dollars, dont 46 % découlent des nouvelles exigences en matière de sécurité.

Le coût additionnel des nouvelles exigences est estimé à 4,5 millions de dollars par année, dont 56 % découlent des exigences additionnelles en matière de sécurité, et 22 % des nouvelles limites de dose.

La CCSN n'a reçu aucune ressource additionnelle pour la mise en oeuvre de la nouvelle loi et de ses règlements; la réaffectation des ressources existantes a donc servi, et servira, à assurer la formation. Le coût de la formation sur la nouvelle loi et ses règlements à l'intention du personnel de la CCSN consiste en frais directs pour des éléments comme les entrepreneurs, le matériel et les installations, en plus du temps que les employés de la CCSN passent loin de leurs tâches régulières. Le programme de formation sera réparti sur trois exercices à partir du 1^{er} avril 1998 et se terminera le 31 mars 2001. Les frais directs sont estimés à 370 000 \$ par année pour chacun des exercices. Cela représente environ 1 % du budget annuel de la CCSN.

Staff time spent in developing and delivering training, plus the time spent by trainees away from their regular duties, will average 9 FTEs (full time equivalents) during each of the three fiscal years. This reallocation, which represents approximately 2% of the Commission's staff allocation, will be accomplished by reducing the number of inspections and increasing the time period between licence renewals for licensees who have a good compliance history.

The *Canadian Environmental Assessment Act* (CEA Act) requires that environmental assessments be completed for some projects proposed for AECB approval. With the introduction of the NSC Act, subsequent changes to CEA Regulations will be required. The Canadian Environmental Assessment Agency is considering amendments to the CEA Regulations but until its regulatory process has been completed, the effect on licensees is unknown. Questions such as environmental assessments at the time of licence renewal for nuclear facilities will be addressed but until the CEA Regulations are amended, an estimate of any incremental costs is not possible.

8. Contact

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Le temps que les employés passent à élaborer et à assurer la formation, plus le temps que les stagiaires passent loin de leurs tâches régulières représente en moyenne neuf (9) ETP (équivalent temps plein) pendant chacun des exercices. La réaffectation, qui touche environ 2 % du personnel de la CCSN, se fera en réduisant le nombre d'inspections et en prolongeant le délai de renouvellement des permis pour les titulaires dont le dossier de conformité est bon.

La *Loi canadienne sur l'évaluation environnementale* exige qu'une évaluation environnementale soit réalisée pour certains projets ou certaines propositions faisant l'objet d'une approbation de la CCEA. L'entrée en vigueur de la *Loi sur la sûreté et la réglementation nucléaires* signifie que des modifications devront être apportées à la réglementation en matière d'évaluation environnementale. L'Agence canadienne d'évaluation environnementale examine cette question, mais tant que son processus de réglementation ne sera pas achevé, on ne peut déterminer l'incidence de ces mesures sur les titulaires de permis. Des considérations telles que les évaluations environnementales au moment du renouvellement des permis des installations nucléaires seront abordées, mais d'ici à ce que la réglementation en matière d'évaluation environnementale soit effectivement modifiée, on ne peut évaluer les coûts additionnels.

8. Personne-ressource

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NOTE: Irrelevant pages below deleted; only the pages comprising the cost-benefit assessment for new rad.prot. rules are retained

Proposals for revised Ionising Radiations Regulations and Approved Code of Practice

This consultative document is issued by the Health and Safety Commission in compliance with its duty to consult, under sections 16(2) and 50(3) of the Health and Safety at Work etc Act 1974, bodies which appear to it to be appropriate before submitting proposals for the making of Regulations and the issue of Approved Codes of Practice.

Comments should be sent to:

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to reach the section no later than 30 June 1998

The Commission tries to make its consultation procedure as thorough and open as possible. Responses to this consultative document will be lodged in the Health and Safety Executive's Information Centres after the close of the consultation period where they can be inspected by members of the public or be copied to them on payment of the appropriate fee to cover costs.

Responses to this consultative document are invited on the basis that anyone submitting them agrees to their being dealt with in this way. Responses, or parts of them, will be withheld from the Information Centres only at the express request of the person making them. In such cases a note will be put in the index to the responses identifying those who have commented and have asked that their views, or part of them, be treated as confidential.

**CONSULTATIVE
DOCUMENT**

COST-BENEFIT ASSESSMENT

INTRODUCTION

1. The proposed revision to the IRR85 will implement most of the requirements of the 1996 BSS Directive for Radiation Protection. This Cost-Benefit Analysis (CBA) is based upon the CBA prepared for the 1996 Directive, which in turn was based upon the CBA of the original 1980 BSS Directive.

Background information and assumptions

2. A detailed list of the activities affected by IRRrev is at Appendix 1. They include industrial radiography, a number of activities in the nuclear industry, mining and medical applications.

3. The original BSS Directive CBA was based upon selective consultation with industry. In view of the difficulties respondents experienced in providing information without a detailed knowledge of the proposals, it is proposed that the formal consultation period is used to check the assumptions in this CBA and collect any further information.

4. Costs to HSE are taken from the 1997/98 average salary ready-reckoner. Costs to industry have been adjusted to broadly 1997/98 prices. 1997/98 has also been taken as the base year for discounting to present values. IRRrev would not be introduced until the year 2000, although recoverable costs to HSE are incurred from 1998/99. It is useful and convenient (see costing for revised procedures for Radiation Protection Advisers) to estimate costs over at least a full ten year period in which the Regulations are in place. Including HSE costs, the time period over which costs are covered is therefore a 12 year one, covering the period 1998/99 to 2009/2010²².

COSTS

Costs to industry

Familiarisation

5. Employers will have to become acquainted with IRRrev and explain them to their employees, safety representatives etc. This would also apply to consultants and Radiation Protection Advisers (RPAs). A question on this is included in the CBA part of the proforma at Annex 10

Risk Assessment

6. IRRrev require employers to assess the risks associated with radiation work before they commence that work. HSE expects the cost of this additional assessment to be small. This provision complements what is already required under general health and safety legislation, such as the Management of Health and Safety at Work Regulations 1992. However, a question on this is included in the CBA part of the proforma at Annex 10 and any significant emerging costs will be assessed.

²² IRRrev has to be introduced by May 2000. However, for convenience we assume 2000/2001 is the first year in which IRRrev is in operation. **Annex C**

Prior authorisation

7. The 1996 BSS Directive contains the necessary flexibility to allow the UK to retain its existing methods and procedures, and thus to minimise additional costs. At present nearly all employers working with ionising radiation have to notify HSE. Under IRRrev, it is likely that prior authorisation will mean that additional information will have to be provided for some industrial uses of ionising radiation. It is estimated that this will involve about 90 minutes of the time of a manager, at about £20 per hour²³. It is conservatively assumed that one-third of the 7,500 sites which currently have to notify HSE will be affected. If so, this gives a one-off cost of £75,000.

8. There will be recurring costs associated with new prior authorisations given each year. HSE does not have any information on this but it is thought that the number is very small. If the number of sites applying for prior authorisation each year was, say, 5 per cent of the total, then recurring costs would be estimated at 5 per cent of £75,000, i.e. £3,750 per year.

Dose constraints

9. IRRrev include a general provision for the use of dose constraints, conditioned by 'where appropriate'. As defined, even where these are appropriate they would only be used at the design or planning stage of new operations. With this flexibility, it is anticipated that there will not be any significant costs resulting from this provision.

Classification of workers

10. The only proposed change to current UK legislation is a reduction in the dose level, from 15 mSv to 6 mSv per year, at which workers become 'classified persons' and thus subject to personal monitoring and medical surveillance. The number of 'classified persons' has fallen steadily from about 57,000 to about 47,000 between 1993 and 1996. The introduction of Ionising Radiations (Outside Workers) Regulations 1993 is thought to be instrumental in this since it required employers to question whether particular individuals needed to be classified.

11. It is believed that the existing prudent approach of UK employers will mean that not many more workers will become classified persons. 95 per cent of classified persons already have recorded doses below 5 mSv per year. Nevertheless, it is expected that the fall in the level from 15 mSv to 6 mSv will result in an increase in the number of workers classified. HSE's best estimate is that, as a maximum, another 5,200 workers might require classification.²⁴ If so, this is estimated to involve an additional initial cost of around £0.6m and an annual cost of around £1.15m. (This is based upon the calculations in the CBA of the original BSS Directive - details of the approach are given in Appendix 2.)

²³ The average hourly wage for "managers and administrators" was £13.31 in April 1996. Adding 30 per cent for non-wage labour costs gives £17.30. This is rounded up to reflect uncertainty over the labour costs of those involved here and to adjust towards 1997/98 prices.

²⁴ It is possible that the introduction of IRRrev may result in some partly offsetting fall - as with OWR - and that the additional number of workers requiring classification will fall over time. However, for simplicity, and to correspond to a likely maximum, we assume a constant net increase of 5,200 workers per year.

Monitoring

12. The changes in dose quantities and dose limits may result in some minor costs to approved dosimetry services (and thus employers who engage them). There is a question on this in the CBA part of the proforma at Annex 10.

Requirements for Medical Examinations

13. As with the current regulations, IRRrev will require adequate medical surveillance, leaving it to the judgement of the appointed doctor when a medical examination is needed as part of the periodic surveillance of classified persons. However, guidance to IRRrev will say that adequate medical surveillance might include a medical examination on a change of post if the new post involves different risks from exposure to ionising radiation (for example, where a person working with external radiation was moved to a job with radioactive substances that might contaminate the skin). This was not clearly expressed in the Approved Code of Practice supporting the current regulations so it might be expected that some extra medical examinations will take place. However, HSE believes that this will be offset by fewer medical examinations resulting from clearer guidance on the purpose of medical surveillance. HSE's initial view is that there is unlikely to be a significant cost impact but there is a question on this in the CBA part of the proforma at Annex 10.

Exposure to Natural Radiation

14. The 1996 BSS Directive requires the identification of work activities which need attention due to enhanced levels of natural radiation. This provision also applies to the presence of materials not usually regarded as radioactive but which contain significant traces of natural radionuclides and which may also significantly increase the exposure of members of the public. However, these requirements are in line with the actions that are already taken in the UK and are therefore not expected to result in increased costs in IRRrev.

Annual Dose Limits: Fixed Annual Limits vs Five Year Averaging

15. The 1996 BSS Directive allows Member States to choose between annual dose limits and five yearly averaged limits. A question on these options and relevant cost information is in the CBA part of the proforma at Annex 10.

Revised Procedures for Radiation Protection Advisers (RPAs)

16. IRRrev seek to clarify and make transparent the UK's implementation of the 1996 BSS Directive's requirement for competent authorities to 'recognise the capacity to act as a qualified expert'. (Qualified experts are RPAs in both the current and proposed regulations.)

17. It is proposed that, to be an RPA under IRRrev, an individual must either hold a certificate of competence in radiation protection issued by a suitable assessing body (HSE will hold a list) or hold a Level 4 N/SVQ in Radiation Protection Practice. In each case, evidence of continued competence/continued professional development will be required, currently proposed as renewed certification or achieving the NVQ Unit in Continuing Professional Development every five years. HSE is proposing that individuals who are currently acting as RPAs will have five years in which to obtain evidence of competence, but that new RPAs will have to satisfy the criteria from day one of IRRrev.

18. It is not known how many RPAs there are, but a very rough, probably conservative, estimate is 1500 to 2000.²⁵ Currently, there are 300 to 400 holders of certificates of competence issued by relevant professional societies and no NVQ holders (the NVQ has only just been launched). There is evidence that some employers are already beginning to demand evidence of competence from contract RPAs, so the number of certificated/NVQ-holding RPAs could rise considerably in the next couple of years, before IRRrev comes into force.

19. The main professional society currently charges members £25 for a new certificate of competence and £20 for renewal. Non-members are charged £45 and £40 respectively. The other professional societies are likely to charge similar fees. These charges may have to increase if the demand for certification increases dramatically, as most of the work is currently voluntary.

20. NVQs are likely to be very much more expensive. This is difficult to quantify at this stage but the cost may possibly average about £1000 per person (this depends upon many factors, including how many NVQs are taken, whether assessment is in house or external etc).

21. We have estimated the cost of certification only (ie no costs of acquiring NVQs have been included). Details of the assumptions and methods use are given at Appendix 3. Costs over a ten year period are estimated at £112,000 in present value terms.

Requirements Relating to Medical Exposure

22. IRRrev will mainly implement article 8 of the Euratom Directive on Medical Exposures. This requires employers to have a Quality Assurance (QA) programme in respect of medical equipment or apparatus. This involves testing of the equipment before it is first used and at appropriate intervals thereafter, and assessing representative doses which have been administered to persons undergoing medical exposure. There is also a requirement for new diagnostic X-ray equipment to include some means of informing the user of the quantity of radiation produced during a procedure, where practicable. It is thought that most of this type of equipment includes an indication of X-ray tube current and exposure time or a specially designed ionisation chamber which indicates the dose-area product either of which should satisfy the additional requirement. HSE believes that much of what is required under article 8 is already undertaken by employers as part of their normal health and safety or work practices. The Department of Health do not envisage significant additional requirements for funding or staff time. It is thought that approximately 80% of the 600 hospitals in the NHS and private sector already have a QA programme in place. The remaining 20% may have to formalise or demonstrate more clearly what they do already, but HSE expects any costs to be small. However, there is a question on this in the CBA part of the proforma at Annex 10 and any emerging significant costs will be assessed.

Radiation passbooks

23. OWR currently require employers to provide their classified persons who work in other employers' controlled areas ('outside workers') with radiation passbooks. Currently about 24,000 have been issued since 1993. The passbooks are not transferable between employers. IRRrev propose to allow such transferability, which will result in a cost saving to

²⁵ While large organisations generally have several RPAs, small employers may either not need one at all or may share one. For example, each RPA in NRPB's RPA service will service around 40 sites, which might equate to 30-35 employers, other consultants may accept similar workloads; in between, other employers may have one each.

employers. The passbooks will need to be redesigned, but transitional arrangements to allow continued use of existing passbooks, where appropriate, for the first year should minimise any additional costs (passbooks cost £3.50 from HSE, but employers may only obtain passbooks through their ADS for record-keeping and current ADS rates are understood to be about £10 per passbook). The overall effect should be cost neutral.

Costs to HSE

24. HSE will have to process prior authorisations under IRRrev. Each authorisation is estimated to involve about 90 minutes of an HSE Band 4's time. For 2,500 authorisations the cost would be approximately £69,000.²⁶ There may be some small recurring costs associated with new prior authorisations granted each year. If these were at 5 per cent of the current number of prior authorisations, costs would also be about 5 per cent, i.e. about £3,450 per year. Costs to HSE of granting prior authorisations may be recovered from industry through charging.

25. Based upon broad estimates of staff time needed, the work involved in completing and implementing the regulations is estimated to cost HSE about £93,000 in 1998/99 and £20,000 in 1999/2000, making a total of approximately £113,000.²⁷ Costs prior to 1998/99 (ie pre-consultation costs) are non-recoverable ('sunk') and therefore excluded.²⁸

26. Overall costs to HSE are therefore estimated at £182,000 (one-off) and £3,450 (annual).

Total costs

27. A summary table of costs is attached as Appendix 4. It shows that one-off costs are estimated at £0.84m and recurring costs at £1.14m to £1.21m per year. Costs over the period 1998/99 to 2009/2010 are estimated at £8.13m to £8.59m in present value terms.

BENEFITS

Health and safety benefits

28. Benefits are unquantifiable because it is not possible at present to estimate the scale of increased worker protection resulting from the proposals or the possible effects in reduced incidence of cancer. However, such benefits would be expected to be very small since most workers are presently exposed below the proposed dose limits.

²⁶ Using the 1997/98 HSE average salary ready-reckoner, the hourly rate of a band 4 (broadly equivalent to the previous Higher Executive Officer grade) administrator based in London is calculated as £18.48. 90 minutes time is therefore valued at £27.73.

²⁷ Calculated using the ready-reckoner. Staff time assumptions: 1998/99 - 0.1 band 1, 1.0 band 2, 1.0 band 4 and 0.5 band 5; 1999/2000 - 0.2 band 2, 0.2 band 4 and 0.2 band 5. Costs beyond 1997/98 are raised by 1.8% per year, which is approximately the average annual growth in whole economy real earnings over the past 25 years or so.

²⁸ 1997/98 costs are estimated at £99,000, based upon 0.3 band 1, 1.5 band 2 and 0.5 band 4. Also excluded are the costs of publishing an estimated 4000 consultative documents. **ex 9**

Other benefits

29. The integration of OWR into IRRrev may involve some cost savings. OWR supplement the current IRR85 in respect of protecting classified workers who go to work in controlled areas which are under the control of someone other than their own employer. Integrating the two sets of regulations reduces some provisions to an absolute minimum, removes some record-keeping requirements and allows transferability of passbooks. A question on this is included in the CBA part of the proforma at Annex 10.

BALANCE OF COSTS AND BENEFITS

30. Overall costs are estimated at £8.13m to £8.59m over a twelve year period in present value terms. It is not possible to make an overall quantitative comparison of costs and benefits because we cannot quantify any health and safety benefits resulting from IRRrev. These are expected, however, to be very small because most workers are currently exposed below the proposed dose limits.

APPRAISAL OF UNCERTAINTIES

31. By far the largest quantified cost results from the expected increase in the number of classified workers. The number of extra workers (5200) is thought to be a maximum. Some of the costs of IRRrev have not yet been quantified. It is expected that many of these (eg monitoring) will involve fairly minor costs. There are particular uncertainties over the impact of the requirements for medical examinations. We have assumed at present that the changes will be cost neutral, but there is a question on this in the proforma under Cost Benefit Analysis. To make a costing of the revised procedures for RPAs it has been necessary to make a number of assumptions and therefore the costings are subject to uncertainty. Furthermore, they only cover costs of certification (since this is the minimum requirement) and do not include costs of obtaining NVQs. It is not possible to quantify any health and safety benefits resulting from IRRrev but they are expected to be very small.

IMPACT ON SMALL AND MEDIUM-SIZED BUSINESSES

32. There are likely to be some economies in larger organisations undertaking activities such as exposure monitoring, assessments and record-keeping. Smaller organisations may therefore incur proportionately higher costs. HSE sought to undertake a small business litmus test for the CBA on the 1996 BSS Directive but found difficulties in establishing contact with small businesses that were conversant with the Directive and its requirements. HSE hopes to use the information arising from consultation, in particular in response to the questions asked in the proforma at Annex 10, to carry out this small business litmus test.

Appendix 1

List of activities where there is work with ionising radiation

These are the occupational categories used for the purposes of the Central Index of Dose Information (CIDI), which is operated by the National Radiological Protection Board under contract to HSE:

Industrial radiography using permanent installations
Industrial radiography on site or works of engineering construction
Nuclear reactor operations
Nuclear reactor maintenance
Nuclear fuel fabrication
Nuclear fuel reprocessing
Radioactive waste treatment
Radiation protection
Application and servicing of machines producing ionising radiation
Application and manipulation of radioactive substances
Transport work
Offshore work activities
Onshore drilling
Mining coal - underground workers (coal mining underground)
Mining coal - surface workers
Mining minerals other than coal - underground workers (non-coal mining underground)
Mining minerals other than coal - surface workers
Dental work
Veterinary work
Medical applications - doctors
Medical applications - nurses
Medical applications - radiographers
Medical applications - physicists and physics technicians
Other medical applications
Quarrying
Academic research and teaching
Industrial research
Industrial applications not mentioned above (other industrial)
Others not specified above (others)
Nuclear decommissioning

Appendix 2**CALCULATION OF COSTS OF INCREASE IN NUMBERS OF CLASSIFIED WORKERS**

Assume an additional 5200 workers are to be classified.

Initial Costs

Record keeping/registration fee	£25
Medical examination	£47
Lost output while attending medical examination (¹ two hours lost time at labour cost of £20 per hour)	£40 ¹
Total initial costs per worker	£112
Total initial costs (£112 x 5200)	<u>£0.582m</u>

Annual Costs

External dose assessment (² based on one dosimeter every four weeks at £2 to £3 each)	£26 to £39 ²
Repeat record keeping/registration fee	£12.50
Repeat medical examination	£28
Loss of output (³ 90 minutes at £20 per hour)	£30 ³
Internal dose assessment (⁴ assumed to apply to only 15% of the 5200 workers)	£750 ⁴
Cost in respect of new workers each year (consists of £47 medical exam and £40 lost output. New workers per year taken to be 5% of 5200 workers.)	£87 ⁵
Allowance for compiling CIDI records	£1.25 to £1.75
Total annual costs	<u>£1.116m to £1.186m⁶</u>

⁶ Sum of:

$5200 \times (\text{£}26 \text{ to } \text{£}39 + \text{£}12.50 + \text{£}28 + \text{£}30) = \text{£}501,800 \text{ to } \text{£}569,400$

$(5200 \times 0.15) \times \text{£}750 = \text{£}585,000$

$(5200 \times 0.05) \times \text{£}87 = \text{£}22,620$

$5200 \times \text{£}1.25 \text{ to } \text{£}1.75 = \text{£}6500 \text{ to } \text{£}9100$

Appendix 3

Costs of Certification for RPAs

The attached table presents an estimate of the cost of RPAs obtaining certificates. They do not include any costs of obtaining NVQs. It is assumed that the fees charged by the issuing organisations represent the full economic costs involved and that there are no significant other costs (we understand that applicants only have to fill in a short form when applying for a certificate). We assume that all those who apply are successful.

The more detailed assumptions made are given at the top of the attached table. The cost of a certificate is taken as £45 and a renewal £40 (both 1997/98 prices). These costs are assumed to increase in line with the historical trend in average real earnings growth (1.8 per cent per year).

There are three groups who incur costs.

Firstly, there are the existing RPAs who do not have certificates. They will have five years in which to obtain them. We assume that during the first five years of IRRrev 20 per cent of these people obtain certificates each year and that these are renewed five years later. Over a ten year period costs are estimated at £73,000 in present value terms.

Secondly, there are existing RPAs who are certificate holders but would not have replaced them without IRRrev. It is assumed that 20 per cent of these renew their certificate each year. Over ten years costs are estimated at about £5,000.

Thirdly, there are those who become an RPA for the first time after IRRrev is introduced. It is assumed that 20 per cent of these would have obtained a certificate without IRRrev and that 75 per cent of them would have renewed it. Over a ten year period costs are estimated at £34,000.

Overall, ten year costs are therefore estimated at £112,000 in present value terms.

Annex C

Assumptions Used in Costing Certification Requirements for RPAs

- a) Number of RPAs 2000 Number of RPAs remains constant at 2000
 b) Number with Certificate 400 (ie 20 per cent) Cost of certificate (1997/98 prices) £45
 Percent of b) that renew certificate 75% Cost of renewal (1997/98 prices) £40
 Turnover of RPAs per year 5% (ie 100 new RPAs pa) Year 3 = 2000/2001 (first year of IRRrev)
 In each of first five years 20% of existing RPAs obtain 20% of new RPAs would have obtained a certificate anyway and
 certificate 75% of these would have renewed them

RPAs at time IRRrev is introduced who do not have certificate

	A	B	C	D	E	F	G	H	I	J
Year	No. of RPAs remaining (lose 5% pa)	No. getting certificate (20% pa) (A x 0.2)	Cost per certificate	Total cost of certificate (B x C)	No. of getting renewals	Cost per renewal	Total cost of renewals (E x F)	Total cost (D + G)	Discount factor	Discounted cost
3	1,520	304	47.47	14,432				14,432	0.84	12,117
4	1,444	289	48.33	13,957				13,957	0.79	11,055
5	1,372	274	49.2	13,498				13,498	0.75	10,087
6	1,303	261	50.08	13,054				13,054	0.71	9,203
7	1,238	248	50.99	12,625				12,625	0.67	8,396
8	1,176				202	46.14	9,305	9,305	0.63	5,838
9	1,117				182	46.97	8,549	8,549	0.59	5,060
10	1,061				164	47.81	7,854	7,854	0.56	4,386
11	1,008				148	48.67	7,216	7,216	0.53	3,801
12	958				134	49.55	6,630	6,630	0.5	3,295
								107,119		73,238

RPAs at time IRRrev is introduced who do have certificates but do not renew them

	A	B	C	D	E	F	G
Year	No. of RPAs remaining (lose 5% pa)	No. certif not renewed (A x 0.25)	Assume 20 per cent renewed pa (B x 0.2)	Cost per renewal	Total cost of renewals (C x D)	Discount factors	Discounted total cost (E x F)
3	380	95	19	42.2	802	0.84	673
4	361	90	18	42.96	775	0.79	614
5	343	86	17	43.73	750	0.75	560
6	326	81	16	44.52	725	0.71	511
7	310	77	15	45.32	701	0.67	466
8	294	74	15	46.14	678	0.63	426
9	279	70	14	46.97	656	0.59	388
10	265	66	13	47.81	634	0.56	354
11	252	63	13	48.67	614	0.53	323
12	239	60	12	49.55	593	0.5	295
					6,929		4,612

New RPAs (ie those who become RPAs after IRRrev is introduced)

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
Year	No. of new RPAs	No. of RPAs not getting certificate anyway (80%)	Cost per certificate	Total cost of certificate (B x C)	No. of B remaining (lose 5% pa)	Cost per renewal	Cost of renewals (E x F)	No. of RPAs getting cert anyway (30%)	No. of H remaining (Lose 5% pa)	No. of I who would not renew (25%)	Cost of additional renewals (J x F)	Total cost (D+G+K)	Discount Factors	Discounted Total Cost
3	100	80	47.47	3,798	76			20	19			3,798	0.84	3,189
4	100	80	48.33	3,866	72			20	18			3,866	0.79	3,062
5	100	80	49.2	3,936	69			20	17			3,936	0.75	2,941
6	100	80	50.08	4,007	65			20	16			4,007	0.71	2,825
7	100	80	50.99	4,079	62			20	15			4,079	0.67	2,713
8	100	80	51.9	4,152	53	46.14	2,449	20	15	4	170	6,770	0.63	4,248
9	100	80	52.84	4,227	50	46.97	2,368	20	14	3	164	6,759	0.59	4,001
10	100	80	53.79	4,303	48	47.81	2,290	20	13	3	159	6,752	0.56	3,770
11	100	80	54.76	4,381	46	48.67	2,215	20	13	3	153	6,749	0.53	3,555
12	100	80	55.74	4,459	43	49.55	2,142	20	12	3	148	6,750	0.5	3,354
				41,208			11,464				794	53,465		33,658

Appendix 4

SUMMARY OF COSTS AND BENEFITS

£ thousands, 1997/98 prices

A: QUANTIFIED COSTS AND BENEFITS	One-off costs/benefits	Recurring costs/benefits	Present values 1998/99 -2009/2010 (a)
COSTS			
Prior Authorisation	75	4	88
Classification of Workers	582	1116 - 1186	7799 - 8257
Revised Procedures for RPAs	-	19 (b)	112
Total costs to industry	657	1139 - 1209	7999 - 8457
Total costs to HSE	182	3	128
Total quantified costs	839	1142 - 1212	8127 - 8585
BENEFITS	-	-	-
B: UNQUANTIFIED COSTS AND BENEFITS	Comment		
COSTS			
Risk Assessment	Expected to be small but asking for more information during consultation		
Monitoring and Dose Control costs	Probably small		
Familiarisation and Medical Examinations	Costs uncertain - asking for information during consultation.		
Quality Assurance Programme	Expected to be small but consulting further		
BENEFITS			
Health and safety	Probably very small		
Cost savings	Collecting information on impact of integration of the OWR into IRRrev and impact of new guidance on medical examinations during formal consultation		

Notes:

- (a) Costs discounted back to 1997/98 base year.
- (b) First year cost.

Annex C

D. (ANNEX I TO CEC IMPACT ASSESSMENT ON ORGANISATIONS IN RP)

Organisations in Radiation Protection

Heads of the European Radiation Control Authorities (HERCA) is an informal body of high-level (“heads”) representations of national authorities with competence in radiation protection. This group was constituted in May 2007 on the initiative of French Nuclear Safety Authority (ASN) and brings together the heads of European radiation protection authorities. At their request, five working groups have been set up to examine a series of themes considered by the authorities as problematic. Each working group is jointly chaired by representatives of different national authorities. The first working group, devoted to the question of “radiological passports”, met in 2008. Two other working groups are devoted to the themes of “justification” and “new medical techniques”.

The Commission was invited to inform on progress with the revision of the BSS at meetings in December 2008 and 2009 as well as in June 2010. At the meeting in June 2010 a working document comparing extensively the draft Euratom BSS with draft 3.0 (January 2010) of the International BSS was presented by the Commission, and the group further supported the Euratom approach.

International Commission on Radiological Protection (ICRP) is an independent Registered Charity, established to advance for the public benefit the science of radiological protection, in particular by providing recommendations and guidance on all aspects of protection against ionising radiation.

ICRP is the worldwide recognised scientific society in radiation protection. Based on the latest available scientific information of the biology and physics of radiation exposure, its recommendations lay out the philosophy and the technical benchmarks in the radiation protection area. Without being of obligatory nature, ICRP recommendations are internationally recognised for the development of radiation protection rules all over the world. A few years ago, ICRP started to revise their Recommendations for a System of Radiological Protection taking account of the latest scientific findings. In view of the importance afforded to ICRP’s recommendations and to ensure that the new recommendations adequately and appropriately address national issues and concerns, the ICRP has initiated an open process involving two phases of international public consultation. The ICRP has received input from a broad spectrum of radiation protection stakeholders, ranging from government institutions and international organisations to scientists and non-governmental organisations. The draft recommendations have been discussed at a large number of international and national conferences and by many international and national organisations with an interest in radiological protection. The European Commission, with the support of the Article 31 Group of Experts, took part in these discussions.

International Radiation Protection Association (IRPA) is an international non-profit organisation that enlists individuals as members who are also members of an affiliated national or regional Associate Society. Today, there are 46 associated societies around the world with membership of nearly all professionals with operational responsibilities in radiation protection. The primary purpose of IRPA is to provide a medium whereby those engaged in radiation protection

activities in all countries may communicate more readily with each other and through this process advance radiation protection in many parts of the world. This includes relevant aspects of such branches of knowledge as science, medicine, engineering, technology and law, to provide for the protection of man and his environment from the hazards caused by radiation, and thereby to facilitate the safe use of medical, scientific, and industrial radiological practices for the benefit of mankind.

International Atomic Energy Agency (IAEA) is an independent international organisation, related to the United Nations system, which seeks to promote the peaceful use of nuclear energy. The IAEA was established as an autonomous organisation on 29 July 1957 with headquarters in Vienna, Austria. Today, IAEA has 151 member states. The IAEA serves as an intergovernmental forum for scientific and technical cooperation in the peaceful use of nuclear technology and nuclear power worldwide. The programs of the IAEA encourage the development of the peaceful applications of nuclear technology, provide international safeguards against misuse of nuclear technology and nuclear materials, and promote nuclear safety (including radiation protection) and nuclear security standards and their implementation. A big part of the IAEA's statutory mandate is the establishment, and promotion, of advisory international standards and guides. The IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionising radiation. They are issued in the IAEA Safety Standards Series, and cover nuclear safety, radiation protection, radioactive waste management, the transport of radioactive materials, the safety of nuclear fuel cycle facilities and quality assurance. The main document in radiation protection is Safety Standard 115 "International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources", edition 2003. These Standards, co-sponsored by FAO¹, ILO², OECD/NEA³, PAHO⁴ and WHO⁵, are based on assessments of the biological effects of radiation made by the United Nations Scientific Committee on the Effects of Atomic Radiation, and on the recommendations of the International Commission on Radiological Protection and the International Nuclear Safety Advisory Group. In 2006 IAEA together with the cosponsors undertook revision of Safety Standard 115. This is ongoing activity also driven by the new ICRP Recommendations 103, published in 2007.

United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) was established by the General Assembly of the United Nations in 1955. Its mandate in the United Nations system is to assess and report levels and effects of exposure to ionising radiation. Governments and organisations throughout the world rely on the Committee's estimates as the scientific basis for evaluating radiation risk and for establishing protective measures.

¹ Food and Agriculture Organisation of United Nations

² International Labour Organisation

³ Organisation for Economic Cooperation and Development, Nuclear Energy Agency

⁴ Pan American Health Organisation

⁵ World Health Organisation

(ANNEX II)

Projects, Studies, Scientific Radiation Protection Publications

A. Summaries of the scientific publications, projects and studies

1. Publication 103 of ICRP. After eight years of discussions, involving scientists, regulators, and users all around the world, the International Commission on Radiological Protection adopted its new recommendations on 21 March 2007 (published in December 2007).

The new Recommendations (Publication N° 103) have two primary aims:

- to take account of new biological and physical information and of trends in the setting of radiation safety standards; and
- to consolidate and rationalise the previous Recommendations (Publication N° 60) and the supplementary reports, issued since their publication in 1991.

The present Recommendations update the radiation and tissue weighting factors in the quantities equivalent and effective dose and update the radiation detriment, based on the latest available scientific information of the biology and physics of radiation exposure. They maintain the Commission's three fundamental principles of radiological protection, namely justification, optimisation, and the application of dose limits, clarifying how they apply to radiation sources delivering exposure and to individuals receiving exposure.

The Recommendations evolve from the previous process-based protection approach using practices and interventions by moving to an approach based on the exposure situation. They recognise planned, emergency, and existing exposure situations, and apply the fundamental principles of justification and optimisation of protection to all of these situations. They maintain the Commission's current individual dose limits for effective dose and equivalent dose from all regulated sources in planned exposure situations. They re-enforce the principle of optimisation of protection, which should be applicable in a similar way to all exposure situations, subject to the following restrictions on individual doses and risks; dose and risk constraints for planned exposure situations, and reference levels for emergency and existing exposure situations. The Recommendations also include an approach for developing a framework to demonstrate radiological protection of the environment.

2. European Study on Occupational Radiation Exposure (ESOREX). The ESOREX was established in 1997 to collect information on how individual monitoring is structured in MS and how data are recorded and reported. The project consisted of surveys on radiation monitoring and exposure of workers for the period from 1995 to 2005. The data collected have allowed statistical evaluation of occupational radiation exposure in different work sectors. The analysis of different years allowed the evaluation of changes and trends after the implementation of the BSS Directive 96/29.

The objective of this European Union survey is to provide the Commission and the national competent radiation protection authorities with reliable information on how personal radiation monitoring, reporting and recording of dosimetric results is structured in European countries. The survey resulted in the following main conclusions:

- To ensure that outside workers receive the same level of protection as workers permanently employed by a licensee, it is imperative that the Outside Workers Directive is coherently incorporated in the Basic Safety Standards Directive 96/29. Definitions need to be made

consistent, and the responsibilities of an undertaking and of the employer of an outside worker for the protection of the outside worker need to be clearly defined.

- To allow free movement of outside workers within Europe it is necessary to establish a harmonised dose limit for occupational exposure. It is therefore recommended to abandon the current dose limit of 100 mSv averaged over 5 years (with a yearly maximum of 50 mSv) and to introduce a single year dose limit of 20 mSv.
- The establishment of a national dose registry allows tracking the doses of exposed workers nationally, in particular the doses of outside workers.
- The introduction of an individual radiological monitoring document (Radiation Passbook) for each outside worker shall further facilitate recording and reporting of individual exposure data. The radiation passbook of an outside worker should furthermore allow undertakings to be informed about the dose history of an outside worker and to easily check compliance with requirements on education and training, medical surveillance and with dose limits.

3. **“European ALARA Network for naturally occurring radioactive material – NORM”** is a forum for communication, knowledge exchange, identification of problems and discussions about possible solutions on different topics related to NORM. The European Commission has used the workshops organised by the European ALARA Network for NORM (EAN_{NORM}) and its website for presenting and discussing different proposals for modifications in the 96/29 Directive with regard to NORM (see public consultation on natural radiation sources). The main European ALARA Network held in 2005 a workshop (**9th European ALARA Network Workshop**), that focused on the control of the exposure received by workers from natural radiation sources, in particular workers in the NORM industries and exposure to radon. The Workshop recommended that national authorities should develop long-term action plans for addressing occupational radon exposures and that the EC clarifies the Scope of Title VII of the BSS Directive, in particular to which workplaces it applies. It also recommended that the regulatory system applied to NORM should focus on significant risks and a graded approach is necessary.

4. **European Platform on Training and Education in Radiation Protection (EUTERP)** was established in 2006 following the results of a survey carried out on behalf of the European Commission and published as Radiation Protection N° 133. EUTERP recommends that the status of the "qualified experts" in the directive is enhanced with particular requirements for their involvement in the supervision and execution of radiation protection tasks. In addition it is proposed to establish two levels of expertise - Radiation Protection Expert and Radiation Protection Officer. These proposals aim to establish harmonised environment for the recognition of these specialist and to contribute to the free movement of these experts. These proposals aim to establish harmonised environment for the recognition of these specialist and to contribute to the free movement of these experts.

5. **International Conference on Modern Radiotherapy: ‘Advances and Challenges in Radiation Protection of the Patients’**, organised by the French Nuclear Safety Authority in cooperation with the International Atomic Energy Agency, the World Health Organization and the European Commission from 2 to 4 December 2009 in Versailles⁶. During this conference detailed consideration has been given to the "accidental or unintended exposures" of patients following the several cases of such accidents that occurred in recent years (France, Belgium...).

⁶ Main findings from the conference are available on www.conference-radiotherapy-asn.com.

6. International Conference on Justification of Medical Exposure in Diagnostic Imaging, organised jointly by the International Atomic Energy Agency and the European Commission from 2 to 4 September 2009 in Brussels⁷. Despite these initiatives, the approach to and compliance with justification is weak in diagnostic radiology and nuclear medicine. Work within the EU SENTINEL Project and a number of IAEA consultations confirm this. It is also probable that there are significant justification problems in radiological practice in the developing world. In the West, recent studies indicate that >20% of examinations may not be appropriate; this can be as high as 45% in special cases, and up to 75% for specific techniques. This situation should be tackled promptly, particularly as tools are now available to improve it. The sense of urgency about the problem is reinforced by newer high dose activities in radiology, newly available tools for justification and clinical audit, the ongoing revision of the IAEA Basic Safety Standards (BSS), the recasting of the European Directives, and the requirement for an effective regulatory approach in a sensitive area. These developments are happening against a background of worryingly increasing medical radiation doses, and the American College of Radiology (ACR) white paper noting "The rapid growth of CT and certain nuclear medicine studies may result in an increased incidence of radiation-related cancer in the not-too-distant future". These concerns provide additional motivation for dealing with justification. Finally there is a need to align medical justification with contemporary ethical and social thinking.

7. IAEA RS-G-1.7. The objective of this Safety Guide is to provide guidance to national authorities, including regulatory bodies, and operating organisations on the application of the concepts of exclusion, exemption and clearance as established in the BSS. The Safety Guide includes specific values of activity concentration for both radionuclides of natural origin and those of artificial origin that may be used for bulk amounts of material for the purpose of applying exclusion or exemption. It also elaborates on the possible application of these values to clearance.

8. International Symposium on Non-Medical Imaging Exposures, organised by the European Commission on 8 and 9 October 2009 in Dublin. The objective of the symposium was to collect up-to-date information and exchange experiences on non-medical/medico-legal exposures, identify the issues of concern and discuss the ways of addressing them in a revision of the Euratom BSS Directive. The meeting concluded that it is clear that there is a need to retain the level of protection and justification that applies to medical exposures, as defined in the current Medical Exposure Directive. However in doing this it is also necessary to ensure that the over-arching framework is such that all practices are regulated and appropriate levels of control are in place. It was clear that the single most important issue in this area is justification and that this must be applied for every practice and individual exposure. The conclusions supported the exclusion of the medico-legal exposures from the legal definition of medical exposure and grouping them together with other similar cases under the new term 'non-medical imaging exposures', for which a detailed new approach should be proposed in the revised BSS Directive.

B. Summaries of the Reports Published in the Euratom Radiation Protection Series

1. Radiation Protection N° 95 "Reference levels for workplaces processing materials with enhanced levels of naturally occurring radionuclides". The purpose of this Guide is to provide advice on work activities where the processing of NORM is subject to the requirements in Title VII of the BSS Directive 96/29. Since the existence of the radiation risk is incidental to the process undertakings are sometimes not aware of the risk. Therefore, simple means of identifying and categorising such industries are needed so that managements can decide whether more detailed radiological assessments are necessary. The report proposes a graded approach to the regulatory control of workers in NORM industries and suggests dose levels at which the different levels of regulatory control would apply;

⁷ <http://rpop.iaea.org/RPOP/RPoP/Content/PastEvents/justification-medical-exposure.htm>.

below 1 mSv per year no regulatory control, between 1-6 mSv per year low level of control, between 6-20 mSv per year high level of control and above 20 mSv exposures should not be accepted. The report also indicates the most significant industries in Europe where processing of NORM can cause increased exposure of workers.

2. Radiation Protection N° 112 "Radiological protection principles concerning natural radioactivity of building materials". The purpose of this publication is to provide guidance for establishing regulatory control of building materials containing enhanced levels of natural radioactivity. The report recommends the establishment of a dose criterion for introducing regulatory control and proposes a methodology for screening material (using an Activity Index formula) to see if the dose criterion is complied with. The study which formed the basis for the report, see RP 96 Enhanced radioactivity in building materials, also included information about national regulation on natural radioactivity in building materials. In 1997 when the RP 96 was published only five Member States had legislation and the Activity Index formula used to screen material varied between those countries.

3. Radiation Protection N° 122 "Practical use of the concepts of clearance and exemption".

Part I "Guidance on general clearance levels for practices" offers default values for any type of material and any pathway of recycling or disposal (in addition to the specific levels for metals and building rubble, published earlier).

Part II "Application of the concept of exemption and clearance to natural radiation sources". The application of the concepts of exemption and clearance to natural radiation sources is discussed in this study within the overall context of regulatory control of natural radiation sources and in particular as laid down in Title VII of the Basic Safety Standards for work activities. The study discusses how these concepts can be used and which clearance levels would be appropriate. The main conclusions were:

- as a result of the large volumes of material processed and released by NORM industries, the concepts merge and it would be appropriate to have one single set of values both for exemption and clearance;
- although the basic concept and criteria for exemption and clearance for NORM work activities are similar to those for practices, it is not meaningful to define levels on the basis of the individual dose criterion for practices (10 μ Sv per year); instead a dose increment in the order of 300 μ Sv is appropriate.

4. Radiation Protection N° 130 "Medico-legal exposures, exposures with ionising radiation without medical indication". Proceedings of the International Symposium, organised by the Commission in 2002⁸. According to the Medical Exposure Directive, all individual exposures are supposed to be justified both by the prescriber and by the practitioner, each with respect to their own expertise and area. In cases where a medical doctor is asked by an insurance company, judge, employer etc. to provide advice and/or a conclusion about the physical state of a person, it is likely that X-ray will be indicated to complete the assessment. However, there are situations where the medical doctor is effectively directed to use X-rays by an employer, judge etc. In those cases, the one who orders the X-ray becomes the prescriber.

5. Radiation Protection N° 133 "The Status of the Radiation Protection Expert in the EU Member States and Applicant Countries". This report provides a survey of the present situation of radiation

⁸ http://ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/130.pdf.

protection experts (RPEs) in the Member States of the European Union and the Applicant Countries (at the time of the survey). Based on the conclusions of the study, some recommendations are made:

- In the context of the single market and the enlargement process, it is recommended to try to achieve harmonisation in the qualifications of the so called "qualified expert" often introduced in national legislations as RPE. This would help promote the achievement of the aims of the Directive on free movement of workers in the European Union and should take due note of the Directive on safety at work.
- Definition, tasks and provisions for recognition of the RPE in the national regulations of EU Member States and Applicant Countries should be compared in detail, in order to expose the obstacles preventing a harmonised implementation of the concept of the "Qualified Expert".

As a means of achieving this goal, it is recommended to establish a Discussion Platform that could serve as a means for exchange of information on education, training, recognition and registration of RPEs. This Platform may provide a vehicle for moving forward to mutual recognition. The topics mentioned in the recommendations hereunder could be addressed in such a Discussion Platform (see part A.5.).

6. Radiation Protection N° 135 "Effluent and dose control from European Union NORM industries: Assessment of current situation and proposal from a harmonised Community approach". This report identifies relevant NORM industries but from the point of view of discharges. Furthermore, it contains an overview of national regulations in 16 Member States' relevant to NORM and proposes a set of screening values based on certain dose criteria for NORM discharges above which a more detailed radiological assessment would be advised. The overview of the national regulations showed that at the time of the publication of the report (2003) most Member States had focused on identification of significant exposures to the workers but that identification of significant exposure to the public from NORM wastes and discharges was still in an early stage. Only nine of the countries had or planned to set up specific discharge controls or assessment procedures for NORM discharges.

7. Radiation Protection N° 154 "European Guidance on Estimating Population Doses from Medical X-Ray Procedures". DG TREN launched in 2004 a study, called **Dose DataMed**, to review the situation in the Member States regarding the doses to the population from medical exposure procedures. The results for 10 European countries participating in the study were published in 2008, demonstrating that there are considerable differences between, and even within, the countries. It was concluded that there is a need for harmonization of the dose data collection among the Member States.

8. Radiation Protection N° 156 "Evaluation of the Implementation of Radiation Protection Measures for Aircrew". The study concluded that current requirements in Directive 96/29/Euratom lead to a satisfactory protection of aircrew against the dangers arising from cosmic radiation and that there is no area where requirements would be incomplete or where regulations would clearly be missing. It is, however, recommended to incorporate the requirements on protection of aircrew coherently in the title on the protection of workers. These conclusions are made on the base of the collected data on the implementation of the requirements of the BSS Directive 96/29 in various EU Member States and other countries.

9. Radiation Protection Publication N° 157 "Comparative Study of EC and IAEA Guidance on Exemption and Clearance levels". The BSS Directive 96/29 contains general requirements on disposal, recycling and reuse of materials used in practices under regulatory control. According to these requirements material can be released from radiation protection control if they comply with

levels of radioactivity set by national competent authorities (clearance levels). The aim of the study is to compare the values in EU Radiation Protection N° 122 and the IAEA document RS-G-1.7 and to provide a basis for deciding whether the IAEA levels could also be used as clearance levels and as a substitution of the level, above which the practices should be notified (exemption levels). After a comprehensive review of the two documents, it is concluded in the report that the IAEA values can be used as general clearance levels, replacing the values recommended by the Commission. It is also justified that the IAEA values can replace the activity concentration values for the exemption of practices from notification and authorisation regime.

10. Radiation Protection Publication N° 166 "Implementation of the Council Directive 90/641/Euratom". According to the final report, the outside workers in European Countries can be estimated to at least 100 000, mainly working for the nuclear industry. Almost all the operators who use outside workers check the medical surveillance and fitness of the outside workers, provide them with specific training and protective equipment; 75% of the operators ensure that radiological data of each worker is recorded into a radiation passport or a network; additionally 50% of the operators set up dose constraints for outside workers. However, the answers provided by outside undertakings (the employers of the outside workers) clearly outline that there is a large variety of situations and there is a need for a harmonisation of both exposure assessment and medical surveillance. The need for a uniform European network or radiation passport is particularly highlighted in this survey.

(ANNEX III)

Article 31 Group of Experts – Statute and Opinion on the Revision of BSS

A. Statute and Work of the Group of Experts referred to in Article 31 of the Euratom Treaty (Article 31 Group of Experts)

Article 31 Group of Experts is established according to Article 31 from the Euratom Treaty with the task to advise on the elaboration of uniform basic safety standards as described in art.30 from the Treaty. The Group consists of scientific experts, in particular public health experts from Member States, appointed by the Scientific and Technical Committee, set up in compliance with Article 134 of the Treaty. The members of the Group are appointed on a personal basis for a term of five years, renewable. The members of the Group speak on their own behalf and act independently of all external influence. The Treaty requires the European Commission to consult this Group when preparing, revising and supplementing the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.

When in 2005 the European Commission undertook the revision of the Basic Safety Standards Directives, Art.31 Group of Experts was asked to investigate and deliver an opinion on this issue. This action was triggered by the fact that the International Commission for Radiological Protection (ICRP) has engaged in a process of revising and updating their Recommendations for a System of Radiological Protection which since decades represent the internationally accepted basis for radiological protection. In this context the revision of the BSS was considered as the most important activity of the Group of Experts to be completed before the end of its mandate in May 2010. Therefore, several working parties (WP) were established to identify the items in the BSS directives that may need revision and to look into the impact of the possible changes:

- WP Basic Safety Standards - established at the June 2005 meeting of the Article 31 Group of Experts to monitor the development of the ICRP recommendations, to oversee the work of the topical WPs and ensure that the developments in these WPs are coherent.
- WP Graded Approach to Regulatory Control – this WP was established with the main objective to discuss current concepts of regulatory control with a view to the introduction in BSS of a more elaborated graded approach to regulatory control.
- WP Natural Sources – established in November 2005 to address questions relating to natural radiation exposures. The WP Natural Sources' first priority was to examine how the requirements on natural radiation sources in Title VII of the present Directive could be strengthened and if it was feasible to integrate the regulatory control of so-called NORM industries into the framework of regulatory control for practices. The second task was to look into the possibility to establish in the BSS Directive requirements related to exposure to radon, taking into account the Commission Recommendation 90/143/Euratom on indoor exposure to radon. The third assignment was to propose a regulatory framework for building materials containing natural radiation sources. For each of these tasks the WP produced comprehensive reports, giving background data on international and Commission standards and guidance, indicating where further guidance and work is necessary and providing proposals for new or modified requirements. The reports have been presented to the Article 31 Group of Experts and agreed upon.

- WP Exemption and Clearance – established in November 2005 with the task to make a review of the existing sets of values for exemption and clearance in the directives, recommendations and international guides. On this basis the WP should advise on possible harmonisation of the values for clearance (choose one set of values) and on harmonisation of the values for exemption and clearance. The conclusions of the WP were expressed in a report submitted to the Article 31 Group of Experts.
- WP on the Recast of Basic Safety Standards – this WP was established in November 2007 to undertake a recast of the BSS directive and four other related directives. According to the mandate WP Recast should focus combining 5 directives into one piece of legislation - BSS Directive (recast). The WP should use the outcomes and the proposals of the other working parties and the results of studies, projects and consultations.

The existing working parties on "Medical exposures" and "Research and Implications on the Health and Safety Standards" (RIHSS) were also involved in the process. WP "Medical exposures" was asked by Article 31 Group of Experts to elaborate on the possible recast of Council Directive 97/43 and BSS Directive and to look into the latest developments in the medical exposures area. RIHSS looked into the scientific basis of the biological effects of radiation, as input both to ICRP and to the revision of the BSS.

After several years of discussions and preparation of the possible revision of BSS Directive and associated directives, Art.31 Group of Experts issued their [opinion](#) in February 2010.

B. Main Points from the Opinion of Article 31 Group of Experts on the Revised Basic Safety Standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation

- 1) A graded approach to the regulatory control of practices needs to be established. It is proposed that the regulatory regime is built on three steps – notification, registration, licensing instead the current 2 levels – notification and authorisation. The Working Party on Graded Approach proposed a list of practices which can be submitted to simple registration instead of licensing.
- 2) In order to ensure equal protection of the workers in different economic sectors it is proposed to submit the so-called NORM industries⁹ to the regulatory control established for the other practices involving radioactivity.
- 3) With regard to the Commission Recommendation 90/143/Euratom on indoor exposure to radon, which is largely introduced in the Member States, the Working Party on Natural Sources recommended to introduce requirements on the control of radon in workplaces, dwellings and public buildings into the revised BSS Directive.
- 4) A new regulatory framework should be established for building materials containing naturally occurring radionuclides present in the earth's crust. Member States shall be required to identify building materials of concern. The national authorities should set a reference level of 1 mSv per year for indoor external exposure from building materials. For the identified types of building materials which are liable to exceed the reference level the competent authority shall decide on appropriate

⁹ Industries involving NORM (Naturally Occurring Radioactive Materials)

measures ranging from registration and general application of relevant building codes, to specific restrictions on the envisaged use of such materials.

5) A revised BSS Directive should propose a set of default activity concentration levels for the clearance of materials from regulated practices involving radiation sources. The levels chosen should be harmonised with international guidance. Based on the findings of the "Comparative Study of EC and IAEA Guidance on Exemption and Clearance levels" (Radiation Protection Series 157) the Working Party on Exemption and Clearance proposed to establish the same set of activity concentration levels for the exemption of practices from regulatory control and for the clearance of materials from regulated practices. Although this will result in lower thresholds above which regulatory control would apply, the study concluded that in practical terms this will not impose additional burden since only a few, if any, practices will be affected.

6) The control of high activity sealed sources (HASS) and orphan sources, now regulated in Council Directive 2003/122/Euratom, is part of the regulatory control regime and covers issues regarding emergency preparedness and response. It is recommended to incorporate the text of Directive 2003/122 into the revised BSS Directive to achieve a more coherent and comprehensive regulation for the control of high activity sealed sources.

7) In view of the development of techniques involving deliberate exposure of individuals for security and other legal purposes like security screening, age determination etc. it is necessary to establish new requirements. The Working Party on Medical Exposures proposed the concept of a regulatory regime for these exposures.

8) In view of new scientific findings regarding enhanced incidence of radiation induced cataracts it is recommended to lower the current organ dose limits for the lens of the eye. This has been supported by reports given at the 2006 Scientific Seminar on New insights in radiation risk and basic safety standards. The proceedings of the 2006 Scientific Seminar are published in the Radiation Protection Publication N° 145 "New Insights in Radiation Risk and Basic Safety Standards".

(ANNEX IV)



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR ENERGY

DIRECTORATE D - Nuclear Energy
D.4 - Radiation Protection

Luxembourg, 9 April 2010

D4/ÅW D(2010)

Summary of the Commission Services' public consultation regarding natural radiation sources in new Euratom BSS

Note to EAN_{NORM}

Consultation and response

A consultation document with the Commission Services' considerations regarding natural radiation sources in the new Euratom Basic Safety Standards Directive (BSS)¹⁰ was launched on the European Commission's website in February 2009. The end date was set to 20 April 2009 although comments kept coming until the end of April. Those have been included as well.

In total forty-seven contributions were received, mostly from industry/industrial organisations or governmental organisations/authorities (around 15 each). A substantial amount of contributions came from individuals (10) and from radiation protection associations or group of experts (5). The contributions from industry were distributed over the following industrial sectors:

- Steel producers
- Zirconium chemicals producers
- Producers of abrasive products
- Building materials industry
- Tiles and bricks industry
- Radon measurement and remediation companies

With regard to the geographical distribution, comments were received from the following countries: Germany(13), UK(5), Spain(4), Italy(4), Belgium(3), Ireland(3), the Netherlands(2), Sweden(2) and Finland, Greece, Poland, Austria, Norway, Switzerland, Australia (one each)¹¹.

A compilation of the comments received was sent to the WP Recast and WP Natural Sources (sub-groups of the Article 31 Group of Experts) for further discussion. It should be noted that the text of the draft BSS has constantly evolved since the Article 31 Group of Experts meeting in November 2008 when the consultation document was approved. Some of the problems raised in the comments were already addressed and solved by the time of the consultation and several issues have been taken care of in the further drafting process during 2009. In February 2010 the Article 31 Group of Experts finalised the draft Euratom BSS and adopted an Opinion on the draft. The Opinion of the Article 31 Group of Experts reflects the broad range of views within the Group of Experts on some issues.

¹⁰ The present BSS is the Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of health of workers and the general public against dangers arising from ionizing radiation.

¹¹ The sum does not equal forty-seven since some contributions cannot be associated to a specific country.

Outcome: In general

The consultation was well received and a large part of the contributors express their appreciation for being invited to comment on ideas this early in the process of revising the Directive. In general the contributions endorsed the goal of the Commission to harmonise, clarify and strengthen the requirements related to natural sources.

The contributors believe the Commission has chosen the right approach when introducing the so-called graded approach to regulatory control but would like to have more information on the regime of notification, registration and licensing. There is also a high demand for guidance and clarification about the rationale for certain issues and about how to implement the requirements in practice. The Commission is planning to further elaborate on principal issues and their implementation in a guidance document which should be published in connection with the adoption of the new Directive. Furthermore there is a demand for clear definitions, e.g. on buildings, dwellings, reuse, recycling, disposal, waste, constructions, natural radiation source and inert material. This has been taken care of and the draft BSS now contain the relevant definitions.

Outcome: Specific topics

The forty-seven contributions contained a number of comments, some detailed, some addressing broader issues. The main concerns are listed below along with comments in italics about how these concerns have been or will be dealt with. Please note that the summary is very brief and does not contain the full reasoning behind neither the comments and concerns nor the outcome shown in italics.

NORM

Positive list

- Some additional industries are suggested.

Two of them have been added:

Geothermal energy production, since it has similar radiation protection issues as other types of fluid extraction, e.g. oil and gas extraction.

Mining of ores other than uranium ore. Although exposure to radon is normally the main pathway of exposure in underground workplaces, some mines have problems with high concentrations of Radon-226 in fissure water.

- The positive list is a good thing but after assessment Member States should have the possibility to remove certain industries

This is not explicitly mentioned in the draft BSS, instead it states that all industries on the list needs to be taken into account when Member States make the initial identification of industries which cannot be disregarded from a radiation protection point of view.

Materials of concern

- Need for clarification about pathways when assessing doses

This is an area where the Commission is considering issuing further guidance although earlier Commission guidance such as RP 122 part II is still relevant for identifying pathways.

Mandatory requirement for notification if the industry is recycling residues into building material

- Does not fit with graded approach
- Will be difficult to implement and to control
- Would it not be enough if the building material complies with what is required in the Directive for building materials (index, reference level, etc)?

The mandatory requirement is kept in the draft BSS since recycling of residues into building materials is one of the pathways that may lead to doses to the public exceeding 1 mSv/y and it is therefore necessary to have some form of regulatory control of the industries recycling residues into building materials. The draft BSS contain an annex with of building materials of concern, including a list of the types of residues. The annex indicates which industries would be affected by this requirement.

Exemption values

- Why not use RP 122, part II values (e.g. 0.5 kBq/kg instead of 1 kBq/kg)?
For the sake of harmonisation with international standards the values in the IAEA report RS-G-1.7 have been incorporated, in the same way as for artificial radionuclides. Some of the Article 31 Experts also prefer the RP 122 values and this is reflected in the Opinion.
- Some contributors mention the need for allowing lower values when drinking water may be affected.
This has been introduced in the draft BSS: without explicitly allowing lower levels, the competent authority may impose restrictions wherever drinking water or other pathways of exposure may be affected.

Graded approach

- How to assess doses to workers? Should conventional health and safety equipment be taken into account?
It has been taken care of by referring to "normal working conditions", which implies that compulsory health and safety requirements relevant to the workplace should be taken into account.
- Why notification already when doses to workers are likely to exceed 1 mSv/y? Some of the German contributors mention that they have good regulatory experience of setting the level for notification at 6 mSv/y.
Why ask for anything more than notification? Licensing or registration requirements would only lead to an unnecessary administrative burden.
The draft BSS now deal with NORM industries in the same regulatory framework as for other practices. The graded approach applies to all practices and the choice of registration or licensing is based on different criteria, e.g. dose assessment to workers and members of the public. However, for doses to workers in the range 1-6 mSv/y the requirements for occupational exposure to NORM are less demanding.

Mixing

- Mixing NORM with other material should be encouraged. Significant amounts of NORM are recycled and end up mixed with other materials, e.g. in cement and concrete. The term "inert" may also not be appropriate.
The term "inert material" is no longer used and the text is modified.

Radon

- There is a clear demand for technical guidance, especially with regard to measurement techniques, and for standards and harmonisation on a European level for this.
According to the website of the International Organization of Standardization (ISO), one of its subcommittees, TC85/SC2, is in the process of developing several ISO standards for Radon-222. With regard to building materials, CEN/TC 351 is presently investigating the possibility of setting a CEN standard for measuring radioactivity concentration (gamma radiation) in building materials.
- There are worries that the action plan will only address radon in dwellings and public buildings. Radon in workplaces needs equal attention.
The draft BSS are clear about the fact that the national action plan must also address radon in workplaces.
- Some contributors question a threshold for recording doses to workers in NORM industries and question the choice of the value of 400 Bq/m³.
This threshold has been removed.
- Modify so that within radon-prone areas all workplaces with a high occupancy are requested to be measured.
This is reflected in the requirements on the content of the national action plan.

- Modify so MS have the possibility to choose a higher reference level for workplaces with a very low occupancy.
It should be noted that a reference level is not a limit. For such workplaces, where radiation protection measures are optimised, the radon concentrations may very well exceed the reference level.
- Include criteria on level of rooms or workplaces in addition to requirements for measurements in radon-prone areas (upper floors excluded?)
The requirements for measurements at workplaces have been slightly modified. For buildings with public access or dwellings setting specific requirements on types of rooms or workplaces would require a high level of detail. It would be more suitable to discuss such a complex issue in a guidance report.

Building materials

- Clarification needed about whether materials used for infrastructure projects are considered building materials.
The draft BSS contain a definition of building materials.
- Some contributors worry about the proposed requirements causing stigmatization of certain groups of materials, whereas others are concerned that the flexibility, for instance when setting up the list of building materials which need to be considered, would lead to problems in shipping and trading products within EU.
These are valid concerns. However, in order to make informed decisions when constructing buildings, so as to not exceed the appropriate levels of exposure to workers or members of the public and to fulfil Annex 1 of the Council Directive related to construction products (89/106/EEC)¹², the building industry should be made aware of the radioactivity content of the materials a Member State has deemed to be of concern. The flexibility for Member States to establish a reference level for building materials has been removed.
- Some contributors question why the value for exemption proposed by RP 112 (0.3 mSv/y) is replaced by 1 mSv/y.
Based on the prevailing activity concentrations in building material produced in the European Union the Article 31 Group of Experts decided that a level of 1 mSv/y would be more appropriate in a Directive, also in order to avoid problems in trade within the EU.
- Harmonisation or guidance on how to measure radionuclide concentrations and calculate the index would be beneficial, as well as on the concept of "superficial material".
Some information can be found in earlier Commission guidance, such as RP 96 and RP 112, but this is an area where the Commission considers issuing further guidance.

¹² Council Directive 98/106/EEC, Annex 1, states that "...the construction work must be designed and built in such a way that it will not be a threat to the hygiene or health of the occupants or neighbours, in particular as a result of ... the presence of dangerous particles or gases in the air [or] the emission of dangerous radiation..."

(ANNEX V)

**Legislation
enacted under Articles 30 and 31 from Euratom Treaty**

Council Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (BSS Directive 96/29) is the main pillar of the body of secondary legislation on basic safety standards, adopted pursuant to Article 31 of the Euratom Treaty. The following acts are based on art.31 from Euratom Treaty:

1. **Council Directive 97/43/Euratom** of 30 June 1997 on health protection of the individuals against the dangers of ionising radiation in relation to medical exposure, repealing 84/466/Euratom of 3 September 1984 (Medical Directive);
2. **Council Directive 90/641/Euratom** of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas (Outside Workers Directive);
3. **Council Directive 2003/122/Euratom** of 22 December 2003 on the control of high-activity sources and orphan sources (HASS Directive);
4. **Council Directive 89/618/Euratom** of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency (Public Information Directive);
5. **Council Decision 87/600/Euratom** of 14 December 1987 on Community arrangements for early exchange of information in the event of a radiological emergency;
6. **Council Regulation 87/3954/Euratom** of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency and the related legislative acts - **Commission Regulation 944/89/Euratom** of 12 April 1989 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency, **Commission Regulation 770/90/Euratom** of 29 March 1990 laying down maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency¹³;
7. **Council Regulation 93/1493** of 8 June 1993 on shipments of radioactive substances between Member States;
8. **Commission Recommendation 2001/928/Euratom** of 20 December 2001 on the protection of the public against exposure to radon in drinking water supplies;
9. **Council Directive 2006/117** of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel;
10. **Commission Recommendation 90/143** of 21 February 1990 on the protection of the public against indoor exposure to radon;
11. **Council Directive 2009/71/Euratom** of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations.

¹³ These acts are subject to recast - Proposal for a Council Regulation (EURATOM) laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency (Recast) COM/2010/0184 final - CNS 2010/0098

(ANNEX VI)

**ESTIMATED CONTRIBUTIONS TO PUBLIC EXPOSURE FROM DIFFERENT SOURCES
(in mSv)
(data published in UNSCEAR Report 2008)**

Figure I

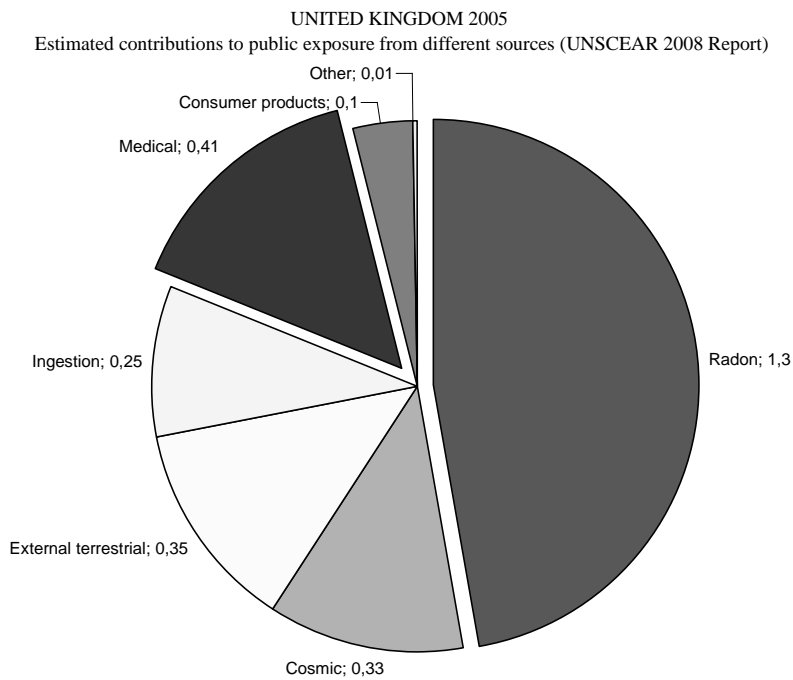


Figure II

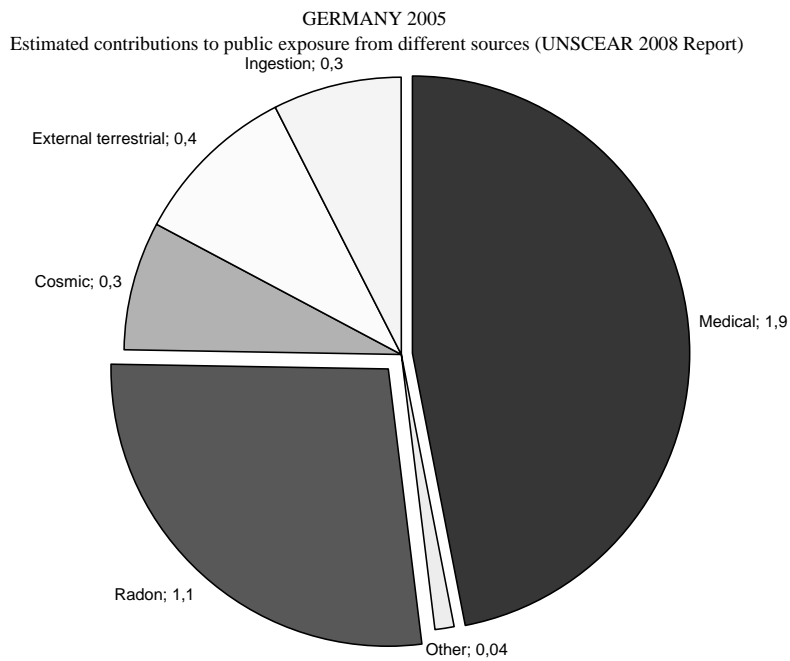


Figure III

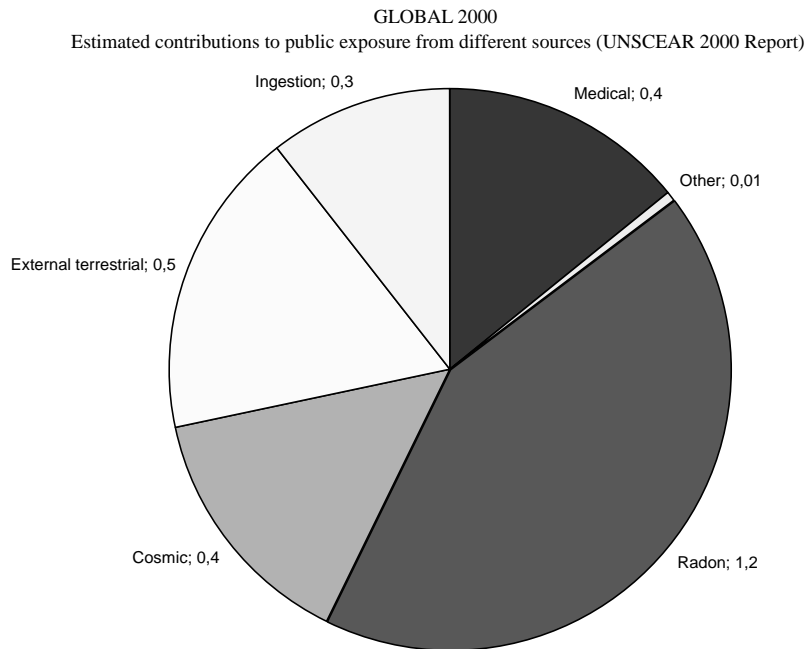
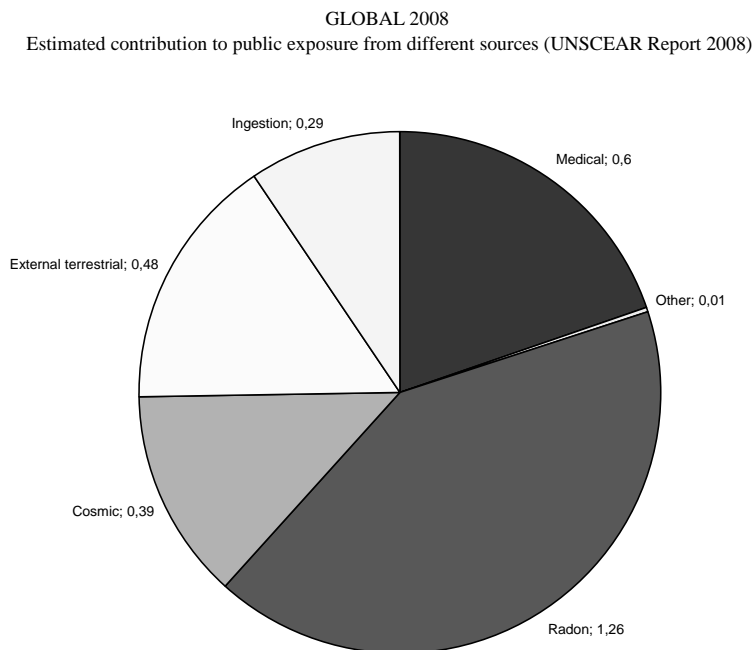


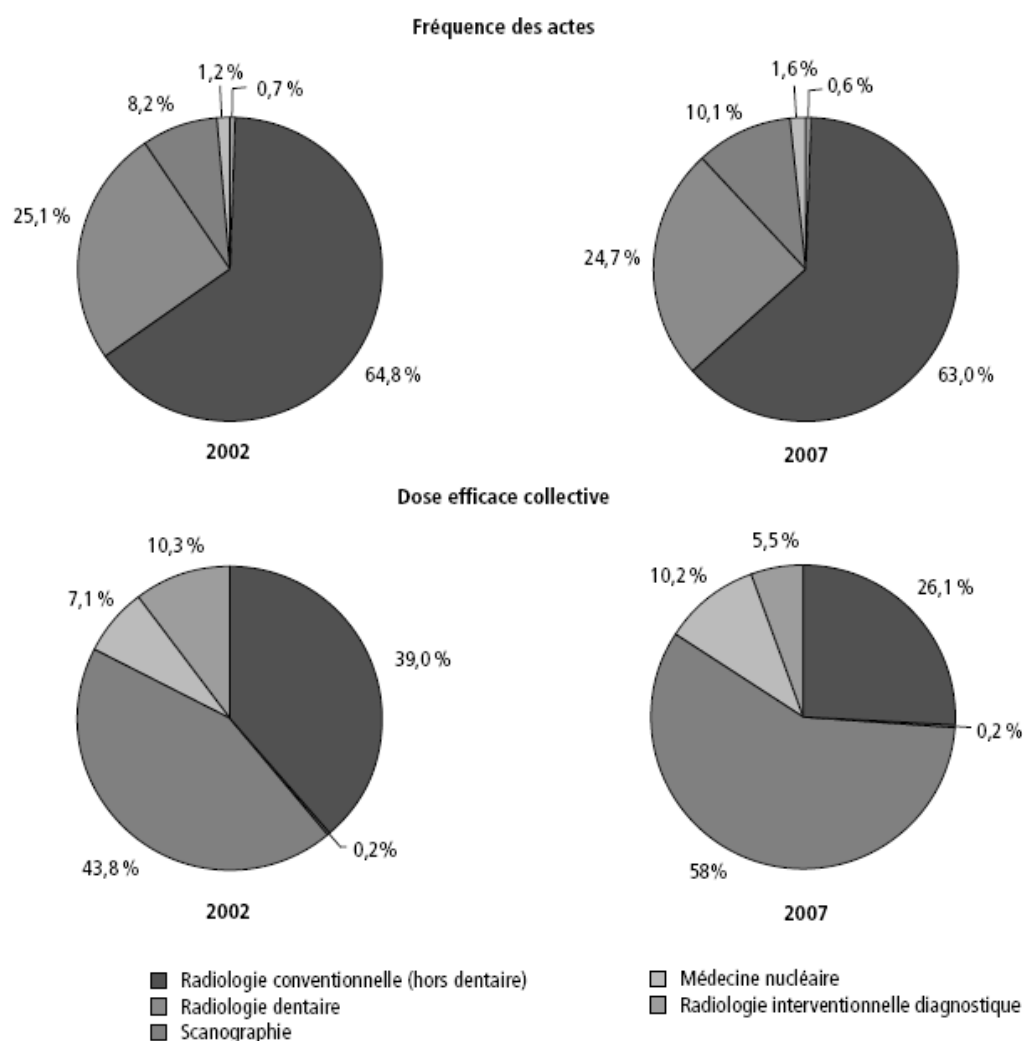
Figure IV



ANNEX VII

EVOLUTION OF THE MEDICAL DIAGNOSTIC EXPOSURE IN FRANCE between 2002 and 2007¹⁴

	Number of procedures	of	Number of procedures of per capita	Collective effective dose in mSv	Annual dose per capita in mSv
2002	73,6 millions		1,2	50 675 472	0,83
2007	74,6 millions		1,2	82 630 000	1,3



The number of performed medical procedures in the period 2002-2007 has increased by only 2%. However the annual dose per capita from these procedures increased by 57% for 5 years. This notable increase is due to the increase of number of procedures in computed tomography and nuclear medicine where the highest dose in diagnostic medicine is delivered. While for 5 years the number of

¹⁴ Etard C, Sinno-Tellier S, Aubert B. Exposition de la population française aux rayonnements ionisants liée aux actes de diagnostic médical en 2007. Saint-Maurice (Fra) : Institut de veille sanitaire, juin 2010, 104 p. Disponible sur : www.invs.sante.fr

procedures in the conventional radiology is stable, in computed tomography and nuclear medicine significant increase of accordingly 26% and 38% is observed. At the same time the collective effective dose from conventional radiology decreased, while the collective effective dose from computed tomography and nuclear medicine increased by 33 % and in 2007 is 68% from the dose delivered due to medical diagnostic exposure as a whole.

(ANNEX VIII [A])**NATURALLY OCCURRING RADIOACTIVE MATERIAL****A. Naturally occurring radioactive material and building material**

The industrial activities covered by the term "NORM industries" are all related to material extracted from the earth's crust. Either the industries use the material (e.g. production of thorium compounds) or they are involved in the extraction itself (e.g. mining of ores). Table 1 shortlists the types of operations that are likely to warrant regulatory control with the type of material involved and range of dose to workers. It is difficult to forecast the number of enterprises likely to be affected since it depends on the industrial process in each enterprise and on the content of radioactivity in the material being processed. As an example the number of enterprises extracting crude petroleum and natural gas in the EU is 381, the number of enterprises producing lead, zinc and tin is 293 and the number of enterprises mining iron ores is estimated to 40¹⁵.

While the protection of workers in the nuclear industry has been discussed since long, resulting in international consensus on monitoring and registering of doses to workers, this is not the case for exposure to workers in NORM industries. Although many reports were consulted, see Table 2, and the Article 31 Working Party Natural Radiation Sources experts shared their knowledge on approaches and situations in their countries, the collection of data for the impact assessment has been difficult and the data available is often based on estimations rather than actual monitored doses to workers. Furthermore, the NORM sector covers a wide range of industrial activities and there is very little compiled data for the whole sector. The proceedings of the NORM V conference did however provide a summary of the data presented on doses to workers and to members of the public. The results are in line with the doses indicated in Table 1. With regard to estimations of doses from NORM industries to members of the public, the proceedings conclude that members of the public in general receive far less than 0.3 mSv per year.

Data on the number of exposed workers are as previously mentioned scarce. The ESOREX database on occupational exposure does however provide certain information. In 2004 the number of exposed workers in the EU employed in workplaces with enhanced exposure to natural radionuclides was 27 000¹⁶. One of the objectives of the SMOPIE project (see Table 2) was to provide information on the number of industrial workers exposed to NORM. The project concludes that this information is very scarce but based on the information received and compiled they estimate the number of potentially exposed workers in EU NORM industries to be around 85 000 (2004). The project further concluded that exposure data based on actual workplace monitoring is very scarce. This lack of data reflects the lack of consistent and harmonised requirements on monitoring of workers and registration of doses in this industrial sector. Far more data should become available once the new Directive is implemented.

The issue of natural radionuclides in building materials was discussed by the Art.31 Working Party Natural Radiation Sources. Based mainly on two reports on activity concentrations in building materials¹⁷ and one study made on Italian building materials¹⁸, the group concluded on a list of

¹⁵ EUROSTAT Basic Statistic for 2007

¹⁶ ESOREX Database

¹⁷ UNSCEAR Report, 1993, and "Extent of Environmental Contamination by Naturally Occurring Radioactive Material (NORM) and Technical Options for Mitigation", Technical Reports Series No 419, IAEA, 2003

materials that Member States should take into account when setting up national lists of materials that would require regulatory control due to their content of radioactivity:

- Natural materials such as alum-shale and materials from natural igneous origin (e.g. granite, basalt and lava)
- Materials incorporating by-products or residues from NORM industries (e.g. fly ash, phosphogypsum and red mud – a residue from Aluminium production)

The Article 31 Group of Experts adopted the list with the some additions (e.g. porphyries and residues from steel production).

To give an indication of amounts, the production of granite (crude or roughly trimmed) in the EU in 2009 was around 4.5 billion kg. The production of porphyry, basalt, quartzite and other monumental or building stone (crude, roughly trimmed, cut) in the EU in 2009 was around 15 billion kg¹⁹.

¹⁸ Radioactivity in Building Materials: Experimental Methods, Calculations and an Overview of the Italian Situation, Proceedings "Radon in the Living Environment", Athens, 19-23 April 1999

¹⁹ EUROSTAT PRODCOM Database 2009

(ANNEX VIII [B]) Types of operation identified, on the basis of worker dose, as likely to require regulatory control^a

Type of operation	Description of material involved	Worker dose (mSv/a)
Rare earth extraction from monazite	Monazite, Thorium concentrate, Scale, Residue	Average 1 to 8, could approach or exceed dose limit
Production of thorium compounds	Thorium concentrate, Thorium compounds	Typically 6 to 15
Manufacture of thorium-containing products	Thorium compounds, Products	<1 to a significant fraction of dose limit
Processing of niobium/tantalum ore	Ore, Pyrochlore concentrate, Residue, Slag	Could reach a significant fraction of dose limit
Some underground mines and similar workplaces such as water treatment facilities	Ore, Scales from Radium-rich water, Air	<1 to a significant fraction of dose limit ^b
Oil and gas production	Scales during removal from pipes/vessels	<1 to a significant fraction of the dose limit
TiO ₂ pigment production	Scales during removal from pipes/vessels	<1 to 6
Thermal phosphorus production	Fume and precipitator dust	0.2 to 5 (average: ~1)
Fused zirconium production	Fume and precipitator dust	0.25 to 3
Production of phosphate fertilizers	Dust and scales	Possible to exceed 1
Metal production: smelters	Dust and dust scales	Possible to exceed 1

^a Information from IAEA Safety Reports Series No 49, *Assessing the Need for Radiation Protection Measures in Work Involving Minerals and Raw Materials* and European Commission Radiation Protection Series No 88.

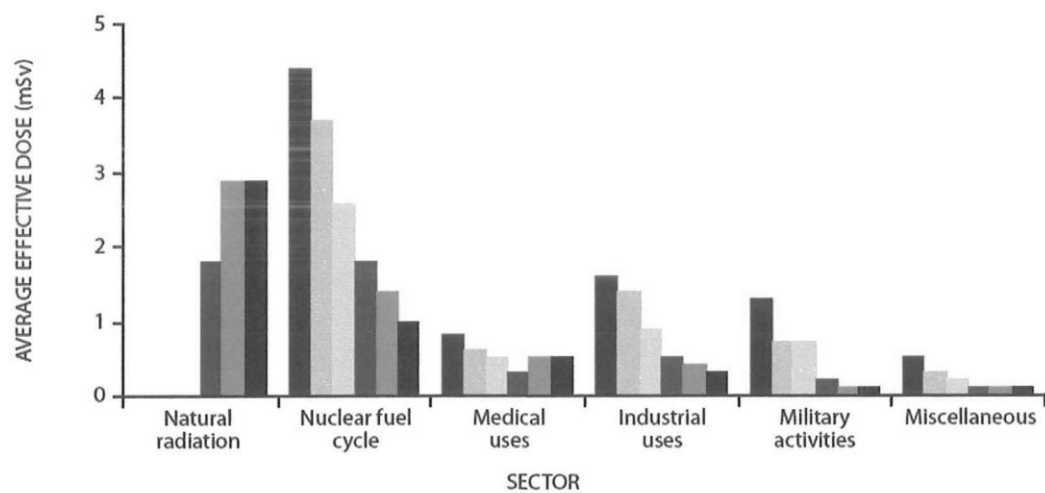
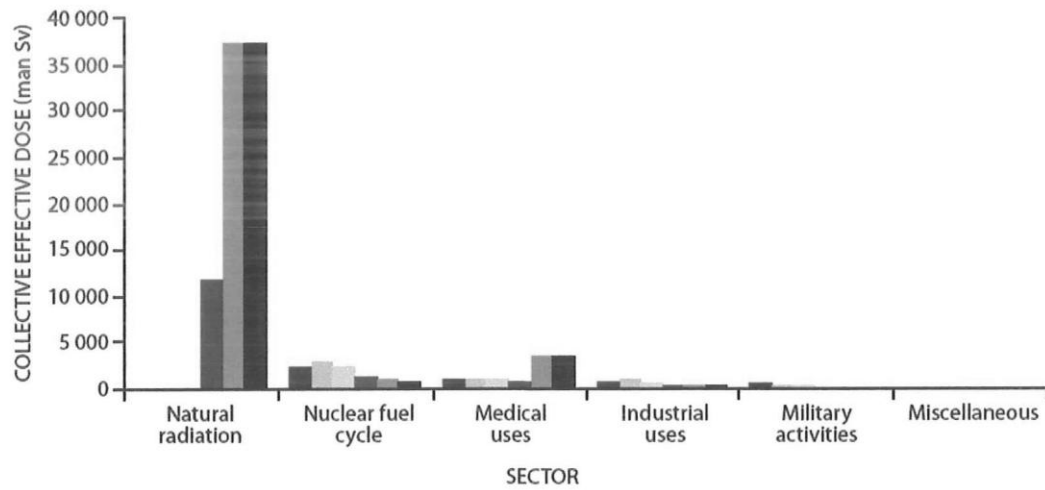
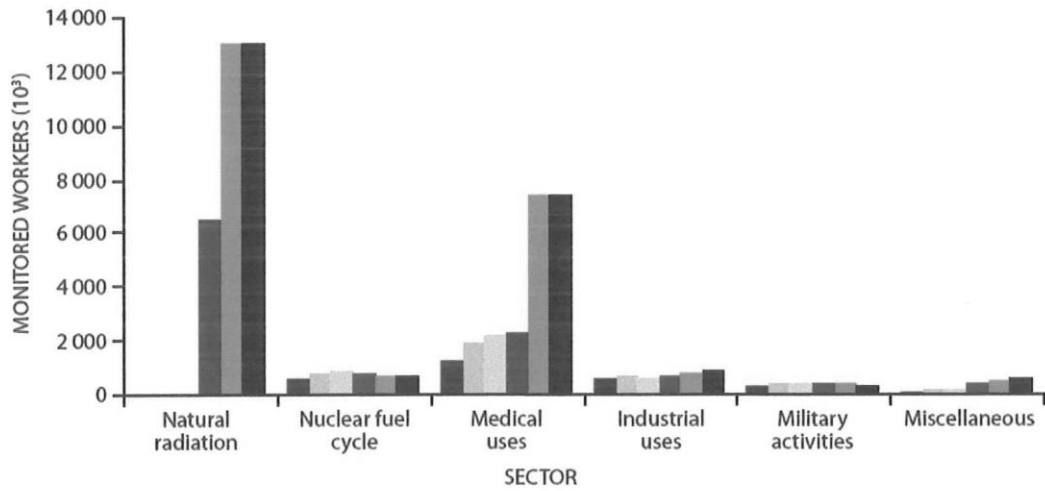
^b Measurements in some metal mines indicate an effective dose from gamma radiation and dust of about 0.5 mSv/a per unit U-238 activity concentration (in Bq/g) in the ore. The effective dose from radon is highly variable and difficult to predict, being strongly dependent on ventilation conditions and other factors.

(ANNEX VIII [C])

DOCUMENTS EXAMINED FOR THE IMPACT ASSESSMENT REGARDING NORM

Title	Published	Organisation
Approaches for regulating management of large volumes of waste containing natural radionuclides in enhanced concentrations, EUR 16956	1996	European Commission
Current practice of dealing with natural radioactivity from oil and gas production in EU Member States, EUR 17621	1997	European Commission
Recommendations for the implementation of Title VII of the European Basic Safety Standards Directive (BSS) concerning significant increase in exposure due to natural radiation sources, Radiation Protection Series N° 88	1997	European Commission
Establishment of reference levels for regulatory control of workplaces where materials are processed which contain enhanced levels of naturally occurring radionuclides, Radiation Protection Series N° 107	1999	European Commission
Radiological impact due to wastes containing radionuclides from use and treatment of water, EUR 19255	2000	European Commission
Monitoring and surveillance of residues from mining and milling of Uranium and Thorium, Safety Reports Series N°27	2002	IAEA
Radiation Protection and the Management of Radioactive Waste in the Oil and Gas Industry, Safety Reports Series N° 34	2003	IAEA
Occupational radiation protection in the mining and processing of raw material, RS-G-1.6	2004	IAEA
Strategies and Methods for Optimisation of Protection against Internal Exposure of Workers from Industrial Natural Sources, EC project N° FIGM-CT2001-00176 (SMOPIE-project)	2004	NRG, NRPB and CEPN
Summary and recommendations from EAN 9 th Workshop, "Occupational exposure to natural radiation"	2005	European Network ALARA
Assessing the need for radiation protection measures in work involving minerals and raw material, Safety Reports Series N° 49	2006	IAEA
Radiation protection and NORM residue management in the Zircon and Zirconium industries, Safety Reports Series N° 51	2007	IAEA
Naturally Occurring Radioactive Material (NORM V), Proceedings from international symposium in Seville, Spain, 19-22 March 2007	2008	IAEA
Sources and effects of ionising radiation, UNSCEAR 2008	2010	United Nations

ANNEX VIII (D) WORLDWIDE TRENDS IN NUMBER OF MONITORED WORKERS AND IN COLLECTIVE EFFECTIVE DOSES AND EFFECTIVE DOSES TO MONITORED WORKERS (UNSCEAR Report 2008)



1975-1979
 1980-1984
 1985-1989
 1990-1994
 1995-1999
 2000-2002

(ANNEX VIII [E])

**EXPOSURE TO IONISING RADIATION FOR WORKERS IN NORM INDUSTRIES
(case study)**

FRANCE, Bilan 2008 de la surveillance de travailleurs exposés aux rayonnements ionisants en France (Institute de Radioprotection et de Sûreté Nucléaire)

Certaines activités industrielles telles que la production de céramiques réfractaires, la combustion de charbon en centrales thermiques ou encore le traitement de minerais d'étain, d'aluminium, etc. mettent en œuvre des matières premières contenant naturellement des radionucléides (chaînes de l'uranium et du thorium). La manipulation et la transformation de ces matières qualifiées de « NORM²⁹ » ou « TENORM³⁰ » peuvent entraîner une augmentation notable de l'exposition des travailleurs.

Cette problématique dite des « expositions naturelles renforcées » a été prise en compte pour la première fois au plan réglementaire au travers de dispositions introduites dans le code du travail par le décret 2003-296 et définies plus précisément par l'arrêté du 25 mai 2005 relatif aux activités professionnelles mettant en œuvre des matières premières contenant naturellement des radionucléides non utilisés en raison de leurs propriétés radioactives. Cet arrêté précise la liste des activités ou des catégories d'activités professionnelles concernées et impose notamment aux chefs d'établissements concernés de réaliser une évaluation des doses reçues par les travailleurs.

4.1.1. BILANS DES ETUDES REÇUES

Fin 2008, le nombre de dossiers reçus dans le cadre de l'application de l'arrêté du 25 mai 2005 s'élevait à 79. La figure 28 en présente la répartition selon les catégories d'activités professionnelles visées par les dispositions de l'arrêté.

La figure 29 présente la distribution des doses efficaces individuelles rapportées dans ces dossiers³¹.

Environ 17 % des doses efficaces individuelles calculées pour les travailleurs sont supérieures à la limite de 1 mSv/an au-delà de laquelle les travailleurs doivent être considérés comme « professionnellement exposés » au sens du code du travail et faire l'objet d'une surveillance individuelle dosimétrique et médicale. Des postes de travail dans certaines catégories professionnelles visées par l'arrêté du 25 mai 2005 présentent des doses efficaces individuelles pouvant même être supérieures à 20 mSv/an. Ces postes de travail font actuellement l'objet d'une analyse plus approfondie de la part de l'IRSN.

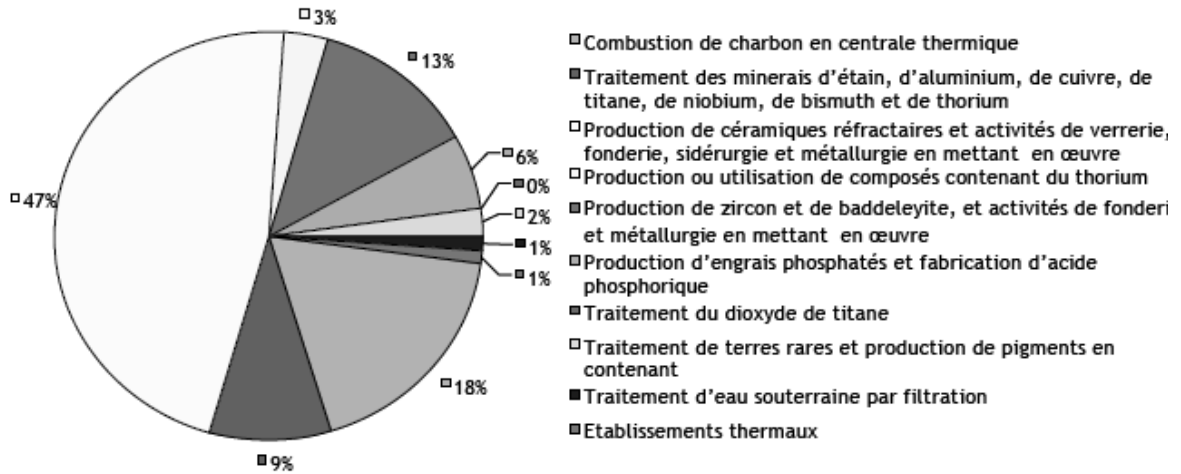


Figure 28 : Répartition des dossiers reçus selon les catégories d'activités professionnelles visées par les dispositions de l'arrêté du 25 mai 2005

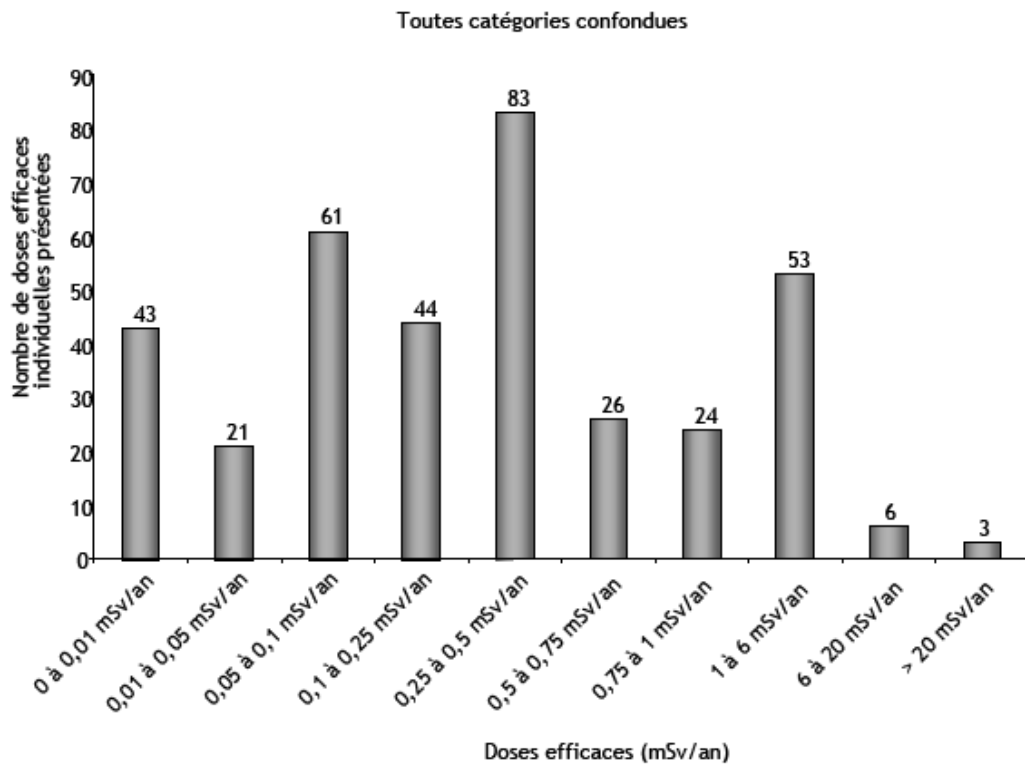
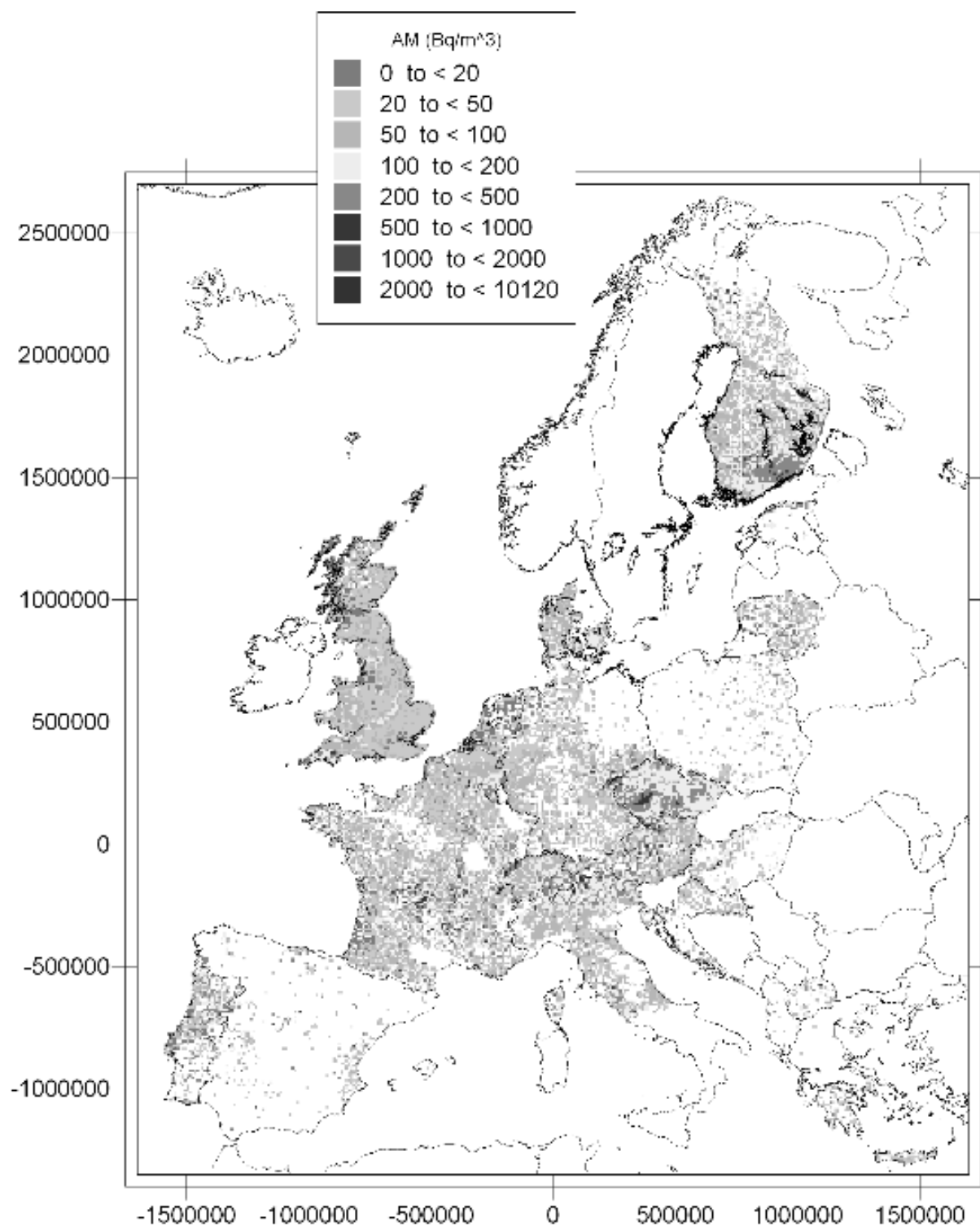


Figure 29 : Distribution des doses efficaces calculées pour les travailleurs

ANNEX IX RADON

(A) Annual Averaged Indoor Radon Concentration



ANNEX IX (B)

Radon in Dwellings

	Finland²⁰	Sweden²¹	United Kingdom²²
Housing stock	1 700 000	4 500 000	27 000 000
Average radon concentrations	96	108	20
Estimated number of dwellings at or above 200 Bq/m ³	200 000	450 000	100 000
Percentage of dwellings at or above 200 Bq/m ³	12	10	< 1

²⁰ Recommendations for radon in dwellings in the Nordic countries, 2009, see Nordic radiation protection authorities' websites, e.g. www.ssm.se

²¹ Recommendations for radon in dwellings in the Nordic countries, 2009

²² Radon and Public Health, Report prepared by the Subgroup on Radon Epidemiology of the independent Advisory Group on Ionising Radiation. Advisory Group to Health and Protection Agency, UK, 2009

(ANNEX X)

(A) Graded Approach to Regulatory Control

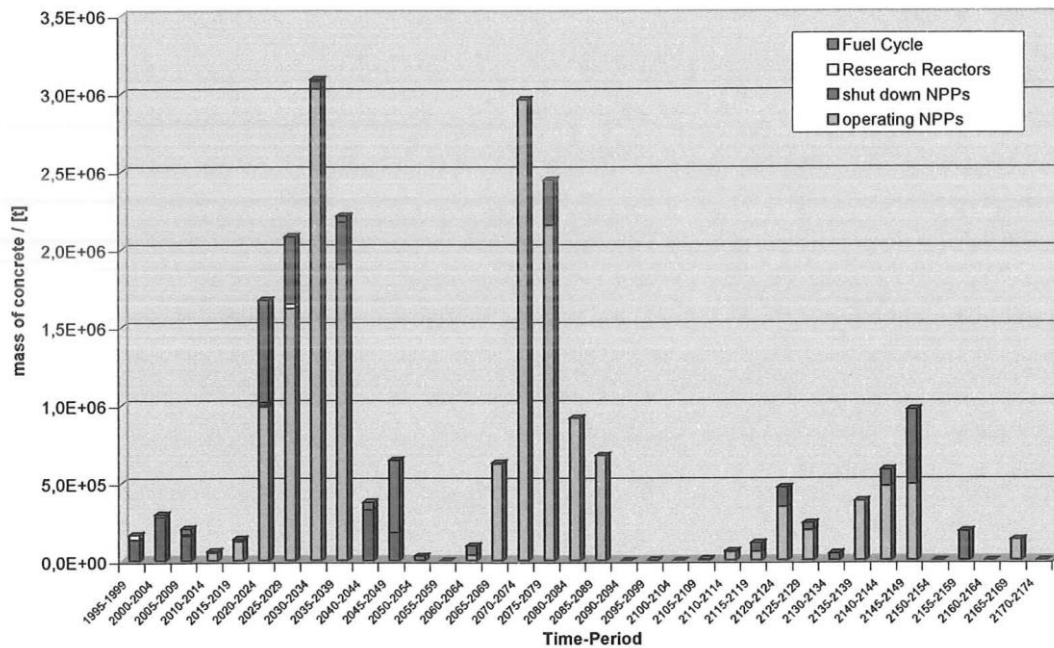
The concept of a graded approach to regulatory control was developed some ten years ago by NEA's Committee on Radiation Protection and Public Health (CRPPH). CRPPH advocated that, in addition to the concept of optimisation of radiation protection, the efficiency of regulatory control could benefit from a similar approach. Hence regulatory authorities would concentrate their supervision on those situations which represent a higher risk of exposure and on those where regulatory intervention is instrumental in reducing overall exposures. The BSS Directive from 1996 already gives indication that as an exception to the rule MS may specify that practices shall not require authorisation in cases where "a limited risk of exposure does not necessitate the examination of individual cases and the practice is undertaken in accordance with conditions laid down in national legislation". This opportunity given by the Directive has been used to little extend, because the requirement is very vague. Given that proper implementation of the graded approach would reduce the administrative burden to the businesses, it is important to clarify and enforce the use of this concept.

In this respect it is necessary to improve the requirements on regulatory control, on the one hand by making the list of practices submitted to authorisation more precise, and on the other hand introducing list of practices that can be submitted to lighter regimes like registration (a two-tier approach replacing the current concept of "prior authorisation" (Article 4 of the BSS). Article 3 of the BSS Directive 96/29 requires all practices to report the conduct of a practice involving ionising radiation or radioactive substances. Practices may be exempted from the requirement to report if certain values, called *exemption levels*, are not exceeded. There are exemption values for the total activity as well as for activity concentrations. These exemption values are laid down in the Directive (on the basis of a European study published in our radiation protection series: RP65) and uniformly transposed in national legislation. The Euratom values were also incorporated in the International Basic Safety Standards of 1996. Later, IAEA adopted a Safety Guide (RS-G-1.7) laying down a different set of radionuclide-specific values (in general lower than those in RP65). As part of the graded approach it is envisaged to make explicit provision for exemption of specific practices, for specific radionuclides, as long as the exemption criteria laid down in the Directive are complied with (essentially that doses should be lower than 1% of the dose limit). The current Directive, again, does not rule out this possibility but it is very vague ("MS's may exempt further practices ...").

A second important aspect of the "graded approach" relates to the release of materials arising from within a regulated practice. In the absence of any criteria all such materials should be regarded as radioactive waste. Taking into account the huge volume of materials arising from the dismantling of decommissioned nuclear power plants, this would be at a tremendous cost and there would be a shortage of disposal sites. Most of this material has in fact no or very little radioactivity, so it could be cleared from regulatory control. The concept of "clearance", for materials with no or very little contamination, for instance steel or building rubble, is very important in this context. In the current BSS Directive the application of the concept of clearance was left to national authorities, being merely required to take Community guidance into account (as was later published in the Radiation Protection Series). Harmonisation of *clearance levels* for materials resulting from dismantling has therefore become a crucial issue, both within the EU as internationally. In the international guidance (IAEA RS-G_1.7) and draft new standards it is envisaged to use the same set of values both for clearance and exemption (with the lower numbers taken from RS-G_1.7). This approach could be incorporated in the Euratom BSS as well.

(B) TOTAL EXPECTED MASS OF BUILDING RUBBLE AND STEEL SCRAP**Figure I TOTAL EXPECTED MASS OF BUILDING RUBBLE PER 5a PERIOD FROM ALL PRESENTLY EXISTING NUCLEAR FACILITIES IN EUROPE²³**

Figure I

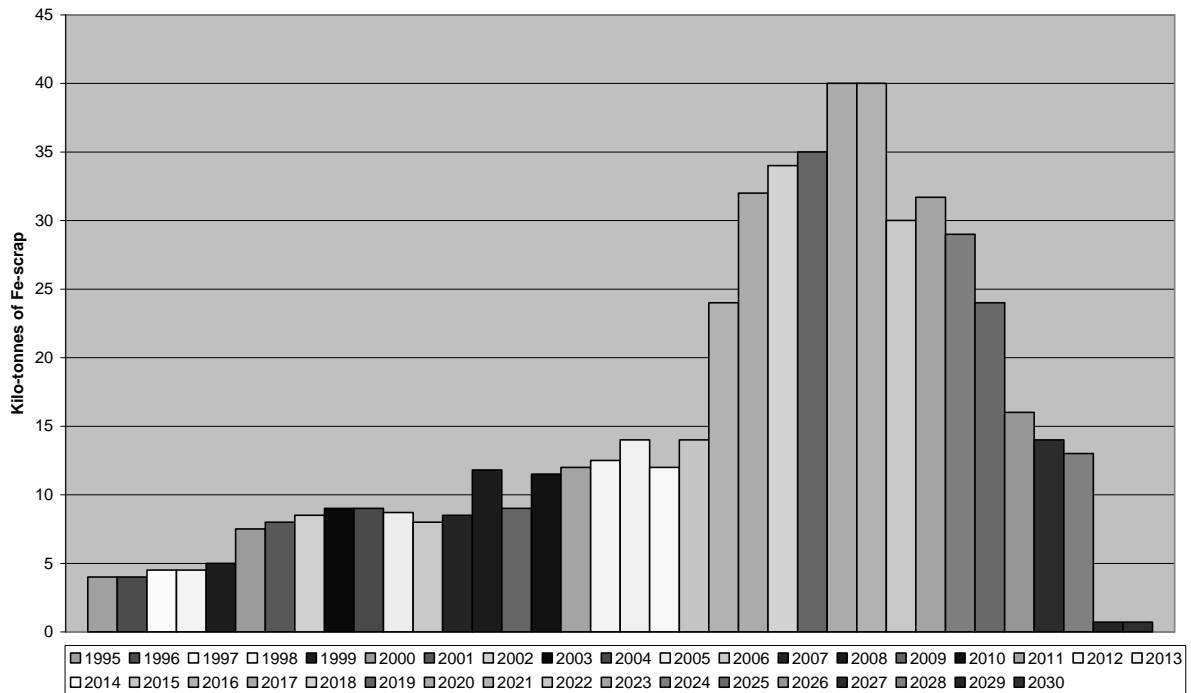


To estimate the total concrete masses arising in Europe and the time of their generation, it is necessary to make generic assumptions. Most of the rubble is produced from the dismantling of nuclear power plants to green field conditions. Because the available data about the concrete masses in power plants is limited, a linear extrapolation of the concrete masses in relation to the power output for smaller and larger units of each type of plant is assumed. The estimation of waste masses in Europe takes into account all types of facilities (nuclear power plants, research reactors and fuel cycle facilities), the number of plants in various countries, the planned operating time, the time for the post-operational period and eventually a safe enclosure and the assumption for the correlation between building masses and electric or thermal power or capacity, respectively. The results of these estimations are presented in figure I. The mass as a function of time shows two distinct peaks in the range between 2020 and 2040 as well as between 2070 and 2090. The first peak is caused by nuclear power plants that will be dismantled soon after their final shut-down, the second peak corresponds to those installations for which a safe enclosure of several decades is foreseen prior to final dismantling. It can be seen that building rubble will also arise in the time after 2100. This corresponds to installations mainly in the UK where a long term safe enclosure with an enclosure period of 130 years is envisaged.

It should be noted that this estimation does not include any new nuclear installations that might be built in the future, any nuclear installations in countries that might become member states of the European Union in the future, and any accelerators

²³ [Radiation Protection Publication 113 "Recommended radiological protection criteria for the clearance of buildings and building rubble from the dismantling of nuclear installations"](#)

Figure II PROJECTED AMOUNT OF CLEARABLE STEEL SCRAP FROM DECOMMISSIONING COMMERCIAL POWER REACTORS IN THE EU (under the assumption that no new reactors are built)²⁴



²⁴ Recommended radiological protection criteria for the recycling of metals from the dismantling of nuclear installations, Radiation Protection N° 89, 1998

(ANNEX XI)

Table 1: Possible solutions for each identified problem area (the numbers refer to the subsections in section 2 where the issues are explained)

Problem	Solution 1	Solution 2	Analysis
2.2.1 <i>Scientific progress (ICRP 103)</i>	Amend methodology for dose calculation in BSS and revise dose limits for the lens of the eye		As dose calculation methodology and dose limits are explicitly stipulated in the current BSS Directive, there is from a legal point of view only one solution possible.
2.2.2 <i>Insufficient protection of workers</i>			
- <i>Outside workers</i>	Revise the BSS, impose an annual occupational dose limit and incorporate Outside Workers requirements	Revise BSS and impose an annual occupational dose limit	Both solutions provide uniform level of protection for these workers. Solution 1 would facilitate the clarification of the responsibilities of undertakings and employers.
- <i>Workers in NORM industries</i>	Strengthen the requirements on NORM industries in BSS	Establish guidance on NORM industries	Uniform protection of workers can only be achieved with Solution 1.
2.2.3 <i>Health protection of patients and the public due to technical progress</i>			
- <i>patients</i>	Strengthen requirements on justification and optimisation in MED Directive	Strengthen implementation of current requirements through guidance	Solution 1 and solution 2 should both enhance patient protection, but in certain areas it is expected that only binding legislation is effective.
- <i>non-medical imaging exposures</i>	Include specific requirements in the BSS and amend MED correspondingly	Amend MED Directive and issue guidance on non-medical imaging exposures	Solution 1 allows best protection of the public from these exposures.

<p>2.2.4 <i>Public exposure to natural radiation sources –radon and building materials</i></p>	<p>Legislative measures: 1. Extension of the scope of BSS Directive 2. new Directive(s) on radon and on building materials</p>	<p>Non-legislative measures such as guidance on national action plans for radon, recommendation on building materials</p>	<p>Solution 1.1 provides for best protection from natural radiation and is in line with the simplification objective.</p>
<p>2.2.5 <i>Protection of the environment (non-human species)</i></p>	<p>Legislative measures: 1. Extension of the scope of BSS Directive 2. new Directive on protection of the environment</p>	<p>Non-legislative measures such as guidance on the protection of the environment</p>	<p>Solution 1.1 offers the best coherence with the protection of human health from environmental radioactivity.</p>

ANNEX XII

Working document: Comparison International and Euratom Basic Safety Standards

This document was drafted to give a comprehensive though not exhaustive overview of the differences in approaches and specific requirements in the international standards (draft 3.0) and the revised and recast Euratom Basic Safety Standards (version 24.02.2010, on which the Group of Experts had given an Opinion).

By and large this document is meant to be descriptive, and does not give views on the need for changes in the international standards, except with regard to the overall approach to natural radiation sources.

The Experts have been invited to discuss this document at their meeting on 3 – 4 June 2010 and where appropriate make recommendations either to IAEA or to the Commission. The Commission will forward the recommendations to IAEA and discuss these at the meeting of the BSS-Secretariat (with IAEA and other co-sponsors) Vienna on 25 June 2010.

The Comparison of the draft Standards has been completed to the extent possible with further relevant issues, brought forward by the Experts. This update will continue in order to provide eventually a comprehensive comparison of the different sets of requirements.

1. INTRODUCTION

Throughout the development of the revised international Basic Safety Standards (BSS) and the revised and recast Euratom Basic Safety Standards there has been good cooperation in order to ensure their consistency to the largest possible extent. The Commission has played an active role in the Secretariat of sponsoring organisations of the international standards. Representatives of EU Member States have provided comments to the different Committees of IAEA, especially RASSC. Reports on progress with the international standards have been presented at each meeting of the Group of Experts by IAEA representatives. The Group of Experts has so far never formally given its own views on the international standards. In view of the eventual co-sponsorship of the standards by the Atomic Energy Community it is now the right time to do so, since draft 3.0 has been sent to IAEA Member States for comment and it is envisaged that the final draft will be approved by the Committees by the end of this year. The Experts invite IAEA to consider these comments together with the comments and corrections that have been proposed by the Commission before the deadline for consultation (31.05.2010).

2. GENERAL COMMENTS

To a very large extent the Euratom and international standards are consistent. There are no essential points that are in contradiction. Numerical values are all the same, with the provisional exception of the definition of High Activity Sealed Sources, pending further consideration of the rationale of the two sets of values.

Nevertheless, there are notable differences. These results on the one hand from the constraint to make as little and few changes to the current standards as necessary. This justification of any changes was an essential component of the DPP for the revision of Safety Series 115, and in the spirit of the "recast" of Euratom Directives this applied to the revision of Council Directive 96/29/Euratom as well. Hence many differences which had appeared already in 1996 continue to exist. In addition, while both organisations started from ICRP Publication 103, they have given a slightly different interpretation to

the introduction of planned, existing and emergency exposure situations in structuring the requirements. This does not matter too much since the main message of ICRP was that throughout the exposure situations the principles of radiation protection apply very much in the same way. Nevertheless, the allocation of responsibilities and the extent of regulatory control have been addressed in different ways for some situations, especially for exposure to natural radiation sources.

This has also led the Euratom Basic Safety Standards to choose a different structure. While initially both standards were developed along a structure reflecting the three exposure situations, Euratom Standards are now structured along the categories of exposure, occupational, medical and public, within which the differences in management along the exposure situations are reflected. This inversion of the matrix has no implications on content, but makes the comparison of the two standards more difficult.

In order to preserve consistency with the current standards, and for IAEA also with the Safety Fundamentals, the requirements use a different set of definitions. The concept of "facilities and activities" in IAEA is reflected in the definition of "Undertaking" in Euratom BSS. The latter definition incorporates better the concept of legal responsibility for the conduct of activities or the introduction of a radiation source. The term "radiation source" has a very general meaning in the Euratom Standards (including "facilities") and is further differentiated between radiation generators, radioactive sources, natural radiation sources etc.). This allows a more precise formulation of the requirements where the term "source" may be cause of confusion. **IAEA is invited to consider introduction of these definitions and explore whether their use would improve clarity of the text.**

The terminology of the Euratom Standards has been adjusted to the international standards on one important point. The requirements for regulatory control are now structured along the concepts of notification, registration and licensing (as opposed to reporting and prior authorisation in Directive 96/29). The graded approach to regulatory control has been worked out in more detail in the Euratom Standards however, and the differentiation between registration and licensing is more explicit. It should be noted that in principle all requirements in the Euratom BSS apply to Member States or to their competent authorities. It is for national law to transpose the requirements and for the authorities to impose them and ensure their enforcement. The international standards differentiate much more between requirements applying to different responsible parties, e. g. designers, employers, registrants and licensees, often with much more detail than in the Euratom Standards.

These different contexts and approaches have led to many small differences in formulation. The most notable differences with regard to requirements for occupational, public and medical exposure as well as on the protection of the environment are listed in a comprehensive albeit not exhaustive way in the next chapter. The more fundamental differences with regard to the approaches to natural radiation sources are discussed separately. Finally, there are important differences in the application of the concepts of exemption and clearance, especially for naturally occurring radionuclides. With regard to artificial radionuclides, while both standards have now introduced the values in IAEA RS-G-1.7, the Euratom Standards give less prominence to the continued use of the old exemption values for "moderate amounts of material", and address more explicitly the role of specific clearance levels for specific materials and pathways of disposal. The Euratom approach allows a better optimisation of the management of materials arising e.g. from dismantling of nuclear facilities. **The Group of Experts hopes that these differences will be resolved through a careful redrafting of the international standards.** The Group of Experts also endorses the comments repeatedly made by the Commission, and now re-introduced with regard to draft 3.0, along the lines of this document.

The System of Protection as laid down respectively in Requirement 1 and Schedule III of the international BSS and Title III of the Euratom BSS are broadly the same, with some differences as a result of the different consideration given to planned and existing exposure situations. It should be noted however that in the Euratom BSS it is in general no longer foreseen that doses be integrated over periods longer than 1 year. The dose limits for the lens-of-the-eye are left open, pending ICRP advice, and dose constraints may apply also to organ doses, as a matter of precaution.

3. COMPARISON OF THE DRAFT STANDARDS

3.1. GENERAL

This chapter compares specific requirements in the international standards (Draft 3.0) with those in the Euratom Basic Safety Standards (draft 24.02.2010) with regard to occupational, public and medical exposures as well as with regard to the protection of the environment.

Draft 3.0, in contrast to the Euratom BSS, contains more detailed requirements, which are often addressed directly to the "responsible parties" (government, regulatory body, licensees and registrants, etc. – defined in Para. 2.40 and 2.41). This approach risks unnecessarily restricting implementation of radiation protection to what is "prescribed" while:

- the level of detail does not seem to correspond to the importance of the issue,
- the requirements and described responsibilities, however detailed, are not exhaustive, and
- the proposed rigid distribution of responsibilities does not allow for national differences and sometimes restricts too much the responsibility of a given party.

3.2. OCCUPATIONAL EXPOSURE

3.2.1. DIFFERENCES

IAEA PARAGRAPHS

3.77: workers exposed to radiation from sources not required by or directly related to their work shall receive "the same level of protection" as if they were members of the public.

Euratom: no such requirements, but for the operational protection of workers specific requirements only apply to those who are "exposed workers": ... who are liable to receive doses exceeding one or other of the dose levels equal to the dose limits for members of the public.

There was a similar requirement in Directive 96/29; the new Directive has been drafted so as to ensure the same level of protection without re-introducing it; the term "the same level of protection" is indeed ambiguous in legal terms, in particular for existing and emergency exposure situations where in some situations (e.g. radon in workplace) it may be understood to mean that the dose limit for public exposure would apply. **IAEA is invited to consider whether paragraph 3.77 offers any additional protection and otherwise delete it.**

3.115: no person under the age of 18 years is allowed to work in a controlled area unless under supervision and then only for the purpose of training for employment involving exposure to radiation or for students required to use sources in the course of their studies.

Euratom: In the Euratom BSS this is covered by Article 9: persons under 18 years may not be assigned to any work which would result in their being exposed workers, and Article 12.2: the limit for effective dose for apprentices (and students) aged between 16 and 18 years ... shall be 6 mSv per year (as for category B workers).

In both cases the exposure of apprentices and students is restricted, either by their access to controlled areas or by the dose.

Schedule III: An effective dose of 20 mSv per year, averaged over five consecutive years.

Euratom: The dose limit for occupational exposure is now simply 20 mSv per year, without averaging. However, a higher effective dose may be authorised in a single year, subject to a maximum effective dose of 50 mSv, ...

EURATOM ARTICLES:

Art. 6.2: categorisation of exposed workers (A or B) with an impact on individual monitoring (Art. 64) and medical surveillance (Art. 69 – 72)

IAEA: the international standards do not introduce different categories of workers but in 3.99 individual monitoring shall be undertaken, where appropriate, adequate and feasible, for any worker who is normally employed in a controlled area or who ... may receive significant occupational exposure. No distinction is made between the health surveillance of different categories of workers or different conditions of work.

Title II: Definitions of Radiation Protection Expert and Radiation Protection Officer

These definitions distinguish between the responsibilities of *experts* (give radiation protection advice) and of *officers* (designated by the undertaking to oversee the implementation of the radiation protection arrangements). The capacity to act as an RPE is recognized by the competent authorities. The RPO shall simply be "technically competent". The arrangements for the recognition of the experts (as well as for the medical physics expert) are laid down in Article 16. The responsibilities of the RPE are spelled out in detail in Article 19.

IAEA: Qualified expert. In the international standards this definition relates to the professional qualifications of an individual. In 2.21 (b) there is formal recognition of these experts by the relevant authority for taking up certain responsibilities (footnote 7)

The involvement of qualified experts is mentioned in several paragraphs throughout the text of the international standards.

3.2.2. IAEA REQUIREMENTS WITH NO CORRESPONDING EURATOM TEXT

WORKERS

3.79: recording of any report received from a worker (see 3.82)

Req. 22: Compliance by workers (3.81, 3.82)

3.86 (a): involve workers in optimization of protection and safety

Euratom: it is not appropriate for a Directive to put requirements on workers.

OPERATIONAL GUIDANCE

- 3.89: delineation of controlled areas
- 3.91: delineation of supervised areas
- 3.92 – 3.94: local rules and personal protective equipment

Euratom: it is not appropriate for a Directive to go into so much practical detail.

CONDITIONS OF SERVICE

- Req. 27: no substitute for protection and safety
- 3.113: conditions of service for pregnant or breastfeeding workers

Euratom: these are basic principles of overall occupational health policy which do not need to be recalled specifically for work with ionizing radiation.

3.2.3. EURATOM REQUIREMENTS WITHOUT CORRESPONDENCE IN THE INTERNATIONAL STANDARDS

NATIONAL DOSE REGISTER

Article 67.1 (d) requires the results of individual monitoring to be submitted to a centralised network. In 67.2 provisions are made for a future European Radiation Passport for outside workers.

In the international standards there are requirements for the establishment of exposure records and for their transmission to workers and other employers registry (Para. 3.102 – 105), but no central. There is no reference to a radiation passport.

NATURAL RADIATION SOURCES

The approach to natural radiation sources in the Euratom standards is quite different from the international standards (see chapter 4 in this document). With regard to occupational exposure the most striking features of the Euratom standards are the following:

Article 59.2 (second sentence): Where the effective dose to workers is less than or equal to 6 mSv per year the competent authorities shall at least require undertakings to keep exposures under review, taking into account the potential for protection to be improved or the potential for doses to increase over time or as a result of changes in the process on work instructions.

This requirement is an important element of a graded approach to regulatory control, which is missing in the international standards. **IAEA is invited to consider a similar graded approach for the Regulatory Control of occupational exposure, especially for workers in NORM industries.**

Article 59.3 specifies the assessment and management of the exposure of aircrew to cosmic radiation. In addition, since in the Euratom standards the exposure to aircrew

occurs within a planned exposure situation, the requirements for the protection of pregnant aircrew and the child to be born (Article 11.1) are fully applicable.

In the international standards exposure of aircrew is regarded as an existing exposure situation, and the detail of its management is left for Member States to consider. **IAEA is invited to apply similar binding requirements for the protection of aircrew and for the registration of their exposure as in the Euratom Directive; indeed, the operation of airlines calls for international harmonisation.**

3.3. PUBLIC EXPOSURE

3.3.1. DIFFERENCES

IAEA addresses public exposure to consumer products more prominently than in the Euratom standards. See:

- 3.117: suppliers of consumer products
- 3.124: responsibilities of suppliers of consumer products
- Req. 33: consumer products
- 3.137: consumer products shall not be made available to members of the public unless exempted or authorised for use by members of the public
- 3.138: responsibility of the regulatory body
- 3.139: compliance with the conditions of authorisation (including optimisation of design)
- 3.140 - 142: labelling and information

Euratom: 1) does not require labelling and information (but this could be part of conditions of use);
2) does not put requirements on the suppliers and designers of the products.

On the other hand the Euratom BSS (Art. 53.2 (b)) require licensing of the deliberate addition of radioactive substances in the production and manufacture of consumer goods and the import or export of such goods. The design features and conditions of use will be specified as part of the licence. The introduction of new types of apparatus or products is subject to justification, their use as a consumer product shall explicitly be permitted and a type-approval granted.

Hence the Euratom Standards achieve the same objective but put all responsibility on the licensing authority: the designer or supplier is not responsible for further uses. There is neither an explicit requirement for information of the user or distributor, nor for labelling: it is generally understood that such labelling is contrary to the concept of exempted consumer good, but it can nevertheless be requested by the licensing authority at the time of manufacture or import. Once the consumer good is placed on the market in the EU, no further trade restrictions should apply. However, since national authorities may conclude differently on the justification or type approval, the use of a consumer good may be prohibited or subject to notification; in order to avoid inconsistencies, competent authorities are required to allow for the information provided by other national authorities.

Schedule III (3b): averaging over five years (maximum 5 mSv) has been deleted in the Euratom Directive.

3.3.2. IAEA REQUIREMENTS WITH NO CORRESPONDING EURATOM TEXT

3.123: Impact outside the country

Euratom Treaty provisions under Article 37 allow the Commission to assess such impact; however, in the Joint Convention there is a similar requirement which may be taken up in legislation on waste management.

3.127: Visitors

A Euratom Directive does not require such detail; in addition the phrase "in cooperation with employers" makes this difficult to understand.

3.128: External exposure (details)

3.129: Avoid spread of contamination (implicit in Euratom)

3.130: Details of radioactive waste management (might appear in a specific legislation)

3.135: Access to monitoring data is foreseen in Articles 35 – 36 of the Euratom Treaty.

3.4. MEDICAL EXPOSURE

3.4.1. DIFFERENCES

Roles and responsibilities are distributed differently in the IAEA and the Euratom drafts:

- In draft 3.0 the *government* (Req. 34, Para.3.145-3.147) and the *regulatory body* (Req. 35, Para.3.148, 3.154, 3.163, 3.166, 3.167, etc.) have specific but quite limited responsibilities with respect to medical exposure while in the Euratom BSS the majority of the requirements are addressed to Member States (i.e. government).
- In draft 3.0 a great deal of responsibility is placed on "*registrants and licensees*" (Req. 36, Para.3.149-3.152, 3.160, 3.164, etc.), who shall ensure that "no person receives medical exposure" unless a series of conditions are fulfilled. In the Euratom BSS the requirements directly addressed to "*undertakings*" are limited to issues like QA and provision of information to patients and there are almost no prohibitive requirements (with the exception of examinations which "can not be justified").

Definitions:

medical exposure: Draft 3.0 mentions asymptomatic individuals in paragraph 3.149: ("whether asymptomatic or not ..."). In the Euratom BSS these are grouped with, but are different from, patients. Draft 3.0 also does not refer to the intended benefit to the health or the wellbeing of the exposed person, as in the Euratom BSS. **IAEA is invited to give explicit consideration to asymptomatic individuals and to exposures benefiting to the well-being of the exposed person, in particular to sharpen the definition of non-medical imaging exposures.**

In the Euratom Directive (Article 5 (b)) medical exposures shall be "as low as reasonably achievable, commensurate with the medical purpose". "ALARA" is here to be distinguished from other contexts where economic and social considerations need to be taken into account. **The Experts believe that the mere reference to "commensurate with ..." is not sufficient.**

optimization of protection and safety for medical exposure: Draft 3.0 states that it is "management of the radiation dose to the patient commensurate with the medical purpose" without any reference to ALARA as is the case in the Euratom BSS.

radiological medical practitioner: Draft 3.0 defines the responsibilities of the *radiological medical practitioner* more rigidly, especially for justification of medical exposure for individual patients (Para. 3.155). This is done in a more indirect and flexible way in the Euratom BSS by Art. 82.2 requiring that the exposure is undertaken under the clinical responsibility (including justification) of a radiological practitioner but allowing Member States to define the level of involvement of the practitioner and the referrer in justification process (Art. 82.1).

medical physicist: The role of the *medical physicist* is more specifically and with more detail defined in Draft 3.0 (Para. 3.152, 3.165, 3.166, 3.168, 3.169, etc.). The IAEA definition of medical physicist (MP) differs from the Euratom definition of medical physics expert (MPE) mainly in that the MP is defined by IAEA as "health professional" (i.e. recognized to practice a profession related to health).

medical radiation technologist: Draft 3.0 defines "*medical radiation technologist*", who is included in the list of "other parties who have responsibilities for protection and safety" (Para. 2.41) and is assigned to a number of tasks and responsibilities – Para. 3.161-3.163, 3.168, 3.173, etc. The Euratom BSS have no such definition.

There are the following differences with regard to **justification**:

- Para. 3.149 (a) effectively prohibits *self-presentation*, which is not explicitly done in Euratom BSS. The same article requires information on the clinical context to be provided.
- Para. 3.149 (b) puts responsibility for justification on the radiological practitioner, in consultation with the referring medical practitioner. The Euratom BSS do not put so much emphasis on the role of the radiological practitioner.
- Para. 3.153 – only *alternative techniques* that do not involve medical exposure shall be taken into account, against the Euratom BSS requirement of taking into account also techniques involving less exposure (Art. 80.1).
- Para. 3.154 – *generic justification* shall be carried out by the health authority in conjunction with the appropriate professional bodies – missing in Euratom BSS.
- Para. 3.155 – there is a requirement that the practitioner shall take into account the *appropriateness* (missing in Euratom BSS) and the *urgency* of the request (required only for pregnant and breastfeeding women in the Euratom BSS – Art. 87.1).
- Para. 3.159 – exposure of *volunteers for biomedical* research is not justified if it doesn't comply with the Helsinki Declaration and the respective guidelines by the CIOMS and the recommendations of ICRP. No such references in Euratom BSS.

In Article 81 on Justification in the Euratom Directive, the requirements are to a large extent written in the passive "shall" style.

Para. 3.146 of draft 3.0 stipulates the government shall ensure that **diagnostic reference levels (DRLs)** are established against the weaker Euratom BSS requirements that Member States "promote the establishment" of DRLs.

3.4.2. IAEA REQUIREMENTS WITH NO CORRESPONDING EURATOM TEXT

Para. 3.152 (c) requiring that registrants and licensees shall ensure that *sufficient medical and paramedical personnel* are available as specified by the health authority does not have correspondence in Euratom BSS.

Para. 3.147 specifies that *dose constraints* are established as a result of consultation between the health authority, relevant professional bodies and regulatory body, which is not specified in Euratom BSS. Dose constraints are required only for research *volunteers* undergoing diagnostic investigations (in Euratom BSS this applies to all medical exposures but restricted to cases where there is no direct health benefit to the exposed person).

Para. 3.160 contains *design considerations* for the medical radiological equipment and software, which shall comply with the IEC and the ISO standards or to national standards "adopted by the regulatory body". This is out of the scope of the Euratom BSS, since design and pre-marketing phases of medical equipment are regulated under Council Directive 93/42/EEC of 14 June 1993 concerning medical devices²⁵.

Para. 3.165 – requirements for *calibration*, missing in the Euratom BSS.

Para. 3.166 – detailed requirements for *clinical dosimetry* in relation to a "typical patient".

Para. 3.168-170 contains detailed (but not exhaustive and not specific to the type of the procedure) requirements on *quality assurance*, which are absent from the Euratom BSS:

- Reference to "principles established by the WHO, PAHO and relevant professional bodies".
- QA shall include verification of physical and clinical factors used in patient diagnosis or treatment, records of procedures and results, periodic checks of dosimetry and monitoring equipment, QA audits.

Quite a few paragraphs require *records and documentation* for instance on personnel with radiation protection responsibilities (3.148 (c)), on advice by a medical physicist (3.152 (e)), on delegations of responsibility (3.152 (f) and 3.181 (a)), on training records (3.181 (b)), on calibrations and periodic checks of relevant clinical parameters (3.182), on data allowing dose assessment (3.183).

Para. 3.177-179 on *unintended and accidental medical exposures*:

- 3.177 defines the main causes of unintended and accidental exposures (design flaws and operational failures of equipment and software and human errors) and puts the responsibility for reducing the likelihood of these exposures with the registrants and licensees. This can be too restrictive since design and software flaws are hard to predict and deal with by the licensees alone.
- 3.178 defines a (exhaustive) list of types of unintended and accidental exposures which should be investigated.

3.4.3. EURATOM REQUIREMENTS WITHOUT CORRESPONDENCE IN THE INTERNATIONAL STANDARDS

²⁵ The Directive's main purpose is to ensure that medical devices placed on the European market do not compromise the safety and health of patients, users and other individuals. The medical devices must meet the essential requirements for their design and construction, including those for justification of the intended use of the equipment on the basis of risk/benefit weighting and for incorporation of technical features for radiation protection of patients, users and other individuals. This is ensured, inter alia, through a system of harmonized standards issued by the European standardization organizations (CENELEC in this case), pre-market conformity assessment procedures and appropriate supervision by the competent authorities.

unintended and accidental medical exposures: the requirement in Euratom BSS Art. 88 (b) that the QA programme for radiotherapeutic practices shall include a study of risk of accidental or unintended exposures is missing in draft 3.0 (see Para. 3.177-179 above).

While the international standards highlight quality assurance and introduce the concept of "radiological reviews" (Para. 3.180), this does not match the more powerful Euratom concept of "***clinical audit***" (Article 83.4).

Draft 3.0 does not contain a requirement for ***estimating population doses*** from medical exposure procedures, as in Euratom BSS (Art. 89).

3.5. PROTECTION OF THE ENVIRONMENT

Both standards address the protection of the environment but in different ways. In principle, the protection of the environment has a prominent place in draft 3.0. It is part of the objectives of the international standards and is specifically addressed in one of the Fundamental Safety Principles referred to in the first chapter of draft 3.0 (Para.1.7 and 1.26). Whenever draft 3.0 speaks about radiation risks, the risks to ecosystems are included in this term (footnote 6 and Glossary), for instance when setting up legal frameworks and regulatory control (Para.2.13 and 2.14), and making arrangements for the protection of the environment (Para.2.25). However, further on in the draft 3.0 there are only general requirements with regard to the protection of the environment for discharge authorisation (Para.3.122 and 3.131), emergency (Para.3.42, 4.2 and 4.5) and monitoring programmes (Para.2.23), and it is difficult to detect if these requirements are issued to protect the environment itself or if they are set to protect the environment as being a resource to humans (food production, recreation, industrial use). In the first case both Standards have the same set of requirements but the Euratom BSS is more to the point consolidating all requirements for the protection of non-human species in one Title. In the second case the Euratom approach is indeed more elaborate as it includes a separate Title with clear and well-balanced requirements for the radiation protection of non-human species while leaving sufficient flexibility for Member States to adopt these requirements to national situations.

4. DIFFERENT APPROACHES WITH REGARD TO NATURAL RADIATION SOURCES

Both set of standards have a comprehensive approach towards natural radiation sources. The Euratom BSS are more explicit when it comes to actual requirements, mainly for building materials where the international standards basically have only one specific requirement, but also for NORM industries, aircrew and radon. The main difference exists however on a philosophical level – whether to classify the different exposure situations as planned or existing according to ICRP terminology.

4.1. NORM

Although the Euratom BSS are clearer about which specific requirements concern NORM, these industries are essentially regulated in the same way in both standards and the same exemption, clearance or threshold values apply, for the benefit of international harmonisation. The Euratom BSS have explicitly incorporated NORM industries in the framework for practices in a planned exposure situation (Title VI), while the international standards regard them as existing exposure situations while applying the requirements in Section 3, Planned Exposure Situations (Para.3.4). Another difference is that the Euratom BSS use the assessment of doses to workers as a tool for identifying the appropriate level of regulatory control and measures to be taken for the protection of workers (above 6 mSv/y then

licensing and full range of requirements in Title VII, between 1-6 mSv/y then registration or licensing and merely requiring undertakings to regularly review exposures) (Art.53), whereas draft 3.0 leaves it to the Member State to decide on which requirements in Section 3 Occupational Exposure (Para.3.68-3.115) should apply. The Euratom BSS also consider doses to members of the public when requiring authorisation for NORM industries (public exposure ≥ 0.3 mSv/y) (Art.53.3.(f)), while draft 3.0 gives no indication of such a criterion. The Euratom Directive is much more clear about which industries may be of concern by introducing a list of industrial sectors (Annex 8).

4.2. RADON

For radon in dwellings or buildings with public access the approaches are the same in both standards and they both use 300 Bq/m³ as the upper boundary on the reference level for existing buildings. Terminology differs slightly where the Euratom BSS talk about buildings with public access (Art.100) when draft 3.0 uses the term "other buildings with a high occupancy factor of the public" (Para.5.19). Draft 3.0 includes kindergartens, schools and hospitals in that term (footnote 35). The Euratom BSS are more specific about the content of a national action plan for radon (Annex 13) and specify also which types of exposure to radon this plan should include - radon exposures in dwellings, buildings with public access and in workplaces, from all sources of radon: soil, building materials or water (Art.38.1). The IAEA approach is to demand an action plan, if appropriate, for public exposure to indoor radon (Requirement 50). Concerning reference levels there are two further differences: Draft 3.0 does not include a requirement for setting reference levels for new buildings and it does not contain any requirements for setting reference levels for the "other buildings with high occupancy factors of the public".

With regard to radon in workplaces; the basic requirements are the same as well as the upper boundary for the reference level (1000 Bq/m³). In reality there are no major differences between the standards on this point.

4.3. COSMIC RADIATION

While exposure to aircrew is addressed in both standards, the Euratom BSS offer detailed requirements such as clarifying what kind of measures to take with regard to occupational doses depending on the dose to the aircrew (Art.59.3). Draft 3.0 includes a more general requirement on the possible assessment of doses to aircrew and subsequent requirements for occupational exposure (Para.5.30). With regard to space crew the Euratom BSS treat this as a specially authorised exposure where specific requirements apply (Art.77.3) whereas draft 3.0 requires that a framework for radiation protection applicable to humans in space-based activities is established, when appropriate (Para.5.31). Another difference is that the Euratom Directive regards both types of exposure as planned exposure situations while draft 3.0 regards them as existing exposure situations.

4.4. BUILDING MATERIALS

With regard to exposure to building materials both standards address this as an existing exposure situation. The Euratom BSS are however much more specific in terms of requirements. While draft 3.0 merely requires that reference levels are set (Para.5.22) that would generally not exceed around 1 mSv/y, the Euratom BSS allocate a whole section of the Directive to new requirements for building materials (Art.101), based on earlier guidelines (RP 112). The aim is to address exposure from building materials in a clear and comprehensive way and enable harmonisation between Member States and smoother trans-boundary movement of these types of material. Another difference is that the Euratom Directive defines the term building materials, deliberately not using the wider term construction material, while the draft 3.0 mentions construction materials without defining the term.

4.5. EXEMPTION AND CLEARANCE

With the introduction of the IAEA RS-G-1.7 values as exemption and clearance levels in the Euratom BSS, the two standards have the same set of values for exemption and clearance. For natural radiation sources the draft 3.0 Schedule I (Para.I-4) gives Member States a large degree of flexibility by stating that exemption should be made on a case by case basis and refers to levels commensurate with natural background levels. On the other hand paragraph 3.4(a) indicates that 1 and 10 Bq/g should be used to detect when an activity should be regulated as a planned exposure situation. This is confusing. For clearance however, draft 3.0 gives the levels 1 and 10 Bq/g. The Euratom BSS also use those values with the difference that they should be used as both exemption and clearance for natural radiation sources. The Euratom approach is more coherent, in particular as it not only sets general criteria for artificial radionuclides but introduces exemption and clearance criteria for natural radionuclides as well (in the order of 0.3 mSv/y or less for members of the public and 1 mSv/y for workers). Furthermore, the Euratom BSS include a comprehensive and cautious use of the clearance criterion for NORM residues, in particular for recycling in building materials and in case of ground water contamination. IAEA is further invited to include relevant isotopes of Uranium and Thorium, Table I-2, for application to clearance of materials arising from the dismantling of nuclear installations such as uranium enrichment or fuel fabrication plants (on the basis of the 10 mSv exemption criterion).

Recommendation: It should be made clear in the international standards what values to use as exemption levels for natural radionuclides. It would also be beneficial to introduce a dose criterion for clearance of natural radionuclides, indicating that if drinking water supplies might be affected this would call for special attention. Basically the whole Schedule I would need to be rewritten. At least the paragraphs in draft 3.0 Schedule I that cause confusion should be deleted, pending on more thorough revision:

- Schedule I Para.I-4

This paragraph is still very confusing. The restriction to "other than incorporated into consumer products..." is redundant with footnote 42. The intention is probably to provide for exemption of bulk amounts. There is no need for such exemption since the scope of "planned exposure situations" is already defined in Para.3.4. A case by case assessment in relation to doses to individuals (workers?) of about 1 mSv per year would only apply for the application for instance of requirements for occupational exposure (after assessment of doses when the concentration exceeds the levels defined in Para.3.4, so on a retrospective basis, not for prospective exemption).

- Schedule I Para.I-5 (b)

It is redundant to include the levels defined in Para.3.4 as clearance levels, since this is the entry point for a planned exposure. In addition, despite footnote 45 this may still easily be misunderstood as applying to building materials or to situations where the residues of NORM industries would contaminate groundwater. There is no clearance criterion (in dose) for natural radionuclides. The criterion in Para.I-4 is more useful in the context of clearance (case-by-case assessment on the basis of a dose criterion which should not exceed 1 mSv per year). However this would require a full restructuring of the requirements or of Schedule I.

5. FURTHER ISSUES IDENTIFIED BY THE ARTICLE 31 EXPERTS

5.1. NON-MEDICAL HUMAN IMAGING EXPOSURE

5.1.1. DIFFERENCES

IAEA PARAGRAPHS

- 3.61. The government shall ensure that the measures described in para. 3.16 for the justification of practices are applied to any imaging procedure that exposes humans to radiation not intended for diagnostic or therapeutic purposes. The justification process shall consider, inter alia,
- (a) Appropriateness of the radiation equipment for the proposed use.
 - (b) The use of alternative techniques that do not utilize ionizing radiation²⁶.
 - (c) The benefits and detriments of implementing the procedure
 - (d) The benefits and detriments of not implementing the procedure.
 - (e) Evaluation of various radiation technologies available, including the effectiveness and limitations of the procedures.
 - (f) Availability of sufficient resources to safely conduct the imaging procedure during the intended period of use.
 - (g) The impact of any legal or ethical issues which may be raised by the use of the technology

Euratom: Items (a) and (c) to (g) are not considered.
Item (b), referring to alternative techniques, differs from EURATOM item (f) of Annex 16 in as far as IAEA requires the use of alternative techniques that do not utilize ionizing radiation to be considered as part of the justification whereas EURATOM requires that alternative techniques which do not involve exposure to ionising radiation are available where the exposure is routinely carried out for security purposes. This item (b) is believed to be redundant (it applies to justification also in other contexts). The Euratom requirement is in addition to justification.

5.1.2. IAEA REQUIREMENTS WITH NO CORRESPONDING EURATOM TEXT

IAEA PARAGRAPHS

- 3.18. Human imaging using radiation performed for occupational, legal or health insurance purposes, and undertaken without reference to clinical indication, shall normally be deemed to be not justified. If, in exceptional circumstances, the justification of such imaging is to be considered, the requirements of paras 3.60 to 3.64 shall apply.

Euratom: no such statement.
However, the list of practices in Annex 16 and the list of the exceptional circumstances mentioned by IAEA (note 19 of para 3.64) are the same.

²⁶ Such techniques may include manual examination, electrical and magnetic source imaging, ultrasound and sonar, magnetic resonance imaging, microwave imaging, terahertz imaging, infrared imaging and visible imaging

- 3.19. Human imaging using radiation for theft detection purposes shall be deemed to be not justified.

Euratom: no such statement

- 3.66. Registrants and licensees shall ensure that all persons that are about to be exposed to radiation for inspection procedures, are informed about the possibility of choosing an alternative technique that does not use ionizing radiation, where available.

Euratom: guarantee that people are informed is not required

5.1.3. EURATOM REQUIREMENTS WITHOUT CORRESPONDENCE IN THE INTERNATIONAL STANDARDS

Art. 49.3: Practices involving the deliberate exposure of humans for non-medical purposes

- (e) Informed consent of the individual to be exposed is sought, allowing for cases when the law enforcement bodies may proceed without consent according to national legislation.

IAEA: informed consent is not sought

- (d) Relevant requirements of Title VIII, including those for equipment, optimisation, responsibilities and special protection during pregnancy, are met for procedures implemented by medical staff using medical radiological equipment.

IAEA: special protection during pregnancy is not mentioned

5.2. GENERAL REQUIREMENTS

5.2.1. SCHEDULE III: TABLE III-I. CONVERSION COEFFICIENTS FOR RADON AND THORON PROGENY

Comment: These coefficients are really obsolete: those for radon are taken from ICRP 65 (1993) and were criticised in the 2009 ICRP Radon statement (2009), those for thoron are taken from ICRP 50 (1987) and they were repeatedly declared scientifically incorrect in international literature. ICRP has announced the publication of new dose coefficients.

Euratom: no mention to dose conversion coefficients for radon and thoron. Reference in general is made in article 14 (b)

“For internal exposure from a radionuclide or from a mixture of radionuclides...ingestion and inhalation dose coefficients in the international basic safety standards published by IAEA shall be used to estimate the effective doses”.

In this way Euratom will also adopt these dose conversion coefficients

IAEA is invited to delete Table III–I pending receipt of new dose coefficients from ICRP

SCHEDULE III: DOSE LIMITS FOR PLANNED EXPOSURE SITUATIONS

For occupational exposure of workers over the age of 18 years, the dose limits are:

...

(b) An equivalent dose to the lens of the eye of 150 mSv in a year;

Euratom: The Experts asked to the Commission to establish a lower value, even if ICRP would not do it, in view of abundant scientific evidence of a higher risk than estimated in the past.

5.2.2. SCHEDULE IV: CRITERIA FOR USE IN EMERGENCY PREPAREDNESS AND RESPONSE

TABLE IV-1: GENERIC CRITERIA FOR ACUTE DOSES AT WHICH PROTECTIVE AND OTHER ACTIONS ARE EXPECTED TO BE UNDERTAKEN UNDER ANY CIRCUMSTANCES TO AVOID OR MINIMIZE SEVERE DETERMINISTIC HEALTH EFFECTS

Euratom: no generic criteria to prevent severe deterministic effects is made

5.2.3. SCOPE

Art.3: Exclusion ("This Directive shall not apply to ...") of radionuclides not usually contained in the human body...

IAEA: Para. 1.31: These Standards shall apply to all situations that are amendable to control (footnote 3 gives some examples of the opposite).

5.3. OTHER EURATOM REQUIREMENTS WITHOUT CORRESPONDENCE IN THE INTERNATIONAL STANDARDS

Metal scrap and orphan sources:

Art. 28.2: Member States shall make arrangements for the establishment of systems aimed at detecting orphan sources in places such as **large metal scrap yards and major metal scrap recycling installations ...**
and

Art. 29: Metal contamination

IAEA: possible melting of a source in metal foundry is not mentioned.

Miscellaneous:

Art. 97 and 98, annex 12A and B: information of the public

IAEA: information of the public is not mentioned

Art. 48: Prohibition of the deliberate addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics, and the import or export of such goods.

IAEA: such practices are not prohibited but only "deemed to be unjustified".

Art. 82.3: The practitioner shall ensure that the patient or legal guardian is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure to enable informed consent.

IAEA only information of the patient is required, informed consent is not required.

Natural radiation sources (see also section 4):

Art. 50: Member States shall ensure the identification of NORM industries which cannot be disregarded from the radiation protection point of view, taking the list of industrial sectors in Annex 8 into account

IAEA: No establishment of a list of NORM industries is required

Reading and comparing par. 3.4 and 5.1 (b) it is not clear how agricultural fertilizers and soil amendments should be considered.

A contradiction seems to be present between para 5.22 and 5.23. Drinking water cannot have a reference level of 1 mSv/y, because WHO recommended a reference level of 0.1 mSv/y, moreover a reference level of 1 mSv/y from each of the cited sources is not acceptable.

It is also not clear how building materials should be managed.

E. INDIVIDUAL COUNTRY RESPONSES TO THE SURVEY

Questionnaire responses from:

Australia
Canada
The Czech Republic
Iceland
Republic of Korea
Norway
The Slovak Republic
Slovenia
Spain
Sweden
United Kingdom

Questionnaire v.2.0 - completed for [country]: **AUSTRALIA**

NEA Project for Obtaining Historical Information on Costs and Impacts of Incorporating ICRP Publ. 60 and Possible Resources for Incorporating ICRP Publ. 103

Part A: incorporating ICRP 60: Key impacts/provisions

NOTE: for EU Member States: references to incorporation of ICRP 60 should be read as implementation of Directives 96/29/Euratom and 97/43/Euratom.

A 1. General	
Questions A 1.1 to A 1.9 are aimed primarily at regulators, and questions A 1.10 – A 1.11 primarily at operators, but we welcome your replies to all queries!	
Question	Your experience
<p><i>Legislation</i></p> <p>A 1.1 Please describe briefly the hierarchy, if applicable, of ionising radiation protection legislation/rules in your country, e.g. national law, national government regulations; central authority regulations; regional or local authority regulations; other (e.g., professional body) rules. Also, please briefly describe what is covered at each level.</p>	<p>A 1.1 Each of the eight States and Territories in Australia has its own radiation control legislation, some dating back to the 1950s. Many of these were updated specifically to incorporate ICRP60. ARPANSA was established by the ARPANS Act in 1998 to regulate Commonwealth government entities (e.g. Defence) and given the function of promoting national uniformity of radiation protection and nuclear safety policies and practices. ARPANSA then became the ninth jurisdiction with its own legislation applicable to government bodies. There are no national laws governing radiation protection. Each jurisdiction has a radiation control (or similar named) Act and Regulations. Some of these explicitly exclude mining and so in those jurisdictions there is separate legislation for that. There is also the Environment Protection and Biodiversity Conservation Act 1999 (EPBC Act) which covers matters of national environmental significance and covers anything that constitutes a 'nuclear action' under that Act (e.g. siting of waste repository). In 1999, the Australian Health Ministers' Conference endorsed the development of the National Directory for Radiation Protection (NDRP) as the means of achieving uniformity in radiation protection practices between jurisdictions. Whilst the NDRP is not legislation, it has been agreed that the regulatory elements will be adopted in each jurisdiction as soon as possible, using existing Commonwealth/State/Territory regulatory frameworks. The NDRP was endorsed as the uniform national framework for radiation protection and published in August 2004. It has the following parts: "<i>Part A of the National Directory for Radiation Protection sets out the agreed overall framework for radiation protection in Australia. It is expected that jurisdictions will adopt these principles as reviews of legislation come forward. Part B of the Directory contains the uniform regulatory elements, which are to be adopted by each jurisdiction, within its particular regulatory framework. Part C of the Directory contains guidance that will assist regulators in adopting consistent approaches, but is not regulatory in nature.</i>"</p>
<p><i>Organisation</i></p> <p>A1.2 Describe the different authorities, and (approximately) how many regulators are involved in making and enforcing radiation protection legislation? Also, if appropriate, please briefly describe how consistency of approach between regulatory organisations is achieved?</p>	<p>A 1.2 Regulatory duties are performed by each of the nine jurisdictions. States/territories are fairly 'strong' and independent. State regulators are usually either in/under the health or the environment departments; at least two states have two regulators (in the health area and in the mining area).</p> <p>For consistency, see A 1.1 above and the regulations summarised in the table attached at the end of the questionnaire.</p>

A 1. General	
<p><i>ICRP 60 incorporation</i></p> <p>A 1.3 To what extent were legislation and regulations rewritten when ICRP 60 was incorporated?</p> <p>A 1.4 What was the procedure, what problems and efforts were there?</p>	<p>A 1.3 Considerably. The National Medical Health and Research Council ('NHMRC') was established in 1926. The <i>National Health and Medical Research Council Act 1992</i> then established the NHMRC as a statutory body. NHMRC functions include advising and making recommendations to the Commonwealth and the States and Territories on health related matters. According to <i>Recommended Radiation Protection Standards for Individuals Exposed to Ionising Radiation</i> (NHRMC, 1981), "<i>The [NHMRC] believes that it will be of assistance to the Commonwealth and the States, as well as to those who use ionising radiations, if from time to time it recommends and publishes relevant Protection Standards. It is of the opinion that these Standards will be of value in considering amendments to legislation on the control of radiation</i>"</p> <p>The NHMRC publication RHS 39 <i>Recommendations for Limiting Exposure to Ionizing Radiation</i> (1995) also highlights that "it will be of assistance in achieving radiation protection procedures <u>which may be adopted in State and Territory legislation or regulations</u>". Thus these Recommendations are only adopted by jurisdictions <i>voluntarily</i>. The first NHMRC amendment incorporating ICRP 1990 rec/s was via the Radiation Health Series No. 33—<i>Interim Statement on Australia's Radiation Protection Standards</i> (published June 1991) and included changes to worker and public dose limits.</p> <p>The National Occupational Health and Safety Commission (NOHSC) publication 1013 <i>National Standard for Limiting Occupational Exposure to Ionizing Radiation</i> (1995) , published jointly as NHMRC's RHS 39 <i>Recommendations for Limiting Exposure to Ionizing Radiation</i> (1995), states "<i>This national standard for limiting occupational exposure to ionizing radiation will serve to identify the provisions which are to be made in the regulations of States, Territories and the Commonwealth for the control of occupation exposure to radiation. It is recognised that legislation, including regulation, may already exist which covers all or part of the Scope of this Standard. It is also recognised that is may not be appropriate to take up this Standard verbatim because of differing legislative frameworks and rafting conventions in each State and Territory and in the Commonwealth. However, it is expected that the <u>implementation of the provisions contained in this Standard will be nationally consistent</u></i>" [s-v]</p> <p>RHS 39 was republished by ARPANSA in 2002 being renamed as Radiation Protection Series 1 (RPS1).The dose limits in RPS1 also appear in the NDRP and are therefore adopted by each jurisdiction.</p> <p>A 1.4 At the time, consultation processes were more cursory than nowadays. ICRP Recommendations tended to be implemented rapidly in practice, even if not necessarily in legislation.</p>
<p><i>Stakeholders</i></p> <p>A 1.5 Who were the stakeholders (e.g. other ministries, operators, etc.) and how was their involvement achieved?</p>	<p>A 1.5</p>

A 1. General	
<p><i>Guidance</i></p> <p>A 1.6 How was guidance on the implementing legislation developed and by whom (e.g.: regulatory authorities; professional societies, trade organisations)?</p>	<p>A 1.6 The NHMRC publications Radiation Health Series (RHS) contain codes of practice, standards, recommendations and guidelines. ARPANSA took over the revision and development of these publications in 2000 and a new series was begun: the Radiation protection Series (RPS). The RHS series ended with RHS 39 which was then republished as RPS1 (see A1.3). The full series can be viewed at http://www.arpansa.gov.au/Publications/codes/index.cfm</p> <p>These documents are developed by a national committee (Radiation Health Committee) with representatives of the radiation regulatory authorities from each jurisdiction and managed by ARPANSA. ICRP documents and IAEA documents are used for guidance purposes in the development process. Any document intended for national adoption must also be forwarded to the Health Ministers Conference for endorsement.</p>
<p><i>Time-scales</i></p> <p>A 1.7 What were the lead-in times for new requirements, i.e., when were they proposed, when decided, when was full compliance by operators required?</p>	<p>A 1.7 See A 1.1 above and the attached table.</p>
<p><i>Burdens and benefits</i></p> <p>A 1.8 Did your regulatory authority perform a cost-benefit analysis of the implications of any new regulations, (regulatory analysis) and if so is there a report available (where)?</p>	<p>A 1.8 Not that we know of. However, even in the 1990s, negotiations and discussions preceded any new legislation, and for instance the ARPANS Act 1998 was the subject of considerable discussion in Parliament.</p>
<p><i>Cost of Not Acting</i></p> <p>A 1.9 Were the costs/savings/ implications of not implementing ICRP 60 assessed? If so, what were they?</p>	<p>A 1.9 Not as far as we know.</p>
<p><i>Actual costs</i></p> <p>ICRP 60 and Euratom Directives 96/29 and 97/43 entailed, e.g., that</p> <ul style="list-style-type: none"> -the annual limit on occupational effective dose was reduced from 50 to 20 mSv, with an option of 5-year averaging; - it was clarified that the annual limit on effective dose to members of the public is 1 mSv, not 5 mSv; - effective dose (with new weighting factors w_R and w_T) replaced the effective dose equivalent; - the concepts of dose and risk constraints were introduced; - diagnostic reference levels were introduced. <p>A 1.10 How did these new requirements arising from ICRP 60 impact on operations?</p> <p>A 1.11 Did the incorporation of ICRP 60 lead to any</p>	<p>A 1.10</p> <p>A 1.11</p>

A 1. General	
reduction of any kind of cost or effort?	

A 2. Application / scope	
Questions A 2.1 to A 2.2 are aimed primarily at regulators. We are grateful for replies from both operators and regulators to questions A 2.3 - A 2.4!	
<p><i>Scope</i></p> <p>A 2.1 Did pre-ICRP 60 legislation in your country cover all uses and users of ionising radiation, e.g.: industrial applications (including industrial radiography), medical applications (diagnostic and therapeutic), nuclear fuel cycle, research and teaching, transport, radioactive waste disposal, occupational exposure to radon (mining and non-mining), agriculture?</p> <p>A 2.2 If not, was new legislation introduced to close the previous gaps?</p> <p>A 2.3 Did the timeframe for implementation vary for the sectors described in A 2.1? If so, how?</p>	<p>A 2.1 Before the implementation of ICRP 60 as described under A 1.1, the Commonwealth government did not have radiological protection regulations, but the state/territory jurisdictions all had earlier regulations. However, the scope of regulations differed between states/territories, thus in some jurisdictions there were certain unregulated applications (e.g. mining).</p> <p>A 2.2 Yes in most cases, see A 1.1 above. Not so for mining yet.</p> <p>A 2.3 Not between sectors, but between jurisdictions as summarised in the table at the end of the questionnaire.</p>
<p><i>Response</i></p> <p>A 2.4 Was there any resistance from those sectors (if any) which were not previously covered? If so, what were the main perceived difficulties and what was done to overcome them?</p>	<p>A 2.4</p>

A 3. Dose limits and dose distribution	
Questions A 3.1 – A 3.3 are aimed primarily at regulators. We would be grateful for replies from both regulators and operators for questions A 3.4 – A 3.10!	
<p><i>Historical limits</i></p> <p>A 3.1 What were your dose limits before you incorporated ICRP 60?</p>	<p>A 3.1</p>
<p><i>Current limits</i></p> <p>A 3.2 What were your dose limits after implementation?</p> <p>A 3.3 Was any flexibility built into dose limits, e.g. public limits allowed up to 5 mSv in exceptional circumstances?</p> <p>A 3.4 If 5-year averaging was chosen for occupational</p>	<p>A 3.2 As per ICRP 60; see RPS1 for nationally agreed limits and hyperlinks in the attached table for slight variations in implementation across jurisdictions.</p> <p>A 3.3 Yes, averaging is permitted with essentially the same wording as in ICRP 60.</p> <p>A 3.4 Although averaging of occupational doses is a formal possibility, we do not believe that it has been used in practice. Note however that we are only now organising a national dose registry. There have been local registers held by the states that have monitoring services, but they</p>

A 3. Dose limits and dose distribution	
doses, what is your experience? Were there any difficulties?	were not comprehensive.
<p><i>Transition experience</i></p> <p>A 3.5 What was your experience of establishing these lower dose limits?</p> <p>A 3.6 Did any installation need significant rebuilding to comply with added shielding requirements? If no, how was this avoided?</p> <p>A 3.7 Were there any other difficulties? If so, what were they and how were they resolved?</p>	<p>A 3.5 There were no significant problems, doses were already mostly below the new limits due to optimisation of protection.</p> <p>A 3.6 We are not aware of any case where shielding had to be amended due to the implementation of ICRP 60. Note, though, that many of our radiotherapy clinics were built after 1990 and could take account of the new requirements from the outset. In any case, the highest doses in the Australian context are to miners, and are due to intake of dust.</p> <p>A 3.7</p>
<p><i>Resulting doses</i></p> <p>A 3.8 What analyses of dose distributions are available for your country, over what period?</p> <p>A 3.9 Have these dose distributions changed? How?</p> <p>3.10 If yes, what was (were) the main factor(s) influencing these changes?</p>	<p>A 3.8 Since we are only now organising a national dose registry, we do not have comprehensive information. However, we know that improved ventilation in mines led to significant dose reductions over the last 20 years, and that doses in connection with medical procedures have also gone down significantly. This is a result of optimisation, not of limitation.</p> <p>A 3.9</p> <p>A 3.10</p>

A 4. Experience with specific technical aspects	
We would appreciate answers from both regulators and operators to all of these questions!	
<p><i>Pregnant workers</i></p> <p>A 4.1 What happens when an occupationally exposed worker becomes pregnant?</p> <p>A 4.2 Did the introduction of the 2 mSv limit for the abdomen (ICRP 60) or the 1 mSv limit for the embryo / fetus (Euratom Directive) cause any problems or costs?</p> <p>A 4.3 If yes, what were they and how were they resolved?</p>	<p>A 4.1 It depends on the industry. Medical staff will usually continue to work but not with screening/fluoroscopy equipment or similar. If required, the person is moved temporarily to an alternative position within the organisation. Currently, ARPANSA is discussing with airlines how to handle pregnant staff, because earlier industry limits on hours worked have been revoked.</p> <p>A 4.2 No, employers where doses could be high usually understand the concerns.</p> <p>A 4.3</p>
<p><i>Constraints</i></p> <p>A 4.4 What is your experience of the introduction and use of dose constraints for occupational and public exposures?</p> <p>A 4.5 Were there any difficulties? If yes, what were</p>	<p>A 4.4 Constraints are used to good effect in the industrial context (mining, ANSTO nuclear facilities) and in many but not all medical contexts. ARPANSA strongly encourages its licensees to set and use dose constraints. Some other jurisdictions also do this. Thus, in line with ICRP recommendations, occupational dose constraints are not normally mandated but set by the operators.</p> <p>A 4.5</p> <p>A 4.6</p>

A 4. Experience with specific technical aspects	
<p>they and how were they resolved?</p> <p>A 4.6 Have you at all used risk constraints? If yes, what is your experience?</p>	
<p><i>Radiation Dosimetry</i></p> <p>A 4.7 Please describe briefly the organisation and regulatory framework for dosimetry in your country.</p> <p>A 4.8 Did the introduction of ICRP 60 radiation and tissue weighting factors lead to any difficulties? If yes, what were they and how were they resolved?</p> <p>A 4.9 Were there any costs associated with the implementation of the ICRP 60 dosimetric approach (e.g. dose coefficients, modelling, instrument calibration, etc.), if so, how much and borne by whom?</p>	<p>A 4.7 ARPANSA used to be the main provider of personal dosimetry. There are now also private companies providing this service. ARPANSA also provides radon monitoring, e.g., in mines. In some jurisdictions the personal monitoring services must be approved by the regulatory authority and meet appropriate quality standards e.g. ISO.</p> <p>A 4.8 No, there were no huge changes or problems.</p> <p>A 4.9</p>
<p><i>Radon</i></p> <p>A 4.10 Please describe briefly the current arrangements with respect to radon, in dwellings and at the workplace.</p> <p>A 4.11 Did the implementation of ICRP 60 cause any new efforts or costs? If yes, what were they and how were they resolved?</p>	<p>A 4.10</p> <p>A 4.11</p>

A 5. Training implications	
<p>Question A 5.1 – A 5.2 are aimed primarily at regulators, and questions A 5.3 – A 5.5 at both regulators and operators!</p>	
<p><i>Regulators' staff</i></p> <p>A 5.1 What methods did you use to ensure that relevant members of staff were aware of and understood the revised legislation?</p> <p>A 5.2 Were there any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly</p>	<p>A 5.1 People were already well aware of what went on in ICRP so ICRP 60 was not 'a great shock of horror'.</p> <p>A 5.2.</p> <p>A 5.3</p> <p>A 5.4</p>

A 5. Training implications	
<p>describe?</p> <p>A 5.3 Were you involved in ensuring that stakeholders were aware of and understood the revised legislation?</p> <p>A 5.4 If so, how did you do this?</p>	
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>A 5.5 What was the extent of training and information required? Was this an entirely new effort, or could it be integrated into existing schedules of recurring training? What were the costs of training?</p>	<p>A 5.5</p>

Part B: incorporating ICRP 103: Anticipated key impacts/provisions

B 1. General	
<p>Questions B 1.1 to B 1.6 are aimed primarily at regulators, and questions B 1.7 - B 1.8 primarily at operators, but we welcome your replies to all queries!</p>	
<p><i>Legislation</i></p> <p>B 1.1 Do you expect to have to change your ionising radiation protection legislation/rules if/when ICRP 103 is incorporated?</p> <p>B 1.2 If appropriate, please briefly describe the anticipated changes.</p>	<p>B 1.1 Yes, we are currently updating RPS1 (cf. A 1.3 above) to incorporate ICRP 103 and the international BSS. The amended RPS1 will be part of the NDRP (see A 1.1 above) and then effectively become law by adoption in all jurisdictions. At the drafting stage, experts including licensee representatives are involved. Committees including public representatives will look at the drafts before they are released for consultation. There are extensive public consultation systems, following the government's Best Practice Regulation guidance, both at the national and at the local jurisdiction levels. The process of implementing RPS1 into local legislation varies between jurisdictions and because of the considerable variety of legislation update mechanisms, this may take quite a while. Advice from IAEA is very important in this process; we are also using, e.g., US calculations on doses in the radioactive waste area. We expect this to take another 2 years.</p> <p>B 1.2 It may be worth mentioning that in the context of environmental protection, e.g. in the mining industry, tools like ERICA are used. There is a substantial amount of work going on to obtain transfer factors etc relevant for Australia.</p>
<p><i>Organisation</i></p> <p>B 1.3 Do you expect that the incorporation of ICRP 103 will lead to any changes to the organisation and/or resources of the radiation protection regulators, compared with that reported in Section A?</p>	<p>B 1.3</p> <p>B 1.4</p>

B 1. General	
<p>B 1.4 If appropriate, please briefly describe how consistency of approach between regulatory organisations is to be achieved?</p>	
<p><i>Burdens and benefits</i> B 1.5 Does your regulatory authority expect to perform a cost-benefit analysis of the implications of any new regulations (regulatory analysis) and if so, when might a report become available (where)?</p>	<p>B 1.5 Yes, a Regulatory Impact Statement including a CBA at the national level will be required. This needs to be signed off by the government's Office of Best Practice before any regulation can be implemented.</p>
<p><i>Cost of Not Acting</i> B 1.6 Will the costs / savings / implications of not implementing Publication 103 be assessed? If so, when?</p>	<p>B 1.6</p>
<p><i>Anticipated costs</i> ICRP 103 and the new Euratom Directive will entail, e.g., - amended w_R and w_T; - added emphasis on dose constraints. B 1.7 How do you expect these new requirements arising from ICRP 103 to impact on operations? B 1.8 Do you anticipate that the incorporation of ICRP 103 may lead to any reduction of any kind of cost or effort?</p>	<p>B 1.7 B 1.8</p>

B 2. Experience with specific technical aspects	
<p>We would appreciate answers from both regulators and operators to all of these questions!</p>	
<p><i>Pregnant workers</i> B 2.1 Do you envisage that the introduction of the 1 mSv limit for the embryo / fetus (ICRP 103) will cause any problems or costs? <i>(Note: this question does not apply to EU member countries since the current Euratom BSS Directive already prescribes such a limit).</i> B 2.2 If yes, what might they be, and how do you plan to resolve them?</p>	<p>B 2.1 B 2.2</p>

B 2. Experience with specific technical aspects	
<p><i>Constraints</i></p> <p>B 2.3 Is the added emphasis on dose constraints in ICRP 103 expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p> <p>B 2.4 Are risk constraints likely to be introduced with the implementation of ICRP 103?</p>	<p>B 2.3</p> <p>B 2.4</p>
<p><i>Dosimetry</i></p> <p>B 2.5 Are the new ICRP 103 radiation and tissue weighting factors expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.5</p>
<p><i>Radon</i></p> <p>B 2.6 Is the implementation of ICRP 103 expected to cause any new efforts or costs with respect to radon? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.6 The main problem is that relevant dose coefficients are not yet available. We follow the ICRP advice to use existing coefficients until new information is provided. Miners would like this information, but they have good expertise in house.</p>

B 3. Training implications	
<p>Questions 3.1 – 3.3 are aimed primarily at regulators, and question 3.4 at both regulators and operators!</p>	
<p><i>Regulators' staff</i></p> <p>B 3.1 What methods do you plan to use to ensure that relevant members of staff were aware of and understood the revised legislation?</p> <p>B 3.2 Do you anticipate any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?</p> <p>B 3.3 Do you expect to be involved in ensuring that stakeholders are aware of and understood the revised legislation? If so, how do you anticipate doing this?</p>	<p>B 3.1</p> <p>B 3.2</p> <p>B 3.3</p>
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p>	<p>B 3.4</p>

B 3. Training implications	
B 3.4 What do you expect will be the extent of training and information required? Will this be an entirely new effort, or could it be integrated into existing schedules of recurring training? What may be the anticipated costs of training?	

And finally: Is there anything else that you wish to add?

[Please add any 'open' comments here!]

Even in cases where ARPANSA is not the direct regulator, our presence is strong and operators regard our documents as binding for them. However, we try to use professional bodies when possible, particularly in the medical area. This is time-consuming, but works well so it's worth the effort.

JURISDICTION	DATE OF EFFECT	ENABLING LEGISLATION	SPECIFIC CLAUSE	DETAILS
VIC	25 October 1994	Health (Radiation Safety) Regulation 1994	R33&34; Schedule 1	There is no copy of the regulations on Austlii nor the VIC Law Publisher. This link goes to a summary.
NSW	1 September 1993	Radiation Control Regulations 1993	R6; Schedule 2	The first state to adopt ICRP60 recommendations into regulations. Clause links go to specific links to regulation available on the Austlii website.
QLD	1 January 2000	Radiation Safety Regulation 1999	R30(2)	Austlii does not have a copy of this regulation. Therefore, you must scroll through the PDF from QLD Law Publisher to find the specific clause.
SA	1 September 2000	Ionizing Radiation Regulations 2000	R14	This regulation has since been renamed in later reprints <i>Radiation Protection and Control (Ionising Radiation) Regulations 2000</i> . You can download a copy from the website (click here) and scroll down to click on 'Display Older Versions') clicking on the oldest version.
WA	22 July 1997	Radiation Safety (General) Regulations 1983	R3&24 Schedule 1	Austlii has commencement as date of publication in the WA government gazette.
TAS	19 December 1994	Radiation Control Regulations 1994	R8	Neither Austlii nor TAS Law Publisher has a copy of these regulations. Tas regulator representatives advised that these old regulations incorporated ICRP60 with worker dose limits enforced through licence conditions.
NT	15 September 1999	Radiation (Safety Control) Act 1999	R23; Schedule3	NT regulator representatives were able to confirm that these regulations first incorporated ICRP 60. This link opens the copy on the NT Law Publisher Website.
ACT	5 March 2002	Radiation Regulations 2002	R6	The ACT Law Publisher has copies of old legislation. This was the last jurisdiction to incorporate ICRP60.
Commonwealth	1999	Australian Radiation Protection and Nuclear Safety Regulations 1999	Reg 59 and 62	

Questionnaire v.2.0 - completed for [country]: CANADA

**NEA Project for Obtaining Historical Information on Costs and Impacts of Incorporating ICRP Publ. 60 and Possible Resources for Incorporating ICRP Publ. 103
Part A: incorporating ICRP 60: Key impacts/provisions**

NOTE: for EU Member States: references to incorporation of ICRP 60 should be read as implementation of Directives 96/29/Euratom and 97/43/Euratom.

A 6. General	
Questions A 1.1 to A 1.9 are aimed primarily at regulators, and questions A 1.10 – A 1.11 primarily at operators, but we welcome your replies to all queries!	
Question	Your experience
<p><i>Legislation</i></p> <p>A 1.1 Please describe briefly the hierarchy, if applicable, of ionising radiation protection legislation/rules in your country, e.g. national law, national government regulations; central authority regulations; regional or local authority regulations; other (e.g., professional body) rules. Also, please briefly describe what is covered at each level.</p>	<p>A 1.1 The Canadian Nuclear Safety Commission regulates the use of nuclear energy and materials to protect the health, safety and security of Canadians and the environment; and to implement Canada's international commitments on the peaceful use of nuclear energy.</p> <p>CNSC was established in 2000 under the <i>Nuclear Safety and Control Act</i> and reports to Parliament through the Minister of Natural Resources. CNSC was created to replace the former Atomic Energy Control Board (AECB), which was founded in 1946.</p> <p>While the CNSC is responsible for the regulation of ionizing radiation from nuclear energy, there is another federal body (Health Canada) responsible for the regulation of non-ionizing radiation, radon, and x-rays. In addition, there are provincial/territorial authorities who set requirements. It should also be noted that the Department of National Defense regulates their own activities which involve ionizing radiation and these activities do not fall under the jurisdiction of the CNSC.</p> <p>Medical sector contribution – FEDERAL:</p> <p>Federal regulatory body: The Canadian Nuclear Safety Commission (CNSC). All nuclear facilities and activities in Canada are governed by the Nuclear Safety & Control Act (NSCA), which came into force in 2000.</p> <p>Through this Act, the CNSC regulates licensees and organizations that produce, use, store or transport nuclear materials in Canada. The NSCA and its regulations are designed to protect the public, the people who work in the nuclear sector, and our environment. The CNSC collaborates with a number of other Government of Canada departments to regulate Canadian nuclear facilities and activities, namely; Natural Resources Canada, Environment Canada, Health Canada, Transport Canada, National Defence and Canadian Forces and Foreign Affairs and International Trade Canada.</p> <p>The CNSC also works with provincial and territorial regulatory bodies with respect to environmental and radiation protection. In terms of jurisdiction or scope, the CNSC licenses the use of all radioactive materials or devices capable of producing radioactive materials. All other radiation emitting devices fall under provincial jurisdiction.</p> <p>In the healthcare setting, applications such as nuclear medicine, cyclotron/radiopharmacy, cobalt teletherapy, brachytherapy, linear accelerators producing photons 10 MV or greater, radioisotopes used in research, are subject to federal oversight. Whereas diagnostic x-ray devices, linear accelerators of energies less than 10 MV (i.e. tomotherapy), CT simulators, On-Board- Imaging systems accompanying linear accelerators, are subject to provincial oversight.</p> <p>PROVINCIAL:</p> <p>In the Province of Ontario, the Ministries of Health and Labour regulate the use of medical x-rays under the Healing Arts Radiation Protection (HARP) Act and the Occupational Health and Safety Act and regulations. The Ministry of Labour regulates the use of non-medical X-ray sources under the Occupational Health and Safety Act. X-ray sources which produce X-rays of high energy capable of inducing radioactivity in materials exposed to them are regulated and licensable federally (as explained above).</p>

A 6. General	
<p><i>Organisation</i></p> <p>A1.2 Describe the different authorities, and (approximately) how many regulators are involved in making and enforcing radiation protection legislation? Also, if appropriate, please briefly describe how consistency of approach between regulatory organisations is achieved?</p>	<p>A 1.2 Federally, the CNSC is the responsible authority for regulating the use of nuclear substances or the operation of nuclear facilities.</p> <p>Health Canada is the federal authority for regulating the use of non-ionizing radiation and x-rays.</p> <p>Provincial authorities (there are 10 provinces and three territories) provide the necessary oversight in radiation protection practices in their jurisdiction. Generally speaking, Health Canada approves x-ray devices and the provinces regulate their use.</p> <p>Department of National Defence is responsible for the regulation of their own activities related to nuclear substances and devices.</p> <p>Consistency of approach is achieved through communication. In addition, there is a 'Federal/Provincial/Territorial Radiation Protection Committee whose mission is to advance the development and harmonization of practices and standards for radiation protection within Federal, Provincial and Territorial jurisdictions. The committee meets annually to discuss common concerns with the objective of aligning practices and regulations. In addition, there are memorandums of understanding between the federal bodies which formally document the linkages and respective responsibilities of each party.</p> <p>Medical sector contribution: Canada's nuclear safety standards are benchmarked against international standards. To do this, the CNSC relies on the work of IAEA and other organizations such as UNSCEAR and the ICRP, as well as Health Canada and Environment Canada.</p> <p>The Nuclear Safety Control Act states "...it is essential in the national interest that consistent national and international standards be applied to the development, production and use of nuclear energy." (<i>excerpt from CNSC presentation by Amy Hicks [Ref. Ca3]</i>)</p> <p>Furthermore, the directive on streamlining regulation from the Cabinet states: "...agencies are to take advantage of opportunities for...adopting or contributing to...international standards...limiting the number of specific Canadian regulatory requirements...to instances when they are warranted by specific Canadian circumstances." (<i>excerpt from Hicks [Ref. Ca3]</i>)</p> <p>As the provincial authorities look to the same international recommendations/standards when developing their regulations, for the most part, there is consistency of provincial and federal approach to radiation protection. As well, there is an intergovernmental committee; the Federal Provincial Territorial Radiation Committee whose mission is "to advance the development and harmonization of practices and standards for radiation protection within Federal, Provincial and Territorial jurisdictions."</p> <p>In practice, we have workers in healthcare who use equipment that is federally regulated and provincially regulated (sometimes in operating a single machine, ie. A 10 MV linear accelerator equipped with On-Board-Imaging). Therefore most workers are designated as both Nuclear Energy Workers (federal classification), and X-ray workers (provincial classification), and in cases of inconsistency, the stricter of the approaches is applied. This works quite well – the main challenge in practice is that it is impossible in many cases to separate the dose received from provincial regulated devices versus federally regulated devices/applications as staff wear a single dosimeter monitoring their occupational dose, the record of which is kept by the National Dose Registry</p>
<p><i>ICRP 60 incorporation</i></p> <p>A 1.3 To what extent were legislation and regulations rewritten when ICRP 60 was incorporated?</p> <p>A 1.4 What was the procedure, what problems and efforts were there?</p>	<p>A 1.3 ICRP 60 was incorporated into regulations when the CNSC was established in 2000 under the <i>Nuclear Safety and Control Act and Regulations</i>.</p> <p>It should be noted that the establishment of the CNSC and the Act were not initiated as a result of the ICRP 60 recommendations. However, the regulatory authority incorporated the recommendations into the new regulatory framework.</p> <p>Medical sector contribution: See consultative document C-122, 'Proposed Amendments to the Atomic Energy Control Regulations for Reduced Dose Limits Based on the 1991 Recommendations of the International Commission on Radiological Protection' [<i>Ref. Ca1</i>]</p> <p>A 1.4 See above. The CNSC as an agent of the Government of Canada and as Canada's nuclear regulator recognizes and understands the</p>

A 6. General	
	<p>importance of consulting and building relationships with Canada. All amendments to regulations undergo a comprehensive public review process which includes ensuring that key stakeholders are informed and be provided the opportunity to comment on the draft regulations.</p>
<p>Stakeholders A 1.5 Who were the stakeholders (e.g. other ministries, operators, etc.) and how was their involvement achieved?</p>	<p>A 1.5 Below describes the general process for developing regulatory documents and how to involve the key stakeholders. In general, the CNSC would identify and directly involve key licensees, organized groups and citizens based on past experience. However, in order to allow for a transparent process with access to all Canadians, all changes are identified on the website.</p> <p>To ensure content integrity and soundness of information, the regulatory document development process at the Canadian Nuclear Safety Commission (CNSC) involves the following steps</p> <ol style="list-style-type: none"> 1. <i>Drafting the regulatory document:</i> CNSC technical experts prepare the draft regulatory document for an extensive internal review by CNSC technical and legal personnel. 2. <i>Consulting with stakeholders:</i> The consultation process for draft regulatory documents take place in two steps: <ol style="list-style-type: none"> a). First consultation: The draft regulatory document is posted to the CNSC Web site. The public, licensees and interested organizations are invited to comment on the regulatory document. Information sessions may also be held. b). Second consultation: Comments received are posted on the CNSC Web site. All stakeholders have an opportunity to view the comments received during the first consultation and provide additional feedback. 3. <i>Reviewing comments received and revising the draft regulatory document:</i> Once the consultation period has ended, public comments are reviewed, assessed and considered in revising the draft regulatory document. 4. <i>A Consultation Report</i>, which includes comments received, is compiled and presented to the Commission Tribunal. 5. <i>Receiving final Commission Tribunal approval:</i> After reviewing the revised draft regulatory document and the Consultation Report, the Commission Tribunal may ask for clarification and make additional recommendations. Once revised and approved, the regulatory document is prepared for publishing (following is from Wayne Gratton, Regulatory Policy Analysis Division). 6. A regulation is "made" when it is officially established by the regulation-making authority. Under Section 44 of the Nuclear Safety and Control Act, the Canadian Nuclear Safety Commission (Tribunal) may, with the approval of the Governor in Council, make regulations. Following examination and approval by the Governor in Council, the regulation is published in Canada Gazette, Part II. 7. All Governor in Council regulations must be approved by the Governor General to become law. The Governor General completes the making of regulations by signing the Order in Council. The approved regulations are sent to the Registrar of Statutory Instruments for registration. 8. The Governor in Council is the Governor General of Canada acting on the advice of the Queen's Privy Council for Canada (i.e., the Cabinet) 9. Generally speaking, regulations come into force on the day on which they are approved by the Governor in Council. A regulation may come into force at a date later than the date of registration, in which case the later date is expressly stated in the coming-into-force provision. <p>Medical sector: The AECB (the federal regulatory body at the time) issued consultative document C-122 [<i>Ref. Ca1</i>]. The Ottawa Hospital Regional Cancer Centre, as a stakeholder, participated in an analysis of the expected impact of the proposed amendments to regulations (C-122) on the Ontario Cancer Treatment and Research Foundation (collaboration of 8 Cancer Centres in Ontario) [<i>Ref. Ca2</i>]</p>

A 6. General	
<p><i>Guidance</i></p> <p>A 1.6 How was guidance on the implementing legislation developed and by whom (e.g.: regulatory authorities; professional societies, trade organisations)?</p>	<p>A 1.6 Assuming by "guidance" you mean radiation protection guidance, the radiation protection regulations were drafted largely "in-house" as the AECB (now the CNSC) had a number of radiation protection experts, including those who were on a number of ICRP committees and task groups. In addition, some Canadian radiation protection experts were consulted for specific reviews such as pregnant worker dose limits.</p> <p>Also, as mentioned above, there was a comprehensive consultation process on the regulations.</p>
<p><i>Time-scales</i></p> <p>A 1.7 What were the lead-in times for new requirements, i.e., when were they proposed, when decided, when was full compliance by operators required?</p>	<p>A 1.7 The current regulations were initially drafted in the early 1990's and the radiation protection regulations came into effect when the Nuclear Safety and Control Act came into force on May 31, 2000. Some of the regulations were phased in over five years to allow time for licensees to become compliant, such as licensing of dosimetry providers.</p>
<p><i>Burdens and benefits</i></p> <p>A 1.8 Did your regulatory authority perform a cost-benefit analysis of the implications of any new regulations, (regulatory analysis) and if so is there a report available (where)?</p>	<p>A 1.8 Yes, Canadian Law requires that a Regulatory Impact Assessment statement be provided with the regulations. In this case, it can be downloaded at: http://www.gazette.gc.ca/archives/p2/2000/2000-06-21/pdf/g2-13413.pdf [= Annex B]</p>
<p><i>Cost of Not Acting</i></p> <p>A 1.9 Were the costs/savings/ implications of not implementing ICRP 60 assessed? If so, what were they?</p>	<p>A 1.9 There was a cost estimation for implementing the regulations, but we are not aware of one for not implementing ICRP recommendations, . See the reference in A 1.8.</p> <p>Medical sector contribution: The cost/implications of not implementing ICRP 60 was assessed in depth for the proposed pregnancy limit of 2 mSv. As explained in the CNSC presentation by Amy Hicks [Ref. Ca3], the costs/implications of the proposed pregnancy limit were too high (see response 4.2). A formal report justifying why this particular ICRP 60 was not implemented was issued by the Atomic Energy Control Board, the federal regulatory body that predated the CNSC [Ref. Ca5].</p>
<p><i>Actual costs</i></p> <p>ICRP 60 and Euratom Directives 96/29 and 97/43 entailed, e.g., that</p> <ul style="list-style-type: none"> -the annual limit on occupational effective dose was reduced from 50 to 20 mSv, with an option of 5-year averaging; - it was clarified that the annual limit on effective dose to members of the public is 1 mSv, not 5 mSv; - effective dose (with new weighting factors w_R and w_T) replaced the effective dose equivalent; - the concepts of dose and risk constraints were introduced; - diagnostic reference levels were introduced. <p>A 1.10 How did these new requirements arising from ICRP 60 impact on operations?</p> <p>A 1.11 Did the incorporation of ICRP 60 lead to any reduction of any kind of cost or effort?</p>	<p>A 1.10 The CNSC did not determine what the actual costs were, other than that identified in the RIAS. Generally speaking though, more worker monitoring was required and changes had to be made to our National Dose Registry. Some operations, notably industrial radiographers and uranium mines had to find means to reduce dose further. Derived release limits were recalculated to one millisievert, however the releases in almost all cases were so low that the new lower limits did not impact the actual effluent releases. The CNSC did not include dose constraints per se, but we did include a somewhat similar concept called Action Levels, which has investigation and reporting requirements if the level is reached.</p> <p>NPP Operator: Dose reduction initiatives were already in progress, so impact was minimal.</p> <p>Medical sector: The AECB (the federal regulatory body at the time) issued consultative document C-122 [Ref. Ca1] for comments on July 15, 1991.</p> <p>An assessment of impact by 8 cancer centres in Ontario prepared in 1994 [Ref. Ca2] anticipated the following costs;</p> <ul style="list-style-type: none"> -re-classification of ~ 350 workers necessitating, most workers were already badged, therefore cost was deemed minimal (perhaps 20 additional badges required) - dose limit violations were not anticipated (also supported by paper by Denis Brown, addressing potential impact to medical practice in Canada [Ref. Ca4], -shielding – no additional shielding required to meet occupational dose limits in ICRP 60, public may be under-shielded in a total of 3 treatment rooms of the 8 centres. Approach suggested was to use radiation surveys and/or TLD experiments to assess compliance with 1 mSv/yr limit.

A 6. General	
	<p>Operational changes would be first approach to remedy any non-compliance, followed by additional shielding if operational changes were not successful.</p> <p>The minimal shielding changes needed reflect the application of AECB document entitled, "AG-5. A guide to Applicants for Medical Accelerator License" at the time. The design dose limits in this guide were more stringent than C-122, with annual dose design limits that shielding maintain annual doses to below 5.0 for Atomic Radiation Workers, 0.5 for other staff, and 0.05 mSv for public. Many medical physicists at the time were applying these design dose limits partly or wholly to shielding design of equipment other than medical accelerators.</p> <p>A 1.11 There was no cost reductions that we are aware of. NPP Operator: Nothing to add. Medical sector: No, none that I could find reference to.</p>

A 7. Application / scope	
<p>Questions A 2.1 to A 2.2 are aimed primarily at regulators. We are grateful for replies from both operators and regulators to questions A 2.3 - A 2.4!</p>	
<p><i>Scope</i></p> <p>A 2.1 Did pre-ICRP 60 legislation in your country cover all uses and users of ionising radiation, e.g.: industrial applications (including industrial radiography), medical applications (diagnostic and therapeutic), nuclear fuel cycle, research and teaching, transport, radioactive waste disposal, occupational exposure to radon (mining and non-mining), agriculture?</p> <p>A 2.2 If not, was new legislation introduced to close the previous gaps?</p> <p>A 2.3 Did the timeframe for implementation vary for the sectors described in A 2.1? If so, how?</p>	<p>A 2.1 Yes, it was previously all covered but as noted above in 1.2, not all uses of ionizing radiation is covered by the CNSC.</p> <p>A 2.2 n/a</p> <p>A 2.3 n/a</p>
<p><i>Response</i></p> <p>A 2.4 Was there any resistance from those sectors (if any) which were not previously covered? If so, what were the main perceived difficulties and what was done to overcome them?</p>	<p>A 2.4 n/a</p>

A 8. Dose limits and dose distribution

A 8. Dose limits and dose distribution

Questions A 3.1 – A 3.3 are aimed primarily at regulators. We would be grateful for replies from both regulators and operators for questions A 3.4 – A 3.10!

Historical limits

A 3.1 What were your dose limits before you incorporated ICRP 60?

A 3.1 Under the previous AECB regulations, there were quarterly and annual dose limits, but there were no "effective" dose limits *per se*. The following table provides our former dose limits. In addition to these, with respect to radon progeny, there was a 4 WLM limit per year, 2 WLM per quarter and 0.4 WLM for non-atomic radiation workers.

SCHEDULE II
(ss. 2, 7, 9, 15, 17, 19 and 21)
*Maximum permissible doses**

Column I Organ. Tissue	Column II Atomic Radiation Workers		Column III Female Atomic Radiation Workers of Reproductive Capacity		Column IV Any Other Person
	Rems** per Quarter of a Year	Rems** per Year	Rems per Quarter of a Year	Rems per Year	Rems per Year
Whole body, gonads, bone marrow	3	5	1.3***	5***	0.5
Bone, Skin, Thyroid	15	30	15	30	3****
Any tissue of hands, forearms, feet and ankles	38	75	38	75	7.5
Other single organs or tissues	8	15	8	15	1.5

*The maximum permissible doses specified in this Table do not apply to ionizing radiation

(a) received by a patient in the course of medical diagnosis or treatment by a qualified medical practitioner; or

(b) received by a person carrying out emergency procedures undertaken to avert danger to human life.

**The Board may, where appropriate alternatives are unavailable or impractical, permit single or accumulated doses up to twice the annual maximum permissible doses, unless, in the case of irradiation of the whole body, gonads or bone marrow, the average dose received from age 18 years up to and including the current year exceeds 5 rems per year.

***The dose to the abdomen shall not exceed 0.2 rem per two weeks, and if the person is known to be pregnant, the dose to the abdomen shall not exceed 1 rem during the remaining period of pregnancy.

****The dose to the thyroid of a person under the age of 16 years shall not exceed 1.5 rems per year.

NOTE: In determining the dose, the contribution from sources of ionizing radiation both inside and outside the body shall be included.

Current limits

A 3.2 What were your dose limits after implementation?

A 3.3 Was any flexibility built into dose limits, e.g. public limits allowed up to 5 mSv in exceptional circumstances?

A 3.4 If 5-year averaging was chosen for occupational doses, what is your experience? Were there any difficulties?

A 3.2 CNSC Dose Limits

Item	Column 1 Person	Column 2 Period	Column 3 Effective Dose (mSv)
1.	Nuclear energy worker, including a pregnant nuclear energy worker	(a) One-year dosimetry period	50
		(b) Five-year dosimetry period	100
2.	Pregnant nuclear energy worker	Balance of the pregnancy	4
3.	A person who is not a nuclear energy worker	One calendar year	1

A 8. Dose limits and dose distribution

(2) For the purpose of item 1 of the table to subsection (1), the effective dose shall be calculated using the following formula and expressed in millisievert:

$$E + 5RnP + 20 \Sigma I / ALI$$

(3) For the purpose of item 2 of the table to subsection (1), the effective dose shall be calculated using the following formula and expressed in millisievert:

$$E + 20 \Sigma I / ALI$$

(4) For the purpose of item 3 of the table to subsection (1), the effective dose shall be calculated using either of the following formulas and expressed in millisievert:

$$E + Rn / 60 + 20 \Sigma I / ALI$$

$$E + 4RnP + 20 \Sigma I / ALI$$

(5) For the purpose of subsection (1), where the end of a dosimeter-wearing period or a bioassay-sampling period does not coincide with the end of a dosimetry period set out in column 2 of the table to that subsection, the licensee may extend or reduce the dosimetry period to a maximum of two weeks so that the end of the dosimetry period coincides with the end of the dosimeter-wearing period or bioassay-sampling period, as the case may be.

EQUIVALENT DOSE LIMITS

14. (1) Every licensee shall ensure that the equivalent dose received by and committed to an organ or tissue set out in column 1 of an item of the table to this subsection, of a person described in column 2 of that item, during the period set out in column 3 of that item, does not exceed the equivalent dose set out in column 4 of that item.

TABLE

	Column 1	Column 2	Column 3	Column 4
Item	Organ or Tissue	Person	Period	Equivalent Dose (mSv)
1.	Lens of an eye	(a) Nuclear energy worker	One-year dosimetry period	150
		(b) Any other person	One calendar year	15
2.	Skin	(a) Nuclear energy worker	One-year dosimetry period	500
		(b) Any other person	One calendar year	50
3.	Hands and feet	(a) Nuclear energy worker	One-year dosimetry period	500
		(b) Any other person	One calendar year	50

A 3.3 There was no specified flexibility in the legislation, but the Commission (the tribunal that decides on licensing issues) has the authority to grant exemptions to the regulations.

Medical sector: Yes, caregivers have 5 mSv limit.

A 3.4 There were no great difficulties, but certainly a number of growing pains. Computer codes had to be changed in our National Dose Registry as well of course those of the operators and licencees. Some licencees and some of the other jurisdictions, i.e. provinces used a rolling five year period whereas the CNSC adopted a five year block. Some of the smaller licencees, such as radiographers, initially did not realize there was a five year limit.

Medical sector: While most centres do 5 year tracking for staff at their facility, I could not find examples in Canada of medical institutes who contact previous employers of new staff to apply 5-year averaging to staff with dose history at a previous institute of work/study. This would be the

A 8. Dose limits and dose distribution	
	<p>main challenge in healthcare is the turnover of staff and students with respect to the 5 year period.</p>
<p><i>Transition experience</i></p> <p>A 3.5 What was your experience of establishing these lower dose limits?</p> <p>A 3.6 Did any installation need significant rebuilding to comply with added shielding requirements? If no, how was this avoided?</p> <p>A 3.7 Were there any other difficulties? If so, what were they and how were they resolved?</p>	<p>A 3.5 The original RP Regulations proposed an annual dose limit of 20 mSv/y with no five year limit. There was considerable opposition to this, notably from uranium mines, who did not believe they could meet that limit. Also, the NPPs indicated that they would have difficulties meeting the limits when the reactors underwent refurbishment. As such, the five year limit was also added. Also, there was objection to reducing the pregnant dose limit which is discussed below.</p> <p>NPP Operator: Initial scepticism on the part of field-level managers. However, buy-in followed soon after.</p> <p>Medical sector: Due to typical occupational doses in medical applications at the time (well below the recommended changes), there were no problems meeting the lower dose limits in Canada, again, with exception to the limit for pregnancy workers which was not reduced as significantly as recommended by ICRP 60. The lower limits did require re-classification of workers, and a small increase in the number of dosimeters issued.</p> <p>A 3.6 Not that we are aware. Many of the operations were already ALARA and had taken dose savings where they could.</p> <p>NPP Operator: None</p> <p>Medical sector: None that I could find reference to (note: most information for this period was for the 8 cancer treatment centres in Ontario). Presumably the strategies discussed in response 1.10 were effective, followed by the application of stricter design dose limits to future renovations (in accordance with CNSC regulatory document G-129). G-129 states</p> <p>"Licenses are expected to reduce doses where this can be done without significant expenditures. To minimize the commitment of resources that are likely to have a poor return in safety improvement, the CNSC may consider that an ALARA assessment beyond the initial analysis, is not required in the following circumstances:</p> <ol style="list-style-type: none"> 1. the individual occupational doses are unlikely to exceed 1mSv per year. 2. Dose to individual members of the public is unlikely to exceed 50 µSv per year, and 3. The annual collective dose (both occupational and public) is unlikely to exceed 1 person-Sv." <p>To access full report, visit http://nuclearsafety.gc.ca/pubs_catalogue/uploads/G129rev1_e.pdf</p> <p>Most facilities have set design targets to meet the above criteria.</p> <p>A 3.7 Don't recall any.</p> <p>Medical sector: None of the interviewees recalled any particular difficulties with the transition experience.</p>
<p><i>Resulting doses</i></p> <p>A 3.8 What analyses of dose distributions are available for your country, over what period?</p> <p>A 3.9 Have these dose distributions changed? How?</p> <p>3.10 If yes, what was (were) the main factor(s) influencing these changes?</p>	<p>A 3.8 Health Canada's National Dose Registry publishes summary's and trends of all worker doses. They can be downloaded here: http://www.hc-sc.gc.ca/ewh-semt/pubs/occup-travail/index-eng.php#expose . The CNSC also published a review of occupational doses called Occupational Dose Data for Major Canadian Nuclear Facilities 2001-07 which can be downloaded at: http://www.nuclearsafety.gc.ca/pubs_catalogue/uploads/INFO_0775_e.pdf</p> <p>Medical sector: Health Canada publishes reports on occupational radiation exposures in Canada. Starting from 2006, these reports are available online as above</p> <p>A 3.9 Generally speaking, there has been a rise in the collective dose.</p> <p>Health sector: The overall trend in medical occupational exposures has been a decrease since ICRP 60. This can be seen by comparing the histogram for radiation therapists in 1993 to those reported from 2005 - 2010 [Ref. Ca6]. In radiation therapy, this downward trend is attributed to a reduction in design dose limits over time, a reduced manual</p>

A 8. Dose limits and dose distribution	
	<p>brachytherapy program (increased use of brachytherapy afterloaders). There are areas in healthcare where an upward trend has been reported. Once such area is radiology.</p> <p>From 2005 to 2007 a consistent trend of increasing occupational exposures was evident among Diagnostic Radiologists, Therapeutic Radiologists and Physicians. The occupational radiation exposures to other medical professionals appear to be decreasing or unchanged. These trends are consistent with our experience at The Ottawa Hospital.</p> <p>A second area where an upward trend has been closely analyzed is in the radiopharmacy (conducted by Marc Lamoureux, Medical Health Physicist, The Ottawa Hospital). At our particular facility, it was found that increase of staff and management of dose has been addressing the increased production demands for radiopharmaceuticals (cyclotron produced PET isotopes), however it is quite possible at other facilities in Canada (and internationally) that an upward trend to this group of healthcare workers is more pronounced.</p> <p>A 3.10 This is due to two major reasons, one being more frequent inspections at aging NPPs and two, the refurbishment of older reactors.</p> <p>Medical sector: The main factors attributed to the increase at the hospital were presented by Jon Aro at the 2011 Canadian Radiation Protection Association Conference as follows;</p> <ul style="list-style-type: none"> - Increase in fluoroscopy cases - 140 % increase in number of fluoroscopy cases since 2003 with no significant increase in staff. - Increase in case complexity, particularly in the Electrophysiology Lab (EP) <p>As mentioned above dose distributions in the radiopharmacy setting have increased only slightly in our experience. This has been attributed to increased production demands for PET-isotopes.</p>

A 9. Experience with specific technical aspects	
We would appreciate answers from both regulators and operators to all of these questions!	
<p><i>Pregnant workers</i></p> <p>A 4.1 What happens when an occupationally exposed worker becomes pregnant?</p> <p>A 4.2 Did the introduction of the 2 mSv limit for the abdomen (ICRP 60) or the 1 mSv limit for the embryo / fetus (Euratom Directive) cause any problems or costs?</p> <p>A 4.3 If yes, what were they and how were they resolved?</p>	<p>A 4.1 The regulations restrict the dose to 4 mSv for the balance of pregnancy. This usually requires increased monitoring and in some instances, restrictions on occupational duties.</p> <p>Medical sector: According to CNSC regulations, the following is required: Practice at our facility, the Ottawa Hospital: The pregnant worker</p> <p>1) informs supervisor in writing as soon as possible; 2) completes and signs declaration of pregnancy form description of current work with ionizing radiation; 3) informs her supervisor as soon as possible if the pregnancy is terminated.</p> <p>The supervisor analyzes work duties and advises of special work precautions/restrictions on the declaration of pregnancy form, forwards to Radiation Safety & Health Physics (RSHP) Department.</p> <p>Thus forward, the supervisor is responsible for the close monitoring of that worker's dose records. The RSHP Dept. provides advice and direction on potential risks, evaluated dose history, analyzes work duties, advises on work precautions/modifications/restrictions, monitors dose records, and may assign an electronic personal dosimeter to obtain daily dose readings/TLD for bi-weekly dose readings.</p> <p>A 4.2 Yes.</p> <p>Medical sector: N/A. The 2 mSv <i>dose limit</i> was not adopted in Canada as explained in response 1.9. That being said, the <i>recommendation</i> of 2 mSv to the surface of the abdomen for the balance of pregnancy is found in Health Canada Safety Code 20A.</p> <p>A 4.3 The original draft regulations included a dose limit of 2 mSv to the</p>

A 9. Experience with specific technical aspects	
	<p>abdomen for the balance of pregnancy. During the consultation process, there was considerable objection to the proposal from women working in radiation related fields who felt that because a dose limit of 2 mSv could lead to discrimination against women, because some employers might conclude that the only effective method of compliance with the very low dose limit would be to remove a pregnant worker from work with radiation, or not hire women at all.</p> <p>As a result, the CNSC increased the dose limit to 4 mSv for the balance of pregnancy. Notably, Health Canada, Canada's Department of National Defence and many of the provinces have also adopted the 4 mSv limit.</p> <p>Medical sector: We have not experienced difficulties meeting the ICRP 60 /Health Canada recommendation. That being said, perhaps the concern about discriminatory hiring has been addressed through the fact that these limits were somewhat voluntarily (adopted internally where senior management responsible for hiring has stakeholder input via their participation in The Ottawa Hospital Radiation Safety Committee) as opposed to a strict regulatory limit.</p>
<p><i>Constraints</i></p> <p>A 4.4 What is your experience of the introduction and use of dose constraints for occupational and public exposures?</p> <p>A 4.5 Were there any difficulties? If yes, what were they and how were they resolved?</p> <p>A 4.6 Have you at all used risk constraints? If yes, what is your experience?</p>	<p>A 4.4 The CNSC does not have any constraints as defined by the ICRP.</p> <p>Medical sector: In Canada, G-129. At the Ottawa Hospital, Investigation Levels and Action Levels for occupational exposure are employed. The numerical values of these levels are specific to the role of the healthcare worker (different levels exist for a nuclear medicine technologist versus a radiation therapist). Modified work duties are triggered when such levels are reached.</p> <p>A 4.5 N/A</p> <p>Medical sector: Determining the actual values for the levels was perhaps the most challenging aspect. CNSC guidance document G-228 "Developing and Using Action Levels" (2001) was followed. Dose history and careful consideration of operations was conducted to determine levels that would not be overly restrictive, achieving the goal of optimisation.</p> <p>A 4.6 We have used regulatory tools similar to constraints. Where applicable our regulations require Action Levels where an Action Level is a monitored level of some type, typically dose or effluent release, which if exceeded, may indicate a loss of control. In these instances, an investigation must be initiated by the licensee, the CNSC must be notified and corrective actions taken if necessary.</p> <p>The CNSC has also included secondary release limits in some licences that could be viewed as a constraint.</p> <p>Medical sector: No</p>
<p><i>Radiation Dosimetry</i></p> <p>A 4.7 Please describe briefly the organisation and regulatory framework for dosimetry in your country.</p> <p>A 4.8 Did the introduction of ICRP 60 radiation and tissue weighting factors lead to any difficulties? If yes, what were they and how were they resolved?</p> <p>A 4.9 Were there any costs associated with the implementation of the ICRP 60 dosimetric approach (e.g. dose coefficients, modelling, instrument calibration, etc.), if so, how much and borne by whom?</p>	<p>A 4.7 CNSC Act and radiation protection regulations require that licencees ascertain and record the dose of any persons with duties in respect to the licenced activities. If there is a possibility that the person may receive an effective dose of greater than five mSv, then that licensee must use a licenced dosimetry service to measure and monitor that worker's dose. Dosimetry services are licenced under the CNSC regulations and there is a regulatory document, S-106, to provide the licence criteria. The dose records are reported by the dosimetry service to Health Canada's National Dose Registry (NDR) which is the official repository of occupational dose records. The NDR will notify the CNSC, licencees and provincial authorities (where applicable) of dose exceedences and provide dose records to workers and licencees according to Privacy regulations.</p> <p>Medical sector: Occupational exposures are monitored by CNSC approved dosimetry providers. Regulations specify when occupational doses must be reported to the CNSC, and the timeframe for notification and reporting. Annual compliance reports are submitted for every CNSC license stating the average and maximum doses for each licenced activity. Results are kept in a National Dose Registry.</p> <p>A 4.8 Yes. The new regulations required the calculation and reporting of the effective dose. While internal doses were monitored previously, they were not reported as an effective dose. This required significant modifications to the National Dose Registry and the licencing of dosimetry</p>

A 9. Experience with specific technical aspects	
	<p>services. Note</p> <p>Medical sector: None that I could find reference to.</p> <p>A 4.9 Yes there were significant costs to modify the NDR as well as licence dosimetry services. The direct cost of the NDR modifications was about \$100,000 Can. The licensing of dosimetry services was partially cost recoverable, initially at about \$5k per year per dosimetry service although this does not reflect the full regulatory cost. In addition, the dosimetry service requires participation in blind intercomparisons which is run cost-free to the licensee by Health Canada.</p> <p>Medical sector: None that I could find reference to.</p>
<p><i>Radon</i></p> <p>A 4.10 Please describe briefly the current arrangements with respect to radon, in dwellings and at the workplace.</p> <p>A 4.11 Did the implementation of ICRP 60 cause any new efforts or costs? If yes, what were they and how were they resolved?</p>	<p>A 4.10 CNSC licensees are required to monitor and report exposures to radon progeny where applicable, but presently this only occurs in uranium mines. Health Canada and the provinces have a radon guideline of 200 Bq/m³ for residences work areas not under the jurisdiction of the CNSC, although federally owned buildings are required to become compliant with that limit.</p> <p>A 4.11 Other than the issues discussed above with respect to dosimetry licensing (there is one licenced radon progeny dosimetry service), there were no additional efforts in regards to radon (although the forth coming increase in the radon risk by the ICRP will impact the uranium mine industry).</p> <p>NPP Operator: None of any significance</p>

A 10. Training implications	
<p>Question A 5.1 – A 5.2 are aimed primarily at regulators, and questions A 5.3 – A 5.5 at both regulators and operators!</p>	
<p><i>Regulators' staff</i></p> <p>A 5.1 What methods did you use to ensure that relevant members of staff were aware of and understood the revised legislation?</p> <p>A 5.2 Were there any issues associated with the implement-ation of new terminology, dose coefficients, calculation meth-ods or record keeping / report-ing? If so, briefly describe?</p> <p>A 5.3 Were you involved in ensuring that stakeholders were aware of and understood the revised legislation?</p> <p>A 5.4 If so, how did you do this?</p>	<p>A 5.1 The CNSC has a comprehensive training program for employees which includes training on the intent and interpretation of all the regulations.</p> <p>A 5.2. Not too many as I recall as most were already using dose coefficients. Some licencees still use the older units (curies and REMS) which still causes some confusion.</p> <p>A 5.3 The CNSC offered training on the Act and regulations to licensees and others that are interested</p> <p>Medical sector: No not personally. Interviewing the Corporate RSO of the Ottawa Hospital, Michele Legare-Vezina, this coincided with the Nuclear Safety Control Act (NSCA) coming into effect, thus training efforts related to adoption of ICRP 60 recommendations are difficult to separate from the training efforts required for the NCSA.</p> <p>A 5.4 Medical sector: This was included in overall training needed. This large regulatory change in Canada resulted in the increase of resources allocated for the administration of the Radiation Safety Program at the Ottawa Hospital, which helped addressed the increased resources needed for training and education during the transition.</p>
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>A 5.5 What was the extent of training and information</p>	<p>A 5.5 NPP Operator: Update and Refresher training already existed as part of the overall RP Training Program.</p> <p>Medical sector: As stated in response 5.3 it was incorporated with training efforts which were required due to significant regulatory changes in Canada at the time.</p>

A 10. Training implications	
required? Was this an entirely new effort, or could it be integrated into existing schedules of recurring training? What were the costs of training?	

Part B: incorporating ICRP 103: Anticipated key impacts/provisions

B 1. General	
Questions B 1.1 to B 1.6 are aimed primarily at regulators, and questions B 1.7 - B 1.8 primarily at operators, but we welcome your replies to all queries!	
<p><i>Legislation</i></p> <p>B 1.1 Do you expect to have to change your ionising radiation protection legislation/rules if/when ICRP 103 is incorporated?</p> <p>B 1.2 If appropriate, please briefly describe the anticipated changes.</p>	<p>B 1.1 We are currently undergoing the initial stages of a review of our radiation protection regulations and will take the opportunity to update them to the applicable ICRP recommendations, although this was not the sole reason for the review.</p> <p>Medical sector: This question is best answered by the regulator. Please see presentation by Amy Hicks, CNSC [Ref. Ca3].</p> <p>B 1.2 The main topics that will be considered are the new radon and eye dose limits, constraints and weighting factors.</p>
<p><i>Organisation</i></p> <p>B 1.3 Do you expect that the incorporation of ICRP 103 will lead to any changes to the organisation and/or resources of the radiation protection regulators, compared with that reported in Section A?</p> <p>B 1.4 If appropriate, please briefly describe how consistency of approach between regulatory organisations is to be achieved?</p>	<p>B 1.3 No major changes are anticipated.</p> <p>B 1.4 By communication, principally the Canadian Federal/Provincial/Territorial Radiation Protection Committee as discussed above.</p>
<p><i>Burdens and benefits</i></p> <p>B 1.5 Does your regulatory authority expect to perform a cost-benefit analysis of the implications of any new regulations (regulatory analysis) and if so, when might a report become available (where)?</p>	<p>B 1.5 Yes, Canadian Law requires that a Regulatory Impact Analysis Statement be submitted to our governing body with the draft regulations. This will not be available for until the draft regulations are ready and that will not be for 3 to 4 years. We have attached the RIAS from the 2000 Regulations.</p>
<p><i>Cost of Not Acting</i></p> <p>B 1.6 Will the costs / savings / implications of not implementing Publication 103 be assessed? If so, when?</p>	<p>B 1.6 Not directly, but we would not imagine it being any different than the current status quo.</p>

B 1. General	
<p><i>Anticipated costs</i> ICRP 103 and the new Euratom Directive will entail, e.g., - amended w_R and w_T; - added emphasis on dose constraints.</p> <p>B 1.7 How do you expect these new requirements arising from ICRP 103 to impact on operations?</p> <p>B 1.8 Do you anticipate that the incorporation of ICRP 103 may lead to any reduction of any kind of cost or effort?</p>	<p>B 1.7 N/A (Operator response?) Medical sector: As discussed in response B.2.3, significant health physics resources are anticipated to determine projected effective doses from each individual source in the hospital and to validate those projections. Health physics resources would also be required to re-work bio-kinetic models for uptake of radiopharmaceuticals used in estimation of patient doses, which is performed routinely for volunteers participating in human studies and on a case-by-case basis for patients under special circumstances (i.e. pregnancy discovered after procedure). The only other area where additional costs might be for waste disposal, depending on how the new recommendations focused on protection of the environment are incorporated into the Nuclear Safety Control Act in Canada (dose restrictions to flora and fauna). Disposal limits determined by the CNSC and are clearly set out in our CNSC issued licenses. Reducing these limits would result in increased costs to the licensee.</p> <p>B 1.8 N/A (operator response?) Medical sector: No</p>

B 2. Experience with specific technical aspects	
<p>We would appreciate answers from both regulators and operators to all of these questions!</p>	
<p><i>Pregnant workers</i> B 2.1 Do you envisage that the introduction of the 1 mSv limit for the embryo / fetus (ICRP 103) will cause any problems or costs? <i>(Note: this question does not apply to EU member countries since the current Euratom BSS Directive already prescribes such a limit).</i></p> <p>B 2.2 If yes, what might they be, and how do you plan to resolve them?</p>	<p>B 2.1 While the current dose limit for pregnant workers would be open to change during the review, it has undergone two major consultation processes and so we don't anticipate changing it, Medical sector: Due to the impact of stakeholder comments and concerns with reducing the dose limit for pregnant workers when ICRP 60 pregnancy dose limits were considered, most notably the concern about discriminatory hiring, I believe the same problem can be anticipated. If adopted, one significant problem would be that staff who do not have a reasonable probability of exceeding 1 mSv/yr are not currently classified as Nuclear Energy Workers, and not required to declare their pregnancy to their employer. This would require revisiting classification of workers, and redefining requirements for the "declaration of pregnancy" in the regulations.</p> <p>B 2.2 n/a Medical sector: I am not sure how the risk of discriminatory hiring can be resolved.</p>

B 2. Experience with specific technical aspects	
<p><i>Constraints</i></p> <p>B 2.3 Is the added emphasis on dose constraints in ICRP 103 expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p> <p>B 2.4 Are risk constraints likely to be introduced with the implementation of ICRP 103?</p>	<p>B 2.3 Yes, there is already wide opposition to the use of dose constraints, both inside and outside of the CNSC. Nevertheless we will put them forward for discussion.</p> <p>NPP Operator: Firm dose constraints could cause difficulties if they're implemented as <i>de facto</i> source-specific (meaning from our operations) dose limits set at values lower than existing dose limits. Depending on the dose levels chosen or imposed, operations and refurbishment projects could be impacted. The impacts are likely to be restricted to occupational exposure,</p> <p>Medical sector: With the many sources used at the hospital, it would take significant health physics resources to determine the projected effective dose from each source. That being said, the radiological protection requirements outlined in the framework (Table 9, p.), are already standard practice (information on the level of exposure (survey results) and how to reduce their dose is provided in regular radiation safety training). One resolution would be to restrict efforts to roles in which hospital staff are receiving dose above a certain threshold, and those in which doses have been stable or increasing over the last several years (increases seen in radiology and processing of cyclotron produced radiopharmaceuticals), identifying dominant sources, and applying constraints.</p> <p>B 2.4 Very difficult to predict at this time, but for it to happen, there must be a demonstrated of need or benefit for dose constraints and that is not apparent at this time.</p> <p>Medical sector: Yes, in emergency preparedness and response, though the concept fits well with the current guidance /best practice in these areas.</p>
<p><i>Dosimetry</i></p> <p>B 2.5 Are the new ICRP 103 radiation and tissue weighting factors expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.5 No, the new weighting factors should not cause any undue difficulties.</p> <p>Medical sector:</p> <p>Radiation Weighting Factors. No. Neutron and proton weighting factors are not used in our applications.</p> <p>Tissue Weighting Factors. No. As occupational exposures in healthcare applications do not involve partial irradiation to the organs/tissues for which significant changes have been recommended, we do not feel the new radiation and tissue weighting factors will affect occupational radiation safety. Clinically, we cannot foresee changing the administered doses of radiopharmaceuticals for diagnosis/treatment based on these new tissue weighting factors. The only change we expect is the re-working of our bio kinetic models used to estimate doses to patients or volunteers involved in human studies</p>
<p><i>Radon</i></p> <p>B 2.6 Is the implementation of ICRP 103 expected to cause any new efforts or costs with respect to radon? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.6 NPP Operator: N/A</p> <p>Medical sector - No, not in our applications.</p>

B 3. Training implications	
<p>Questions 3.1 – 3.3 are aimed primarily at regulators, and question 3.4 at both regulators and operators!</p>	
<p><i>Regulators' staff</i></p> <p>B 3.1 What methods do you plan to use to ensure that relevant members of staff were aware of and understood the revised</p>	<p>B 3.1 There will be a formal training program for the new regulations.</p> <p>B 3.2 No, no issues anticipated.</p> <p>B 3.3 Yes, stakeholders will be widely informed and consulted during the entire regulation amendment process. This will be done by bulletins, web</p>

B 3. Training implications	
<p>legislation? B 3.2 Do you anticipate any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe? B 3.3 Do you expect to be involved in ensuring that stakeholders are aware of and understood the revised legislation? If so, how do you anticipate doing this?</p>	<p>postings and public meetings.</p>
<p><i>Stakeholders (primarily licensees, users, and employers)</i> B 3.4 What do you expect will be the extent of training and information required? Will this be an entirely new effort, or could it be integrated into existing schedules of recurring training? What may be the anticipated costs of training?</p>	<p>B 3.4 N/A NPP Operator: Integration into existing training programs and schedules. Medical sector: If Canadian regulations and guidance documents are amended, I expect training/information required to include;</p> <ul style="list-style-type: none"> - Presentation to senior management - Presentation to Radiation Safety Committee - Revision to internal Radiation Safety Manual to align with any amendments to Canadian Regulations - Amendment to CNSC licenses to reference newly revised Radiation Safety Manual - Revision to radiation safety training to reflect any amendments to Canadian Regulations - Incorporation of changes to operators in annual training <p>With the exception to presentation to senior management and amendments to the Radiation Safety Manual, information can be incorporated into standing Radiation Safety Committee meetings, annual radiation safety training, and training for new staff.</p>

And finally: Is there anything else that you wish to add?

[Please add any 'open' comments here!]

Medical sector: The impact of ICRP 103 to medical facilities will ultimately depend on how federal and provincial regulatory bodies incorporate these concepts into regulation. The outreach to stakeholders analogous to the issuance of C-122 for stakeholders comment in 1991 addressing ICRP 60 recommendations has not yet happened for ICRP 103.

That being said, as discussed in the above questionnaire, the impact of ICRP 103 is anticipated to be minimal on current medical practice, as many of the changes do not apply/significantly impact our operations. With doses to patients from medical procedures not currently addressed in Canadian Legislation, such standards (i.e. Dose Reference Levels, concepts of justification and optimization) provide guidance for practitioners, however do not fit into current regulatory framework. Should the regulatory framework in Canada change to encompass oversight of doses to patients, this would have large implications in the practice of Radiation Safety/Health Physics at the Ottawa Hospital. Currently our mandate is limited to occupational exposures, unless a malfunction of a radiation-emitting device is involved.

Many thanks to the following individuals who were interviewed about the transition experience when ICRP 60 recommendations were adopted in Canada [listed in Section 6, Acknowledgements].

Questionnaire v.2.0 - completed for [country]: CZECH REPUBLIC

**NEA Project for Obtaining Historical Information on Costs and Impacts of Incorporating ICRP Publ. 60 and Possible Resources for Incorporating ICRP Publ. 103
Part A: incorporating ICRP 60: Key impacts/provisions**

NOTE: for EU Member States: references to incorporation of ICRP 60 should be read as implementation of Directives 96/29/Euratom and 97/43/Euratom.

A 11. General	
Questions A 1.1 to A 1.9 are aimed primarily at regulators, and questions A 1.10 – A 1.11 primarily at operators, but we welcome your replies to all queries!	
Question	Your experience
<p><i>Legislation</i></p> <p>A 1.1 Please describe briefly the hierarchy, if applicable, of ionising radiation protection legislation/rules in your country, e.g. national law, national government regulations; central authority regulations; regional or local authority regulations; other (e.g., professional body) rules. Also, please briefly describe what is covered at each level.</p>	<p>A 1.1</p> <p>Atomic act (No 18/1997 Coll. as amended) – covering position and competences of State office for nuclear safety (as national regulatory body on the field of nuclear safety and radiation protection) and rights and obligations of licensees and other persons involved in this field</p> <p>Regulations issued by State office for nuclear safety:</p> <p>Radiation protection regulation (No 307/2002 Coll. as amended) – covering details on handling and other related activities with ionizing sources and radioactive waste, including medical exposure, natural sources etc.</p> <p>Other regulations (on type approval of sources, qualification and training etc.)</p> <p>Recommendations issued by State office for nuclear safety (not binding): methodologies and procedures specific for different types of sources and workplaces</p>
<p><i>Organisation</i></p> <p>A1.2 Describe the different authorities, and (approximately) how many regulators are involved in making and enforcing radiation protection legislation? Also, if appropriate, please briefly describe how consistency of approach between regulatory organisations is achieved?</p>	<p>A 1.2</p> <p>State office for nuclear safety of the Czech republic is main regulator (independent authority subordinated directly to the government).</p> <p>Some issues interfere with other departments; especially medical exposure is partly covered by ministry of health.</p> <p>Consistency is achieved on the practical level through sharing findings, results and experiences and on the legislation level through mandatory comment procedures during law and regulation making process (governmental legislation council is guarantee)</p>
<p><i>ICRP 60 incorporation</i></p> <p>A 1.3 To what extent were legislation and regulations rewritten when ICRP 60 was incorporated?</p> <p>A 1.4 What was the procedure, what problems and efforts were there?</p>	<p>A 1.3</p> <p>Due to political and social changes in our country in the nineties whole law system was revised. Newly created atomic law and regulations mentioned above were prepared with regard to the ICRP 60 recommendation</p> <p>A 1.4 It was very specific situation because radiation protection was “delimited”/moved from the resort of Ministry of Health to Nuclear Safety Administration and quite new legislation was developed.</p>

A 11. General	
<p><i>Stakeholders</i></p> <p>A 1.5 Who were the stakeholders (e.g. other ministries, operators, etc.) and how was their involvement achieved?</p>	<p>A 1.5</p> <p>Ministries and other governmental bodies were involved through mandatory comment procedure.</p> <p>NPP operator and professional public (as professional societies, universities etc.) were also addressed to make their comments and suggestions.</p>
<p><i>Guidance</i></p> <p>A 1.6 How was guidance on the implementing legislation developed and by whom (e.g.: regulatory authorities; professional societies, trade organisations)?</p>	<p>A 1.6</p> <p>It was mainly developed by State office for nuclear safety or on its initiative and under its support.</p>
<p><i>Time-scales</i></p> <p>A 1.7 What were the lead-in times for new requirements, i.e., when were they proposed, when decided, when was full compliance by operators required?</p>	<p>A 1.7</p> <p>Full compliance was required when atomic law entered into force in 1997. New requirements were proposed, discussed and agreed during its preparation process (starts at 1994).</p>
<p><i>Burdens and benefits</i></p> <p>A 1.8 Did your regulatory authority perform a cost-benefit analysis of the implications of any new regulations, (regulatory analysis) and if so is there a report available (where)?</p>	<p>A 1.8</p> <p>No, it was not mandatory at that time. (now it is obligatory part of the legislation process)</p>
<p><i>Cost of Not Acting</i></p> <p>A 1.9 Were the costs/savings/implications of not implementing ICRP 60 assessed? If so, what were they?</p>	<p>A 1.9</p> <p>No, it was not mandatory at that time. (now it is obligatory part of the legislation process)</p>
<p><i>Actual costs</i></p> <p>ICRP 60 and Euratom Directives 96/29 and 97/43 entailed, e.g., that</p> <ul style="list-style-type: none"> -the annual limit on occupational effective dose was reduced from 50 to 20 mSv, with an option of 5-year averaging; - it was clarified that the annual limit on effective dose to members of the public is 1 mSv, not 5 mSv; - effective dose (with new 	<p>A 1.10 There were not identified any significant problems on operational level.</p> <p>A 1.11</p>

A 11. General	
<p>weighting factors w_R and w_T) replaced the effective dose equivalent;</p> <ul style="list-style-type: none"> - the concepts of dose and risk constraints were introduced; - diagnostic reference levels were introduced. <p>A 1.10 How did these new requirements arising from ICRP 60 impact on operations?</p> <p>A 1.11 Did the incorporation of ICRP 60 lead to any reduction of any kind of cost or effort?</p>	

A 2. Application / scope	
<p>Questions A 2.1 to A 2.2 are aimed primarily at regulators. We are grateful for replies from both operators and regulators to questions A 2.3 - A 2.4!</p>	
<p><i>Scope</i></p> <p>A 2.1 Did pre-ICRP 60 legislation in your country cover all uses and users of ionising radiation, e.g.: industrial applications (including industrial radiography), medical applications (diagnostic and therapeutic), nuclear fuel cycle, research and teaching, transport, radioactive waste disposal, occupational exposure to radon (mining and non-mining), agriculture?</p> <p>A 2.2 If not, was new legislation introduced to close the previous gaps?</p> <p>A 2.3 Did the timeframe for implementation vary for the sectors described in A 2.1? If so, how?</p>	<p>Yes, it covered all listed uses and users.</p>
<p><i>Response</i></p> <p>A 2.4 Was there any resistance from those sectors (if any) which were not previously covered? If so, what were the main</p>	

A 2. Application / scope	
perceived difficulties and what was done to overcome them?	

A 13. Dose limits and dose distribution
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Questions A 3.1 – A 3.3 are aimed primarily at regulators. We would be grateful for replies from both regulators and operators for questions A 3.4 – A 3.10!

<i>Historical limits</i> A 3.1 What were your dose limits before you incorporated ICRP 60?	A 3.1 50 mSv/y for effective dose
<i>Current limits</i> A 3.2 What were your dose limits after implementation? A 3.3 Was any flexibility built into dose limits, e.g. public limits allowed up to 5 mSv in exceptional circumstances? A 3.4 If 5-year averaging was chosen for occupational doses, what is your experience? Were there any difficulties?	A 3.2 100 mSv/5years and 50mSv/y A 3.3 yes, but in fact no practical use A 3.4 no difficulties, because of national register of doses we are able to control sum of doses
<i>Transition experience</i> A 3.5 What was your experience of establishing these lower dose limits? A 3.6 Did any installation need significant rebuilding to comply with added shielding requirements? If no, how was this avoided? A 3.7 Were there any other difficulties? If so, what were they and how were they resolved?	A 3.5 A 3.6 No, as we remember it A 3.7 generally it is difficult for us to answer these questions – all persons deeply involved in that time in creation of new legislation and working as inspectors are not any more in our office
<i>Resulting doses</i> A 3.8 What analyses of dose distributions are available for your country, over what period? A 3.9 Have these dose distributions changed? How?	A 3.8 we have distribution of doses from 1997 – so only after new legislation entered into force A 3.9 A 3.10

A 13. Dose limits and dose distribution	
3.10 If yes, what was (were) the main factor(s) influencing these changes?	
A 14. Experience with specific technical aspects	
We would appreciate answers from both regulators and operators to all of these questions!	
<p><i>Pregnant workers</i></p> <p>A 4.1 What happens when an occupationally exposed worker becomes pregnant?</p> <p>A 4.2 Did the introduction of the 2 mSv limit for the abdomen (ICRP 60) or the 1 mSv limit for the embryo / fetus (Euratom Directive) cause any problems or costs?</p> <p>A 4.3 If yes, what were they and how were they resolved?</p>	<p>A 4.1 When woman (radiation worker) becomes pregnant the exposure of foetus should be reduced by a modification of working conditions so that the sum of effective doses from external exposure and committed effective doses from internal exposure of the foetus shall not exceed 1 mSv over the remaining period of pregnancy. It is fully in responsibility of her employer. After notifying that as a radiation worker, the woman is breastfeeding, the exposure of an infant by intake of radionuclides from milk shall be immediately reduced by a modification of working conditions or her suspension from work in the controlled area</p> <p>A 4.2 The introduction of the limit (1 mSv for the embryo/fetus) does not cause any problems.</p>
<p><i>Constraints</i></p> <p>A 4.4 What is your experience of the introduction and use of dose constraints for occupational and public exposures?</p> <p>A 4.5 Were there any difficulties? If yes, what were they and how were they resolved?</p> <p>A 4.6 Have you at all used risk constraints? If yes, what is your experience?</p>	<p>A 4.4 we have not actually a dose constraints for occupational exposures</p> <p>A 4.5 For public exposure, the dose constraint is an upper bound of the annual dose that members of the critical group of the public could receive from a discharge of radioactive substances into environment. The dose constraint for a total discharge of radioactive substances from a workplace where radiation activities are performed is set to average effective dose of 250 µSv per year for a member of a critical group of public, for nuclear power plants to 200 µSv for airborne discharges and to 50 µSv for watercourse discharges. Nuclear power plants perform an optimization process and on the base of its results the SUJB sets down authorized discharge limits for the NPP. The authorized discharge limits are site specific. Currently there are set down authorized limits for NPP Dukovany 40 µSv for airborne discharges and 6 µSv for watercourse discharges and for NPP Temelín 40 µSv for airborne discharges and 3 µSv for watercourse discharges.</p> <p>A 4.6</p>
<p><i>Radiation Dosimetry</i></p> <p>A 4.7 Please describe briefly the organisation and regulatory framework</p>	<p>A 4.7 for personal dosimetry the license is required, metrological control every one year,</p> <p>A 4.8 no</p>

A 14. Experience with specific technical aspects	
<p>for dosimetry in your country.</p> <p>A 4.8 Did the introduction of ICRP 60 radiation and tissue weighting factors lead to any difficulties? If yes, what were they and how were they resolved?</p> <p>A 4.9 Were there any costs associated with the implementation of the ICRP 60 dosimetric approach (e.g. dose coefficients, modelling, instrument calibration, etc.), if so, how much and borne by whom?</p>	<p>A 4.9 as we know - NO</p>
<p><i>Radon</i></p> <p>A 4.10 Please describe briefly the current arrangements with respect to radon, in dwellings and at the workplace.</p> <p>A 4.11 Did the implementation of ICRP 60 cause any new efforts or costs? If yes, what were they and how were they resolved?</p>	<p>A 4.10 Dwellings: There is a guidance level of 400 Bq/m³ for existing dwellings and of 200 Bq/m³ for new dwellings. The Radon Program of the Czech Republic is under go, free of charge detectors for radon concentration measurement are provided, methods and technologies for remediation are available. If the radon concentration in a flat is higher than 1000 Bq/m³, there is a possibility of state financial subsidy up to 6000 Eur.</p> <p>Workplaces: In the decree on radiation protection there is a list of workplaces with increased possibility of exposure to radon. The owners must ensure radon concentration measurement in such a workplaces. If the radon concentration is higher than 400 Bq/m³, other investigation must be done to evaluate, if the annual effective dose can be higher than 6 mSv. In that case appropriate measures must be accepted to lower the radon concentration or the workers must be protected in the same way like workers in controlled areas.</p> <p>A 4.11 Since 1991 exposure to radon has been regulated by the legislative of the Czech Republic. There was state financial support mainly for measurement of radon concentration and for development of technologies for remediation. The Radon Program of the Czech Republic continues up to now.</p>

A 15. Training implications	
<p>Question A 5.1 – A 5.2 are aimed primarily at regulators, and questions A 5.3 – A 5.5 at both regulators and operators!</p>	
<p><i>Regulators' staff</i></p> <p>A 5.1 What methods did you use to ensure that relevant members of staff were aware of and understood the revised legislation?</p> <p>A 5.2 Were there any issues associated with the</p>	<p>A 5.1 Each licensee shall appoint at least one person in charge of radiation protection matters – a Radiation protection officer (RPO) and a corresponding number of persons with direct responsibility for radiation protection. These persons shall have a special professional competence taking into account the ionising radiation sources and a job profile. RPOs are responsible for annually on-job-training of radiation workers. According to the SONS regulation, a medical physicist (MP) shall be involved in the medical unit using X-ray practice. He/she shall be responsible for accuracy and safety of ionizing radiation application in clinical practice, for managing the testing of ionizing radiation sources. However, MP is a health profession according to legislation of Ministry of Health (competence requirements, activities of MPs are defined in the Ministry of Health regulation), the legislation of SONS will not be in full agreement with legislation of Ministry of Health, due to different competence requirements on MP</p>

A 15. Training implications	
<p>implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?</p> <p>A 5.3 Were you involved in ensuring that stakeholders were aware of and understood the revised legislation?</p> <p>A 5.4 If so, how did you do this?</p>	<p>and RPO.</p> <p>A 5.2.</p> <p>A 5.3 The verification of special professional competence of RPO is carried out before the examining commission of the SONS. The requirements for an RPO are education, 1 year experience in RP, 4 days course on RP (if working in the controlled area). The training facilities providing the courses are accredited by SONS, SONS inspectors participate as a lecturers.</p> <p>A 5.4</p>
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>A 5.5 What was the extent of training and information required? Was this an entirely new effort, or could it be integrated into existing schedules of recurring training? What were the costs of training?</p>	<p>A 5.5</p>

Part B: incorporating ICRP 103: Anticipated key impacts/provisions

B 1. General	
<p>Questions B 1.1 to B 1.6 are aimed primarily at regulators, and questions B 1.7 - B 1.8 primarily at operators, but we welcome your replies to all queries!</p>	
<p><i>Legislation</i></p> <p>B 1.1 Do you expect to have to change your ionising radiation protection legislation/rules if/when ICRP 103 is incorporated?</p> <p>B 1.2 If appropriate, please briefly describe the anticipated changes.</p>	<p>B 1.1</p> <p>Yes. But revision of the atomic law and related regulations are planned anyway due to changes in European law, expected construction of the new nuclear source and experience collected during the validity of current law</p> <p>B 1.2</p> <p>Some changes of terminology and values, incorporating of the “exposure situation” concept, changes in the approach to optimalization etc.</p>
<p><i>Organisation</i></p> <p>B 1.3 Do you expect that the incorporation of ICRP 103 will lead to any changes to the organisation and/or resources of the radiation protection regulators,</p>	<p>B 1.3</p> <p>No.</p> <p>B 1.4</p>

B 1. General	
<p>compared with that reported in Section A?</p> <p>B 1.4 If appropriate, please briefly describe how consistency of approach between regulatory organisations is to be achieved?</p>	
<p><i>Burdens and benefits</i></p> <p>B 1.5 Does your regulatory authority expect to perform a cost-benefit analysis of the implications of any new regulations (regulatory analysis) and if so, when might a report become available (where)?</p>	<p>B 1.5</p> <p>Yes, it is obligatory part of the legislation process. Final report will be available after adoption of the law or regulation.</p>
<p><i>Cost of Not Acting</i></p> <p>B 1.6 Will the costs / savings / implications of not implementing Publication 103 be assessed? If so, when?</p>	<p>B 1.6</p> <p>Yes, it is obligatory part of the legislation process. Final report will be available after adoption of the law or regulation.</p>
<p><i>Anticipated costs</i></p> <p>ICRP 103 and the new Euratom Directive will entail, e.g.,</p> <ul style="list-style-type: none"> - amended w_R and w_T; - added emphasis on dose constraints. <p>B 1.7 How do you expect these new requirements arising from ICRP 103 to impact on operations?</p> <p>B 1.8 Do you anticipate that the incorporation of ICRP 103 may lead to any reduction of any kind of cost or effort?</p>	<p>B 1.7 we are not able to estimate it now</p> <p>B 1.8</p>

B 2. Experience with specific technical aspects	
<p>We would appreciate answers from both regulators and operators to all of these questions!</p>	
<p><i>Pregnant workers</i></p> <p>B 2.1 Do you envisage that the introduction of the 1 mSv limit for the embryo</p>	<p>B 2.1</p> <p>B 2.2</p>

B 2. Experience with specific technical aspects	
<p>/ fetus (ICRP 103) will cause any problems or costs? (<i>Note: this question does not apply to EU member countries since the current Euratom BSS Directive already prescribes such a limit.</i>)</p> <p>B 2.2 If yes, what might they be, and how do you plan to resolve them?</p>	
<p><i>Constraints</i></p> <p>B 2.3 Is the added emphasis on dose constraints in ICRP 103 expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p> <p>B 2.4 Are risk constraints likely to be introduced with the implementation of ICRP 103?</p>	<p>B 2.3 NO</p> <p>B 2.4 maybe</p>
<p><i>Dosimetry</i></p> <p>B 2.5 Are the new ICRP 103 radiation and tissue weighting factors expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.5 No</p>
<p><i>Radon</i></p> <p>B 2.6 Is the implementation of ICRP 103 expected to cause any new efforts or costs with respect to radon? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.6</p> <p>B 2.6 No special new effort or costs are expected.</p>

B 3. Training implications	
<p>Questions 3.1 – 3.3 are aimed primarily at regulators, and question 3.4 at both regulators and operators!</p>	
<p><i>Regulators' staff</i></p> <p>B 3.1 What methods do you plan to use to ensure that relevant members of staff were aware of and understood the revised</p>	<p>B 3.1</p> <p>B 3.2</p> <p>B 3.3</p>

B 3. Training implications	
<p>legislation?</p> <p>B 3.2 Do you anticipate any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?</p> <p>B 3.3 Do you expect to be involved in ensuring that stakeholders are aware of and understood the revised legislation? If so, how do you anticipate doing this?</p>	
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>B 3.4 What do you expect will be the extent of training and information required? Will this be an entirely new effort, or could it be integrated into existing schedules of recurring training? What may be the anticipated costs of training?</p>	B 3.4

And finally: Is there anything else that you wish to add?

[Please add any 'open' comments here!]

Dear Jack, finally (ufffff!) we have filled something – it is not perfect, but I am afraid we are not able to add much more. Concerning the retrospective estimation of the costs I would like to pointed out that the implementation of ICRP60 and IBSS 1994 happened just after political changes in our country and whole legislative system went through dramatic changes – so nobody really took care about the costs – moreover in our “small” field. Now it is obligatory to do a kind of regulatory impact assessment as it is popular everywhere and we do it “ somehow” but for implementation of ICRP 103 is too early for us. We are now in the stage of preparation of quite new Atomic Law and all related legislation where we intent to implement also some aspects of ICRP103 and of course to be prepared also for new European legislation already but we are really in the beginning. We have prepared some kind of “objectives” for new legislation where major changes are identified (but the real major changes are like the complete change of financing of our office or quite new organizational structure or some specific problems of nuclear safety – so in this light our “radiation protection problems” are at this stage too small for more detailed specification of possible impacts.

So our answers are sometimes not so precise and detailed as maybe expected, but we are prepare to provide you always with more info where and if you feel it is for this purpose necessary.

Dear Jack

I have read the questionnaire quickly and regret that I am not in a position to provide a detailed reply due to my work situation which is hectic with so many people on vacation.

There is the legislation passed by parliament and regulations by the ministry followed by guidelines by the regulator. Regulator prepares proposals for new legislation and regulations. Legislation covers the whole field of radiation safety. Geislavarnir is the regulator. ICRP 60 did not prompt changes in legislation but changes were introduced at the time of next revision at minor cost and minor impact on operation. There were no significant problems or cost issues in the implementation of ICRP 60 in Iceland.

I hope that this very short reply is better than no reply at all.

Sigurður M

Questionnaire v.2.0 - completed for [country]: KOREA, Republic of

**NEA Project for Obtaining Historical Information on Costs and Impacts of Incorporating ICRP Publ. 60 and Possible Resources for Incorporating ICRP Publ. 103
Part A: incorporating ICRP 60: Key impacts/provisions**

NOTE: for EU Member States: references to incorporation of ICRP 60 should be read as implementation of Directives 96/29/Euratom and 97/43/Euratom.

A 16. General	
Questions A 1.1 to A 1.9 are aimed primarily at regulators, and questions A 1.10 – A 1.11 primarily at operators, but we welcome your replies to all queries!	
Question	Your experience
<p><i>Legislation</i></p> <p>A 1.1 Please describe briefly the hierarchy, if applicable, of ionising radiation protection legislation/rules in your country, e.g. national law, national government regulations; central authority regulations; regional or local authority regulations; other (e.g., professional body) rules. Also, please briefly describe what is covered at each level.</p>	<p>A 1.1 [Please fill in your reply here!]</p> <p>Atomic Energy Act, Enforcement Decree of the Atomic Energy Act, Enforcement Regulation of the Atomic Energy Act, Regulations on Technical Standards for Nuclear Reactor Facilities, Regulations on Technical Standards for Radiation Safety Control, Ministries Notices for Radiation Protection, etc.</p> <p>Act on Physical Protection and Radiological Emergency, Enforcement Decree, Enforcement Regulation, and related Ministries Notices.</p> <p>Medical Act, Enforcement Decree, Enforcement Regulation, and related Ministries Notices.</p>
<p><i>Organisation</i></p> <p>A1.2 Describe the different authorities, and (approximately) how many regulators are involved in making and enforcing radiation protection legislation? Also, if appropriate, please briefly describe how consistency of approach between regulatory organisations is achieved?</p>	<p>A 1.2</p> <p>MEST(Min. of Education, Science and Technology)/KINS(Korea Institute of Nuclear Safety) and MHW(Min. of Health and Welfare)/KFDA(Korea Food and Drug Administration)</p> <p>MEST/KINS: ~500, MHW/KFDA: ~500</p> <p>MEST/KINS do implement first ICRP recommendations, MHW/KFDA follows.</p>
<p><i>ICRP 60 incorporation</i></p> <p>A 1.3 To what extent were legislation and regulations rewritten when ICRP 60 was incorporated?</p> <p>A 1.4 What was the procedure, what problems and efforts were there?</p>	<p>A 1.3 Fully implemented in 1998; dose limits, dose constraints, radiation weighting factors and tissue weighting factors, exemption and clearance concept(IAEA BSS 115), etc., but there were 5 years of waiving time for radiation worker dose limits considering the impacts to the utilities.</p> <p>A 1.4 KINS studied first the ICRP 60 recommendation as well as the IAEA BSS 115, developed the items of the provision to be revised, held several workshops, meetings, debates and discussions, and then reported the final draft to the MEST. MEST promulgated the revised legislation through another public hearing.</p>

A 16. General	
<p><i>Stakeholders</i></p> <p>A 1.5 Who were the stakeholders (e.g. other ministries, operators, etc.) and how was their involvement achieved?</p>	<p>A 1.5</p> <p>Stakeholders: utilities (NPP designers, constructors, operators), authorized users of the radiation sources, related organizations, intellectuals, public representatives....</p> <p>They were involved in workshops, meeting and debates of KINS, reviewed and asked to modify the draft, and involved also in the process of public hearing of MEST.</p>
<p><i>Guidance</i></p> <p>A 1.6 How was guidance on the implementing legislation developed and by whom (e.g.: regulatory authorities; professional societies, trade organisations)?</p>	<p>A 1.6</p> <p>KINS(regulatory authority) issued the explanation report of the draft of legislation and introduced it through workshops, meetings, debates, etc.</p>
<p><i>Time-scales</i></p> <p>A 1.7 What were the lead-in times for new requirements, i.e., when were they proposed, when decided, when was full compliance by operators required?</p>	<p>A 1.7</p> <p>KINS issued the first draft in July 1994.</p> <p>MEST(MOST, in that time) promulgated the legislation in August 1998.</p> <p>The full compliance by the utilities was from August 2003.</p>
<p><i>Burdens and benefits</i></p> <p>A 1.8 Did your regulatory authority perform a cost-benefit analysis of the implications of any new regulations, (regulatory analysis) and if so is there a report available (where)?</p>	<p>A 1.8</p> <p>No.</p>
<p><i>Cost of Not Acting</i></p> <p>A 1.9 Were the costs/savings/implications of not implementing ICRP 60 assessed? If so, what were they?</p>	<p>A 1.9</p> <p>No.</p>
<p><i>Actual costs</i></p> <p>ICRP 60 and Euratom Directives 96/29 and 97/43 entailed, e.g., that</p> <ul style="list-style-type: none"> -the annual limit on occupational effective dose was reduced from 50 to 20 mSv, with an option of 5-year averaging; - it was clarified that the annual limit on effective dose to members of the public is 1 mSv, not 5 mSv; 	<p>A 1.10</p> <p>The new annual limits on occupational effective dose do not seriously impact on the utilities, because the occupational doses were already far below the new limit.</p> <p>The dose constraints and the optimisation process was a little confused to apply by the utilities as well as the regulatory authority.</p> <p>A 1.11</p>

A 16. General	
<ul style="list-style-type: none"> - effective dose (with new weighting factors w_R and w_T) replaced the effective dose equivalent; - the concepts of dose and risk constraints were introduced; - diagnostic reference levels were introduced. <p>A 1.10 How did these new requirements arising from ICRP 60 impact on operations?</p> <p>A 1.11 Did the incorporation of ICRP 60 lead to any reduction of any kind of cost or effort?</p>	

A 17. Application / scope	
<p>Questions A 2.1 to A 2.2 are aimed primarily at regulators. We are grateful for replies from both operators and regulators to questions A 2.3 - A 2.4!</p>	
<p><i>Scope</i></p> <p>A 2.1 Did pre-ICRP 60 legislation in your country cover all uses and users of ionising radiation, e.g.: industrial applications (including industrial radiography), medical applications (diagnostic and therapeutic), nuclear fuel cycle, research and teaching, transport, radioactive waste disposal, occupational exposure to radon (mining and non-mining), agriculture?</p> <p>A 2.2 If not, was new legislation introduced to close the previous gaps?</p> <p>A 2.3 Did the timeframe for implementation vary for the sectors described in A 2.1? If so, how?</p>	<p>A 2.1 yes, except for radon</p> <p>A 2.2 -</p> <p>A 2.3 -</p>
<p><i>Response</i></p> <p>A 2.4 Was there any resistance from those sectors (if any) which were not previously covered? If</p>	<p>A 2.4</p>

A 17. Application / scope	
so, what were the main perceived difficulties and what was done to overcome them?	
A 18. Dose limits and dose distribution	
Questions A 3.1 – A 3.3 are aimed primarily at regulators. We would be grateful for replies from both regulators and operators for questions A 3.4 – A 3.10!	
<p><i>Historical limits</i> A 3.1 What were your dose limits before you incorporated ICRP 60?</p>	A 3.1 50(N-18) mSv and 30 mSv/3months, etc...(that is, recommendation of the ICRP 9)
<p><i>Current limits</i> A 3.2 What were your dose limits after implementation? A 3.3 Was any flexibility built into dose limits, e.g. public limits allowed up to 5 mSv in exceptional circumstances? A 3.4 If 5-year averaging was chosen for occupational doses, what is your experience? Were there any difficulties?</p>	<p>A 3.2 for occupational dose: 100mSv for 5 years, 50 mSv in any single year; for public 1 mSv in a year.</p> <p>A 3.3 yes (in special circumstances, a higher value could be allowed in a single year, provided the average over 5 years does not exceed 1 mSv per year)</p> <p>A 3.4 No, there isn't.</p>
<p><i>Transition experience</i> A 3.5 What was your experience of establishing these lower dose limits? A 3.6 Did any installation need significant rebuilding to comply with added shielding requirements? If no, how was this avoided? A 3.7 Were there any other difficulties? If so, what were they and how were they resolved?</p>	<p>A 3.5 The most important thing was the understanding of the stakeholders and preparation to implement by them.</p> <p>A 3.6 No, it could be solved by the access control and occupancy control.</p> <p>A 3.7</p>
<p><i>Resulting doses</i> A 3.8 What analyses of dose distributions are available for your country, over what period? A 3.9 Have these dose distributions changed?</p>	<p>A 3.8 We have collecting the occupational exposure data for the employees of NPPs and the radiation source utilities and it has been reported to ISOE since 1996 and UNSCEAR.</p> <p>A 3.9 yes. The occupational dose distributions have been reduced year by year.</p> <p>A 3.10 The main factors of the dose reductions would be the implementation of the optimization principle. The ALARA provision was added in the national regulation in 1995.</p>

A 18. Dose limits and dose distribution	
<p>How?</p> <p>3.10 If yes, what was (were) the main factor(s) influencing these changes?</p>	
A 19. Experience with specific technical aspects	
<p>We would appreciate answers from both regulators and operators to all of these questions!</p>	
<p><i>Pregnant workers</i></p> <p>A 4.1 What happens when an occupationally exposed worker becomes pregnant?</p> <p>A 4.2 Did the introduction of the 2 mSv limit for the abdomen (ICRP 60) or the 1 mSv limit for the embryo / fetus (Euratom Directive) cause any problems or costs?</p> <p>A 4.3 If yes, what were they and how were they resolved?</p>	<p>A 4.1 When pregnancy of a woman employee has been declared, her exposure should be controlled not to exceed 2 mSv to the surface of her abdomen and to limit intakes of radionuclides to about 1/20 of the ALI.</p> <p>A 4.2 No.</p> <p>A 4.3</p>
<p><i>Constraints</i></p> <p>A 4.4 What is your experience of the introduction and use of dose constraints for occupational and public exposures?</p> <p>A 4.5 Were there any difficulties? If yes, what were they and how were they resolved?</p> <p>A 4.6 Have you at all used risk constraints? If yes, what is your experience?</p>	<p>A 4.4 For dose constraints, the regulatory authority provided the shield (?) design targets for occupational exposure and for public exposure and the annual dose standards for gaseous effluents and liquid effluents for public exposure. For the NPP operation, some operational targets such as occupational exposure targets have been made by the management.</p> <p>A 4.5 yes. The utilities considered the dose constraint provided by the regulatory authority as a limit and the final goal, not a step of the optimization process.</p> <p>It couldn't be resolved.</p> <p>A 4.6</p>
<p><i>Radiation Dosimetry</i></p> <p>A 4.7 Please describe briefly the organisation and regulatory framework for dosimetry in your country.</p> <p>A 4.8 Did the introduction of ICRP 60 radiation and tissue weighting factors lead to any difficulties? If</p>	<p>A 4.7 In accordance with the Atomic Energy Act, processors, who are going to provide personal dosimetry service to radiation workers, must be approved for the registration for the service from the Ministry of Education, Science and Technology (MEST). As approval conditions, they must be passed the technical proficiency assessment of personal dosimetry through performance test provided by KINS and Quality Assurance Plan (QAP) composed of quality manual, procedures, and directions including management and technical requirements.</p> <p>A 4.8</p>

A 19. Experience with specific technical aspects	
<p>yes, what were they and how were they resolved?</p> <p>A 4.9 Were there any costs associated with the implementation of the ICRP 60 dosimetric approach (e.g. dose coefficients, modelling, instrument calibration, etc.), if so, how much and borne by whom?</p>	<p>A 4.9</p>
<p><i>Radon</i></p> <p>A 4.10 Please describe briefly the current arrangements with respect to radon, in dwellings and at the workplace.</p> <p>A 4.11 Did the implementation of ICRP 60 cause any new efforts or costs? If yes, what were they and how were they resolved?</p>	<p>A 4.10 Ministry of Environment established the law of controlling indoor air quality to public buildings. In this law, radon is one of the 10 contaminants that should be controlled in indoor air, and the recommendation value is 148 Bq/m³. However, there is no action level or recommendation level for dwellings and workplaces.</p> <p>A 4.11 No</p>

A 20. Training implications	
<p>Question A 5.1 – A 5.2 are aimed primarily at regulators, and questions A 5.3 – A 5.5 at both regulators and operators!</p>	
<p><i>Regulators' staff</i></p> <p>A 5.1 What methods did you use to ensure that relevant members of staff were aware of and understood the revised legislation?</p> <p>A 5.2 Were there any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?</p> <p>A 5.3 Were you involved in ensuring that stakeholders were aware of and understood the revised legislation?</p> <p>A 5.4 If so, how did you do</p>	<p>A 5.1 By the periodic re-education program in KINS, all of the regulators have been aware of the revised legislation.</p> <p>A 5.2. No.</p> <p>A 5.3 yes</p> <p>A 5.4 Experts in KINS have been participated frequently in re-training the stakeholders to aware of the revised legislation.</p>

A 20. Training implications	
this?	
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>A 5.5 What was the extent of training and information required? Was this an entirely new effort, or could it be integrated into existing schedules of recurring training? What were the costs of training?</p>	<p>A 5.5 The new recommendations of the ICRP(ICRP 60), The Basic Safety Standards of the IAEA (BSS 115), and the revised legislation were introduced to the stakeholders.</p> <p>No, it could be integrated to the existing training schedule.</p> <p>The cost of training was provided by the employers, because the training program was asked by regulation.</p>

Part B: incorporating ICRP 103: Anticipated key impacts/provisions

B 1. General	
<p>Questions B 1.1 to B 1.6 are aimed primarily at regulators, and questions B 1.7 - B 1.8 primarily at operators, but we welcome your replies to all queries!</p>	
<p><i>Legislation</i></p> <p>B 1.1 Do you expect to have to change your ionising radiation protection legislation/rules if/when ICRP 103 is incorporated?</p> <p>B 1.2 If appropriate, please briefly describe the anticipated changes.</p>	<p>B 1.1 yes , probably 2013-2014</p> <p>B 1.2 anticipated changes: implementation of dose constraints and reference level, weighting factors, evaluation of effective dose,</p>
<p><i>Organisation</i></p> <p>B 1.3 Do you expect that the incorporation of ICRP 103 will lead to any changes to the organisation and/or resources of the radiation protection regulators, compared with that reported in Section A?</p> <p>B 1.4 If appropriate, please briefly describe how consistency of approach between regulatory organisations is to be achieved?</p>	<p>B 1.3 No</p> <p>B 1.4</p>
<p><i>Burdens and benefits</i></p> <p>B 1.5 Does your regulatory authority expect</p>	<p>B 1.5 No</p>

B 1. General	
to perform a cost-benefit analysis of the implications of any new regulations (regulatory analysis) and if so, when might a report become available (where)?	
<i>Cost of Not Acting</i> B 1.6 Will the costs / savings / implications of not implementing Publication 103 be assessed? If so, when?	B 1.6 No
<i>Anticipated costs</i> ICRP 103 and the new Euratom Directive will entail, e.g., - amended w_R and w_T ; - added emphasis on dose constraints. B 1.7 How do you expect these new requirements arising from ICRP 103 to impact on operations? B 1.8 Do you anticipate that the incorporation of ICRP 103 may lead to any reduction of any kind of cost or effort?	B 1.7 On amended w_R and w_T , we expect that it will require a significant/additional resources for the licensees to update its current system of dose assessment and it will take time. We are going to provide them assistance as much as we can. On the dose constraints, for NPP sides, the concept is already in implementation so that we do not expect any new extra significant burden. However, we also expect that the current system should be carefully reviewed in due course. B 1.8 No

B 2. Experience with specific technical aspects	
We would appreciate answers from both regulators and operators to all of these questions!	
<i>Pregnant workers</i> B 2.1 Do you envisage that the introduction of the 1 mSv limit for the embryo / fetus (ICRP 103) will cause any problems or costs? (Note: this question does not apply to EU member countries since the current Euratom BSS Directive already prescribes such a limit). B 2.2 If yes, what might they be, and how do you plan to resolve them?	B 2.1 No B 2.2
<i>Constraints</i>	B 2.3 Yes. But we resolved it in a way that the requirements would not be a part of legal requirements but a part of regulatory guides that the

B 2. Experience with specific technical aspects	
<p>B 2.3 Is the added emphasis on dose constraints in ICRP 103 expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p> <p>B 2.4 Are risk constraints likely to be introduced with the implementation of ICRP 103?</p>	<p>licensees do not have to implement it.</p> <p>B 2.4 No</p>
<p><i>Dosimetry</i></p> <p>B 2.5 Are the new ICRP 103 radiation and tissue weighting factors expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.5 Difficulties come from the new added tissues. But, we have developed new phantoms which incorporated the new added tissues and are under the process of resolving them.</p>
<p><i>Radon</i></p> <p>B 2.6 Is the implementation of ICRP 103 expected to cause any new efforts or costs with respect to radon? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.6 Radon is one of difficult and hot and remaining issue. And a lot of discussions are underway, the national consensus is not yet reached. But, it is expected that the conclusion will come soon with the enactment of new law of Living Environment Radioactivity Act.</p>

B 3. Training implications	
<p>Questions 3.1 – 3.3 are aimed primarily at regulators, and question 3.4 at both regulators and operators!</p>	
<p><i>Regulators' staff</i></p> <p>B 3.1 What methods do you plan to use to ensure that relevant members of staff were aware of and understood the revised legislation?</p> <p>B 3.2 Do you anticipate any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?</p> <p>B 3.3 Do you expect to be involved in ensuring that</p>	<p>B 3.1 Open seminar, workshop and specific training courses</p> <p>B 3.2 No</p> <p>B 3.3 Stakeholders involvement on the implementation of ICRP 103 will be carried out in accordance with the existing rules.</p>

B 3. Training implications	
<p>stakeholders are aware of and understood the revised legislation? If so, how do you anticipate doing this?</p>	
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>B 3.4 What do you expect will be the extent of training and information required? Will this be an entirely new effort, or could it be integrated into existing schedules of recurring training? What may be the anticipated costs of training?</p>	<p>B 3.4 The training is expected to be integrated into existing schedules of recurring training. Not much cost.</p>

And finally: Is there anything else that you wish to add?
[Please add any 'open' comments here!]

Questionnaire v.2.0 - completed for [country]: ..Norway.....

**NEA Project for Obtaining Historical Information on Costs and Impacts of Incorporating ICRP Publ. 60 and Possible Resources for Incorporating ICRP Publ. 103
Part A: incorporating ICRP 60: Key impacts/provisions**

NOTE: for EU Member States: references to incorporation of ICRP 60 should be read as implementation of Directives 96/29/Euratom and 97/43/Euratom.

A 21. General	
Questions A 1.1 to A 1.9 are aimed primarily at regulators, and questions A 1.10 – A 1.11 primarily at operators, but we welcome your replies to all queries!	
Question	Your experience
<p><i>Legislation</i></p> <p>A 1.1 Please describe briefly the hierarchy, if applicable, of ionising radiation protection legislation/rules in your country, e.g. national law, national government regulations; central authority regulations; regional or local authority regulations; other (e.g., professional body) rules. Also, please briefly describe what is covered at each level.</p>	<p>A 1.1 [Please fill in your reply here!]</p> <ol style="list-style-type: none"> 1. Law of 12 may 2000 no 36 about radiation protection and use of radiation (national parliament) 2. Regulation of 29 october 2010 no. 1380 about radiation protection and use of radiation. (central authority – ministry) 3. Several guides for different topics (national authority – NRPA)
<p><i>Organisation</i></p> <p>A1.2 Describe the different authorities, and (approximately) how many regulators are involved in making and enforcing radiation protection legislation? Also, if appropriate, please briefly describe how consistency of approach between regulatory organisations is achieved?</p>	<p>A 1.2</p> <p>NRPA: 100 persons totally</p> <p>20 involved in regulatory/inspection work.</p>
<p><i>ICRP 60 incorporation</i></p> <p>A 1.3 To what extent were legislation and regulations rewritten when ICRP 60 was incorporated?</p> <p>A 1.4 What was the procedure, what problems and efforts were there?</p>	<p>A 1.3 To a very large extent – (Former law was from 1938)</p> <p>A 1.4 A proposition for the parliament was prepared and passed</p>

A 21. General	
<p><i>Stakeholders</i></p> <p>A 1.5 Who were the stakeholders (e.g. other ministries, operators, etc.) and how was their involvement achieved?</p>	<p>A 1.5 There is allway a process with a broad pubic hearing when new legislation/regulations are proposed.</p>
<p><i>Guidance</i></p> <p>A 1.6 How was guidance on the implementing legislation developed and by whom (e.g.: regulatory authorities; professional societies, trade organisations)?</p>	<p>A 1.6 In such work a so-called chamber proposal document is prepared to explain the consequences of the legislative proposal – In practice written by NRPA.</p>
<p><i>Time-scales</i></p> <p>A 1.7 What were the lead-in times for new requirements, i.e., when were they proposed, when decided, when was full compliance by operators required?</p>	<p>A 1.7 For the majority of requirements 2 months after they were proposed. For radon in scools, kinterggartens etc 3 years.</p>
<p><i>Burdens and benefits</i></p> <p>A 1.8 Did your regulatory authority perform a cost-benefit analysis of the implications of any new regulations, (regulatory analysis) and if so is there a report available (where)?</p>	<p>A 1.8 To some extent</p>
<p><i>Cost of Not Acting</i></p> <p>A 1.9 Were the costs/savings/implications of not implementing ICRP 60 assessed? If so, what were they?</p>	<p>A 1.9 No.</p>
<p><i>Actual costs</i></p> <p>ICRP 60 and Euratom Directives 96/29 and 97/43 entailed, e.g., that</p> <ul style="list-style-type: none"> -the annual limit on occupational effective dose was reduced from 50 to 20 mSv, with an option of 5-year averaging; - it was clarified that the annual limit on effective dose to members of the public is 1 mSv, not 5 mSv; - effective dose (with new 	<p>A 1.10 Not very much – most radiation workers had doses significantly less than 50 mSv. (and even below 20 mSv).</p> <p>A 1.11 Probably not.</p>

A 21. General	
<p>weighting factors w_R and w_T) replaced the effective dose equivalent;</p> <ul style="list-style-type: none"> - the concepts of dose and risk constraints were introduced; - diagnostic reference levels were introduced. <p>A 1.10 How did these new requirements arising from ICRP 60 impact on operations?</p> <p>A 1.11 Did the incorporation of ICRP 60 lead to any reduction of any kind of cost or effort?</p>	

A 22. Application / scope	
<p>Questions A 2.1 to A 2.2 are aimed primarily at regulators. We are grateful for replies from both operators and regulators to questions A 2.3 - A 2.4!</p>	
<p><i>Scope</i></p> <p>A 2.1 Did pre-ICRP 60 legislation in your country cover all uses and users of ionising radiation, e.g.: industrial applications (including industrial radiography), medical applications (diagnostic and therapeutic), nuclear fuel cycle, research and teaching, transport, radioactive waste disposal, occupational exposure to radon (mining and non-mining), agriculture?</p> <p>A 2.2 If not, was new legislation introduced to close the previous gaps?</p> <p>A 2.3 Did the timeframe for implementation vary for the sectors described in A 2.1? If so, how?</p>	<p>A 2.1 Mainly yes – and including non-ionising radiation..</p> <p>A 2.2 The main motive for new legislation was harmonize better with other countries and to update requirements to be more operative.</p> <p>A 2.3 . Not much.</p>
<p><i>Response</i></p> <p>A 2.4 Was there any resistance from those sectors (if any) which were not previously covered? If so, what were the main</p>	<p>A 2.4 Not much but – some questions from oil and gas industry concerning NORM</p>

A 22. Application / scope	
perceived difficulties and what was done to overcome them?	

A 23. Dose limits and dose distribution
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Questions A 3.1 – A 3.3 are aimed primarily at regulators. We would be grateful for replies from both regulators and operators for questions A 3.4 – A 3.10!

<i>Historical limits</i> A 3.1 What were your dose limits before you incorporated ICRP 60?	A 3.1 50 mSv./year
<i>Current limits</i> A 3.2 What were your dose limits after implementation? A 3.3 Was any flexibility built into dose limits, e.g. public limits allowed up to 5 mSv in exceptional circumstances? A 3.4 If 5-year averaging was chosen for occupational doses, what is your experience? Were there any difficulties?	A 3.2 20 mSv/year A 3.3 For worker : 50 mSv in a single year provided that 100 mSv was not exceeded during a 5 year period (must be applied for) A 3.4 No. We require in such (few) cases that a good work plan is prepared with dose budgets)
<i>Transition experience</i> A 3.5 What was your experience of establishing these lower dose limits? A 3.6 Did any installation need significant rebuilding to comply with added shielding requirements? If no, how was this avoided? A 3.7 Were there any other difficulties? If so, what were they and how were they resolved?	A 3.5 no problems with this A 3.6 no A 3.7 no
<i>Resulting doses</i> A 3.8 What analyses of dose distributions are available for your country, over what period? A 3.9 Have these dose distributions changed? How?	A 3.8 A 3.9 Annual national dose reports. A 3.10 In last years - increasing doses for medical staff (interventional procedures). More patients treated with radiological procedures rather than surgical. More sophisticated equipment.

A 23. Dose limits and dose distribution	
3.10 If yes, what was (were) the main factor(s) influencing these changes?	

A 24. Experience with specific technical aspects	
We would appreciate answers from both regulators and operators to all of these questions!	
<p><i>Pregnant workers</i></p> <p>A 4.1 What happens when an occupationally exposed worker becomes pregnant?</p> <p>A 4.2 Did the introduction of the 2 mSv limit for the abdomen (ICRP 60) or the 1 mSv limit for the embryo / fetus (Euratom Directive) cause any problems or costs?</p> <p>A 4.3 If yes, what were they and how were they resolved?</p>	<p>A 4.1 Tasks may be changed locally. Will affect only a few</p> <p>A 4.2 Not really.</p> <p>A 4.3</p>
<p><i>Constraints</i></p> <p>A 4.4 What is your experience of the introduction and use of dose constraints for occupational and public exposures?</p> <p>A 4.5 Were there any difficulties? If yes, what were they and how were they resolved?</p> <p>A 4.6 Have you at all used risk constraints? If yes, what is your experience?</p>	<p>A 4.4 A good planning instrument</p> <p>A 4.5 Not really</p> <p>A 4.6 More or less – yes. OK experience</p>
<p><i>Radiation Dosimetry</i></p> <p>A 4.7 Please describe briefly the organisation and regulatory framework for dosimetry in your country.</p> <p>A 4.8 Did the introduction of ICRP 60 radiation and tissue weighting factors lead to any difficulties? If yes, what were they and</p>	<p>A 4.7 We operate a SSDL at NRPA and have the national norm for dosimetric quantities.</p> <p>A 4.8 No.</p> <p>A 4.9 No. We had this facility even before – (from the 1950-ties)</p>

A 24. Experience with specific technical aspects	
<p>how were they resolved?</p> <p>A 4.9 Were there any costs associated with the implementation of the ICRP 60 dosimetric approach (e.g. dose coefficients, modelling, instrument calibration, etc.), if so, how much and borne by whom?</p>	
<p><i>Radon</i></p> <p>A 4.10 Please describe briefly the current arrangements with respect to radon, in dwellings and at the workplace.</p> <p>A 4.11 Did the implementation of ICRP 60 cause any new efforts or costs? If yes, what were they and how were they resolved?</p>	<p>A 4.10 In schools, kindergardens ang dwellings for hire (not the owner) the action level is 100 Bq/m3 for taking countermeasures.</p> <p>The new absolute limit is 200 Bq/m3.</p> <p>A 4.11 In has grown up a large market for radon measurements</p>

A 25. Training implications	
<p>Question A 5.1 – A 5.2 are aimed primarily at regulators, and questions A 5.3 – A 5.5 at both regulators and operators!</p>	
<p><i>Regulators' staff</i></p> <p>A 5.1 What methods did you use to ensure that relevant members of staff were aware of and understood the revised legislation?</p> <p>A 5.2 Were there any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?</p> <p>A 5.3 Were you involved in ensuring that stakeholders were aware of and understood the revised legislation?</p> <p>A 5.4 If so, how did you do this?</p>	<p>A 5.1 Internal Working groups.</p> <p>A 5.2. Probably</p> <p>A 5.3 NRPA - yes</p> <p>A 5.4 Preparing guidance documents/information material.</p>

A 25. Training implications	
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>A 5.5 What was the extent of training and information required? Was this an entirely new effort, or could it be integrated into existing schedules of recurring training? What were the costs of training?</p>	<p>A 5.5 No info</p>

Part B: incorporating ICRP 103: Anticipated key impacts/provisions

B 1. General	
<p>Questions B 1.1 to B 1.6 are aimed primarily at regulators, and questions B 1.7 - B 1.8 primarily at operators, but we welcome your replies to all queries!</p>	
<p><i>Legislation</i></p> <p>B 1.1 Do you expect to have to change your ionising radiation protection legislation/rules if/when ICRP 103 is incorporated?</p> <p>B 1.2 If appropriate, please briefly describe the anticipated changes.</p>	<p>B 1.1 Probably not</p> <p>B 1.2</p>
<p><i>Organisation</i></p> <p>B 1.3 Do you expect that the incorporation of ICRP 103 will lead to any changes to the organisation and/or resources of the radiation protection regulators, compared with that reported in Section A?</p> <p>B 1.4 If appropriate, please briefly describe how consistency of approach between regulatory organisations is to be achieved?</p>	<p>B 1.3 No.</p> <p>B 1.4</p>
<p><i>Burdens and benefits</i></p> <p>B 1.5 Does your regulatory authority expect to perform a cost-benefit analysis of the</p>	<p>B 1.5 Generally - If regulations is proposed to be changed – a cost analysis must be done also.</p>

B 1. General	
implications of any new regulations (regulatory analysis) and if so, when might a report become available (where)?	
<i>Cost of Not Acting</i> B 1.6 Will the costs / savings / implications of not implementing Publication 103 be assessed? If so, when?	B 1.6 Probably not.
<i>Anticipated costs</i> ICRP 103 and the new Euratom Directive will entail, e.g., - amended w_R and w_T ; - added emphasis on dose constraints. B 1.7 How do you expect these new requirements arising from ICRP 103 to impact on operations? B 1.8 Do you anticipate that the incorporation of ICRP 103 may lead to any reduction of any kind of cost or effort?	B 1.7 Not much B 1.8 May be that cost due to stricter radon requirement will imply more costs – no real overview of this.

B 2. Experience with specific technical aspects	
We would appreciate answers from both regulators and operators to all of these questions!	
<i>Pregnant workers</i> B 2.1 Do you envisage that the introduction of the 1 mSv limit for the embryo / fetus (ICRP 103) will cause any problems or costs? (Note: this question does not apply to EU member countries since the current Euratom BSS Directive already prescribes such a limit). B 2.2 If yes, what might they be, and how do you plan to resolve them?	B 2.1 No. B 2.2
<i>Constraints</i> B 2.3 Is the added emphasis on dose	B 2.3 No. B 2.4

B 2. Experience with specific technical aspects	
<p>constraints in ICRP 103 expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p> <p>B 2.4 Are risk constraints likely to be introduced with the implementation of ICRP 103?</p>	
<p><i>Dosimetry</i></p> <p>B 2.5 Are the new ICRP 103 radiation and tissue weighting factors expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p>	B 2.5 No.
<p><i>Radon</i></p> <p>B 2.6 Is the implementation of ICRP 103 expected to cause any new efforts or costs with respect to radon? If yes, what are they and how do you plan to resolve them?</p>	B 2.6 Yes. Will affect many public buildings and houses. National action plans will be prepared. The costs is difficult to foresee at this stage

B 3. Training implications	
<p>Questions 3.1 – 3.3 are aimed primarily at regulators, and question 3.4 at both regulators and operators!</p>	
<p><i>Regulators' staff</i></p> <p>B 3.1 What methods do you plan to use to ensure that relevant members of staff were aware of and understood the revised legislation?</p> <p>B 3.2 Do you anticipate any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?</p> <p>B 3.3 Do you expect to be involved in ensuring that stakeholders are aware of and understood the</p>	<p>B 3.1 Internal working groups.</p> <p>B 3.2 Not really.</p> <p>B 3.3 Yes – revision of guidance documents.</p>

B 3. Training implications	
revised legislation? If so, how do you anticipate doing this?	
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>B 3.4 What do you expect will be the extent of training and information required? Will this be an entirely new effort, or could it be integrated into existing schedules of recurring training? What may be the anticipated costs of training?</p>	B 3.4

And finally: Is there anything else that you wish to add?
 The questionnaire could be shorter. Have a nice summer !.
 [Please add any 'open' comments here!]

Questionnaire v.2.0 - completed for [country]: .Slovakia

**NEA Project for Obtaining Historical Information on Costs and Impacts of Incorporating ICRP Publ. 60 and Possible Resources for Incorporating ICRP Publ. 103
Part A: incorporating ICRP 60: Key impacts/provisions**

NOTE: for EU Member States: references to incorporation of ICRP 60 should be read as implementation of Directives 96/29/Euratom and 97/43/Euratom.

A 26. General	
Questions A 1.1 to A 1.9 are aimed primarily at regulators, and questions A 1.10 – A 1.11 primarily at operators, but we welcome your replies to all queries!	
Question	Your experience
<p><i>Legislation</i></p> <p>A 1.1 Please describe briefly the hierarchy, if applicable, of ionising radiation protection legislation/rules in your country, e.g. national law, national government regulations; central authority regulations; regional or local authority regulations; other (e.g., professional body) rules. Also, please briefly describe what is covered at each level.</p>	<p>A 1.1 [Please fill in your reply here!]</p> <p>Act. No. 355/2007 Coll. on public health protection</p> <p>Governmental Ordinances:</p> <ul style="list-style-type: none"> – No 345/2006 Coll. – on Basic Safety Standards – implementation of EU Directive 96/29/Euratom – No 340/2006 Coll. on medical exposure - implementation of EU Directive 97/43/Euratom – No 346/2006 Coll. on protection of outside workers - implementation of EU Directive 90/641/Euratom, – No 348/2006 Coll. on control of high-activity sealed sources and orphan sources - implementation of EU Directive 2003/122/ Euratom <p>Regulations of the Health Ministry:</p> <ul style="list-style-type: none"> – No 524/2007 Coll. on radiation monitoring network, – No 528/2007 Coll. on natural radiation – No 545/2007 Coll. on requirements on practices and activities important from radiation protection point of view
<p><i>Organisation</i></p> <p>A1.2 Describe the different authorities, and (approximately) how many regulators are involved in making and enforcing radiation protection legislation? Also, if appropriate, please briefly describe how consistency of approach between regulatory organisations is achieved?</p>	<p>A 1.2</p> <ul style="list-style-type: none"> - Ministry of Health - Public Health Authority of the Slovak Republic (staff of radiation protection department 20 persons) - Regional Public Health Authorities <ul style="list-style-type: none"> - Bratislava (staff 5 persons) - Nitra (staff 2 persons) - Banská Bystrica (staff 12 persons) - Košice (staff 10 persons)
<p><i>ICRP 60 incorporation</i></p> <p>A 1.3 To what extent were legislation and regulations rewritten when ICRP 60 was incorporated?</p> <p>A 1.4 What was the procedure, what problems and efforts were there?</p>	<p>A 1.3 Almost completely</p> <p>A 1.4 Without significantly problems.</p>

A 26. General	
<p><i>Stakeholders</i> A 1.5 Who were the stakeholders (e.g. other ministries, operators, etc.) and how was their involvement achieved?</p>	<p>A 1.5 Large stakeholders, like nuclear industry and chambers of medical professionals, were very active in implementation of basic standards and new requirements.</p>
<p><i>Guidance</i> A 1.6 How was guidance on the implementing legislation developed and by whom (e.g.: regulatory authorities; professional societies, trade organisations)?</p>	<p>A 1.6 Official guidance has not been issued. Mainly authorities are involved, some professional societies have organized training and courses.</p>
<p><i>Time-scales</i> A 1.7 What were the lead-in times for new requirements, i.e., when were they proposed, when decided, when was full compliance by operators required?</p>	<p>A 1.7 Many operators have implied many new requirements (ICRP 60) even before its implementation in the national legislation. Full compliance has been required after period stipulated by the act.</p>
<p><i>Burdens and benefits</i> A 1.8 Did your regulatory authority perform a cost-benefit analysis of the implications of any new regulations, (regulatory analysis) and if so is there a report available (where)?</p>	<p>A 1.8 The cost-benefit analysis has not been performed.</p>
<p><i>Cost of Not Acting</i> A 1.9 Were the costs/savings/implications of not implementing ICRP 60 assessed? If so, what were they?</p>	<p>A 1.9 No</p>
<p><i>Actual costs</i> ICRP 60 and Euratom Directives 96/29 and 97/43 entailed, e.g., that -the annual limit on occupational effective dose was reduced from 50 to 20 mSv, with an option of 5-year averaging; - it was clarified that the annual limit on effective dose to members of the public is 1 mSv, not 5 mSv; - effective dose (with new weighting factors w_R and w_T) replaced the effective dose equivalent; - the concepts of dose and risk constraints were introduced; - diagnostic reference levels were</p>	<p>A 1.10 The new system of limits has not considerable impact on operators as the individual doses of workers and members of the public have been well below the limits. A 1.11 We do not have any relevant information that application of ICRP 60 has lead to the cost reduction.</p>

A 26. General	
<p>introduced.</p> <p>A 1.10 How did these new requirements arising from ICRP 60 impact on operations?</p> <p>A 1.11 Did the incorporation of ICRP 60 lead to any reduction of any kind of cost or effort?</p>	

A 2. Application / scope	
<p>Questions A 2.1 to A 2.2 are aimed primarily at regulators. We are grateful for replies from both operators and regulators to questions A 2.3 - A 2.4!</p>	
<p><i>Scope</i></p> <p>A 2.1 Did pre-ICRP 60 legislation in your country cover all uses and users of ionising radiation, e.g.: industrial applications (including industrial radiography), medical applications (diagnostic and therapeutic), nuclear fuel cycle, research and teaching, transport, radioactive waste disposal, occupational exposure to radon (mining and non-mining), agriculture?</p> <p>A 2.2 If not, was new legislation introduced to close the previous gaps?</p> <p>A 2.3 Did the timeframe for implementation vary for the sectors described in A 2.1? If so, how?</p>	<p>A 2.1 In general, yes.</p> <p>A 2.2</p> <p>A 2.3 No.</p>
<p><i>Response</i></p> <p>A 2.4 Was there any resistance from those sectors (if any) which were not previously covered? If so, what were the main perceived difficulties and what was done to overcome them?</p>	<p>A 2.4</p> <p>Some opposition was presented from the chamber of dentist and chamber of medical doctors against requirement on education in radiation protection and duties in licensing process. Explanation and discussions have been organized.</p>

A 28. Dose limits and dose distribution
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A 28. Dose limits and dose distribution																						
Questions A 3.1 – A 3.3 are aimed primarily at regulators. We would be grateful for replies from both regulators and operators for questions A 3.4 – A 3.10!																						
<p><i>Historical limits</i></p> <p>A 3.1 What were your dose limits before you incorporated ICRP 60?</p>	<p>A 3.1</p> <table border="0" style="width: 100%;"> <thead> <tr> <th style="text-align: left;">Annual limits</th> <th style="text-align: left;">workers</th> <th style="text-align: left;">public</th> </tr> </thead> <tbody> <tr> <td>whole body, gonads, red bone marrow</td> <td>5 rem</td> <td>0.5 rem</td> </tr> <tr> <td>skin, thyroid, bone</td> <td>30 rem</td> <td>3 rem</td> </tr> <tr> <td>hands, foots</td> <td>75 rem</td> <td>7.5 rem</td> </tr> <tr> <td>other</td> <td>15 rem</td> <td>1.5 rem</td> </tr> </tbody> </table> <p>Member of public:</p>	Annual limits	workers	public	whole body, gonads, red bone marrow	5 rem	0.5 rem	skin, thyroid, bone	30 rem	3 rem	hands, foots	75 rem	7.5 rem	other	15 rem	1.5 rem						
Annual limits	workers	public																				
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other	15 rem	1.5 rem																				
<p><i>Current limits</i></p> <p>A 3.2 What were your dose limits after implementation?</p> <p>A 3.3 Was any flexibility built into dose limits, e.g. public limits allowed up to 5 mSv in exceptional circumstances?</p> <p>A 3.4 If 5-year averaging was chosen for occupational doses, what is your experience? Were there any difficulties?</p>	<p>A 3.2</p> <table border="0" style="width: 100%;"> <thead> <tr> <th style="text-align: left;">Annual limits</th> <th style="text-align: left;">workers</th> <th style="text-align: left;">public</th> </tr> </thead> <tbody> <tr> <td>effective dose</td> <td>100 mSv/5y</td> <td></td> </tr> <tr> <td></td> <td>50 mSv/y</td> <td>1 mSv/y</td> </tr> <tr> <td>equivalent dose</td> <td></td> <td></td> </tr> <tr> <td>skin, hands, foots</td> <td>500 mSv/y</td> <td></td> </tr> <tr> <td>skin</td> <td></td> <td>50 mSv/y</td> </tr> <tr> <td>lens of eye</td> <td>150 mSv/y</td> <td>15 mSv/y</td> </tr> </tbody> </table> <p>A 3.3</p> <p>There is not allowed to expose any member of public to 5 mSv/y in our legislation.</p> <p>A 3.4</p> <p>As the individual doses are very low and there is still possibility to expose the worker to 50 mSv in a single year (assumption the limit 100mSv /5y will not be exceeded)</p>	Annual limits	workers	public	effective dose	100 mSv/5y			50 mSv/y	1 mSv/y	equivalent dose			skin, hands, foots	500 mSv/y		skin		50 mSv/y	lens of eye	150 mSv/y	15 mSv/y
Annual limits	workers	public																				
effective dose	100 mSv/5y																					
	50 mSv/y	1 mSv/y																				
equivalent dose																						
skin, hands, foots	500 mSv/y																					
skin		50 mSv/y																				
lens of eye	150 mSv/y	15 mSv/y																				
<p><i>Transition experience</i></p> <p>A 3.5 What was your experience of establishing these lower dose limits?</p> <p>A 3.6 Did any installation need significant rebuilding to comply with added shielding requirements? If no, how was this avoided?</p> <p>A 3.7 Were there any other difficulties? If so, what were they and how were they resolved?</p>	<p>A 3.5</p> <p>The individual doses were low, well below the limits, transition to new limits was not a reasonable problem.</p> <p>A 3.6</p> <p>No</p> <p>A 3.7</p>																					
<p><i>Resulting doses</i></p> <p>A 3.8 What analyses of dose distributions are available for your country, over what</p>	<p>A 3.8</p> <p>A 3.9</p> <p>Dose distribution has been changed considerable, individual doses are</p>																					

A 28. Dose limits and dose distribution	
<p>period? A 3.9 Have these dose distributions changed? How? 3.10 If yes, what was (were) the main factor(s) influencing these changes?</p>	<p>lower now and the number of person in higher dose intervals decreased more significantly. A 3.10 Probably more rigorous implementation of optimalization.</p>

A 29. Experience with specific technical aspects	
<p>We would appreciate answers from both regulators and operators to all of these questions!</p>	
<p><i>Pregnant workers</i> A 4.1 What happens when an occupationally exposed worker becomes pregnant? A 4.2 Did the introduction of the 2 mSv limit for the abdomen (ICRP 60) or the 1 mSv limit for the embryo / fetus (Euratom Directive) cause any problems or costs? A 4.3 If yes, what were they and how were they resolved?</p>	<p>A 4.1 The work organisation should assure that the dose of the fetus will be lower than 1 mSv. Work in controlled area for pregnant workers is not allowed. A 4.2 No. A 4.3</p>
<p><i>Constraints</i> A 4.4 What is your experience of the introduction and use of dose constraints for occupational and public exposures? A 4.5 Were there any difficulties? If yes, what were they and how were they resolved? A 4.6 Have you at all used risk constraints? If yes, what is your experience?</p>	<p>A 4.4 Just on a beginning there has been some problems with understanding. Some clarification has been necessary. A 4.5 No A 4.6 No.</p>
<p><i>Radiation Dosimetry</i> A 4.7 Please describe briefly the organisation and regulatory framework for dosimetry in your country. A 4.8 Did the introduction of ICRP 60 radiation and tissue weighting factors lead to any difficulties? If yes, what were they and how were they resolved?</p>	<p>A 4.7 Personal doses should be monitored in controlled areas. Personal dosimetry is carried out by the approved dosimetry services. A 4.8 No significant problems. A 4.9 The cost of implementation has not been assessed and reported.</p>

A 29. Experience with specific technical aspects	
<p>A 4.9 Were there any costs associated with the implementation of the ICRP 60 dosimetric approach (e.g. dose coefficients, modelling, instrument calibration, etc.), if so, how much and borne by whom?</p>	
<p><i>Radon</i></p> <p>A 4.10 Please describe briefly the current arrangements with respect to radon, in dwellings and at the workplace.</p> <p>A 4.11 Did the implementation of ICRP 60 cause any new efforts or costs? If yes, what were they and how were they resolved?</p>	<p>A 4.10</p> <p>Workplaces: Preferred is individual monitoring, but assessment of dose on base of workplace is allowed.</p> <p>Dwellings: No duty to measure the activity of radon, but the recommendation. The measurement could be provided by approved services.</p> <p>A 4.11</p> <p>The ICRP 60 itself does not cause new efforts except of limiting the exposure. Regulation and control of exposure has been necessary.</p>

A 30. Training implications	
<p>Question A 5.1 – A 5.2 are aimed primarily at regulators, and questions A 5.3 – A 5.5 at both regulators and operators!</p>	
<p><i>Regulators' staff</i></p> <p>A 5.1 What methods did you use to ensure that relevant members of staff were aware of and understood the revised legislation?</p> <p>A 5.2 Were there any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?</p> <p>A 5.3 Were you involved in ensuring that stakeholders were aware of and understood the revised legislation?</p> <p>A 5.4 If so, how did you do this?</p>	<p>A 5.1</p> <p>There were courses for radiation protection officers.</p> <p>A 5.2.</p> <p>There were some explanation and discussions necessary but no special problem could be reported.</p> <p>A 5.3</p> <p>The authorities have organized some seminars and courses for stakeholders and their radiation protection officers.</p> <p>A 5.4</p> <p>Yes.</p>
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>A 5.5 What was the extent of</p>	<p>A 5.5</p> <p>Mainly only basic information has been offered. But some approved services provided more detailed education.</p>

A 30. Training implications	
training and information required? Was this an entirely new effort, or could it be integrated into existing schedules of recurring training? What were the costs of training?	The courses organised by the authorities have been cost free. Commercial companies offered the trainings and courses at common prices.

Part B: incorporating ICRP 103: Anticipated key impacts/provisions

B 1. General	
Questions B 1.1 to B 1.6 are aimed primarily at regulators, and questions B 1.7 - B 1.8 primarily at operators, but we welcome your replies to all queries!	
<i>Legislation</i> B 1.1 Do you expect to have to change your ionising radiation protection legislation/rules if/when ICRP 103 is incorporated? B 1.2 If appropriate, please briefly describe the anticipated changes.	B 1.1 Yes. B 1.2 It depends on the final version of BSS issued by the IAEA and particularly of EU.
<i>Organisation</i> B 1.3 Do you expect that the incorporation of ICRP 103 will lead to any changes to the organisation and/or resources of the radiation protection regulators, compared with that reported in Section A? B 1.4 If appropriate, please briefly describe how consistency of approach between regulatory organisations is to be achieved?	B 1.3 Changes will be necessary, but we expect that this will not cause considerable resources. B 1.4
<i>Burdens and benefits</i> B 1.5 Does your regulatory authority expect to perform a cost-benefit analysis of the implications of any new regulations (regulatory analysis) and if so, when might a report become available (where)?	B 1.5 We do not expect, at present.

B 1. General	
<p><i>Cost of Not Acting</i></p> <p>B 1.6 Will the costs / savings / implications of not implementing Publication 103 be assessed? If so, when?</p>	<p>B 1.6</p> <p>There are not requirements and also capacities to do the assessments of the costs.</p>
<p><i>Anticipated costs</i></p> <p>ICRP 103 and the new Euratom Directive will entail, e.g.,</p> <ul style="list-style-type: none"> - amended w_R and w_T; - added emphasis on dose constraints. <p>B 1.7 How do you expect these new requirements arising from ICRP 103 to impact on operations?</p> <p>B 1.8 Do you anticipate that the incorporation of ICRP 103 may lead to any reduction of any kind of cost or effort?</p>	<p>B 1.7</p> <p>The implementation of new weighing factors will not be a problem for the operators. And the application of dose constraints by the operators will be probably more frequently.</p> <p>B 1.8</p> <p>It is possible that the implementation may lead to dose reduction, but we do not expect that the reduction will be significant.</p>

B 2. Experience with specific technical aspects	
<p>We would appreciate answers from both regulators and operators to all of these questions!</p>	
<p><i>Pregnant workers</i></p> <p>B 2.1 Do you envisage that the introduction of the 1 mSv limit for the embryo / fetus (ICRP 103) will cause any problems or costs? <i>(Note: this question does not apply to EU member countries since the current Euratom BSS Directive already prescribes such a limit).</i></p> <p>B 2.2 If yes, what might they be, and how do you plan to resolve them?</p>	<p>B 2.1</p> <p>No</p> <p>B 2.2</p>
<p><i>Constraints</i></p> <p>B 2.3 Is the added emphasis on dose constraints in ICRP 103 expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p> <p>B 2.4 Are risk constraints likely to be introduced with the implementation of ICRP 103?</p>	<p>B 2.3</p> <p>No.</p> <p>B 2.4</p> <p>It depends on EU directive.</p>

B 2. Experience with specific technical aspects	
<p><i>Dosimetry</i></p> <p>B 2.5 Are the new ICRP 103 radiation and tissue weighting factors expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.5</p> <p>We do not expect any serious difficulty.</p>
<p><i>Radon</i></p> <p>B 2.6 Is the implementation of ICRP 103 expected to cause any new efforts or costs with respect to radon? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.6</p> <p>It depends how it will be implemented in EU directives.</p>

B 3. Training implications	
<p>Questions 3.1 – 3.3 are aimed primarily at regulators, and question 3.4 at both regulators and operators!</p>	
<p><i>Regulators' staff</i></p> <p>B 3.1 What methods do you plan to use to ensure that relevant members of staff were aware of and understood the revised legislation?</p> <p>B 3.2 Do you anticipate any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?</p> <p>B 3.3 Do you expect to be involved in ensuring that stakeholders are aware of and understood the revised legislation? If so, how do you anticipate doing this?</p>	<p>B 3.1</p> <p>We will prepare some workshops and training for the regulatory body staff.</p> <p>B 3.2</p> <p>No.</p> <p>B 3.3</p> <p>We expect that the regulatory staff we will be involved and few seminar or workshops for the stakeholders will be organised after the BSS of IAEA and EU will be issued.</p>
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>B 3.4 What do you expect will be the extent of training and information required? Will this be an entirely new effort, or could it be integrated into existing</p>	<p>B 3.4</p>

B 3. Training implications	
schedules of recurring training? What may be the anticipated costs of training?	

And finally: Is there anything else that you wish to add?

[Please add any 'open' comments here!]

Note : Public Health Authority carry on all activities in area radiation protection (legislation, supervision, licensing,). The financial support is given from Ministry of Health.

Questionnaire v.2.0 - completed for [country]: SLOVENIA

**NEA Project for Obtaining Historical Information on Costs and Impacts of Incorporating ICRP Publ. 60 and Possible Resources for Incorporating ICRP Publ. 103
Part A: incorporating ICRP 60: Key impacts/provisions**

NOTE: for EU Member States: references to incorporation of ICRP 60 should be read as implementation of Directives 96/29/Euratom and 97/43/Euratom.

A 31. General	
Questions A 1.1 to A 1.9 are aimed primarily at regulators, and questions A 1.10 – A 1.11 primarily at operators, but we welcome your replies to all queries!	
Question	Your experience
<p><i>Legislation</i></p> <p>A 1.1 Please describe briefly the hierarchy, if applicable, of ionising radiation protection legislation/rules in your country, e.g. national law, national government regulations; central authority regulations; regional or local authority regulations; other (e.g., professional body) rules. Also, please briefly describe what is covered at each level.</p>	<p>A 1.1 The key piece of legislation is Ionising Radiation Protection and Nuclear Safety Act (IRPNSA), it defines responsibilities and prescribes further regulation (decrees), that deal with specific topics. This set of decrees is divided into governmental decrees (use of radiation, allowed levels of radioactivity in the environment, workplace and food&feedstuffs, nuclear matters), decrees from the ministry of environment (use of sources, workers and expert qualification, rad. waste, operational safety, radioactivity monitoring, shipment of rad. and nuclear materials), decrees from the ministry of health (use of sources – together with env. ministry, use of radiation in healthcare, dose assessment for population and workers and surveillance for workers, workers and expert qualification, use of KI in case of nucl. accident) and decrees from the ministry of interior (mostly physical protection)</p>
<p><i>Organisation</i></p> <p>A1.2 Describe the different authorities, and (approximately) how many regulators are involved in making and enforcing radiation protection legislation? Also, if appropriate, please briefly describe how consistency of approach between regulatory organisations is achieved?</p>	<p>A 1.2 2 authorities: Slovenian Nuclear Safety Administration (SNSA) and Slovenian Radiation Protection Administration (SRPA). SNSA is responsible for the nuclear safety, industrial sources and protection of the environment, SRPA for protection of workers and population. In the cases where interests overlap, both bodies are usually involved.</p>
<p><i>ICRP 60 incorporation</i></p> <p>A 1.3 To what extent were legislation and regulations rewritten when ICRP 60 was incorporated?</p> <p>A 1.4 What was the procedure, what problems and efforts were there?</p>	<p>A 1.3 Slovenia declared independence in 1991, so at first old Yougoslav regulation applied as a temporary measure. In this sense, all legislation was rewritten since ICRP 60.</p> <p>A 1.4 Basic law (IRPNSA) was implemented in 2002 (end amended few times since, lat time in 2011). Since then, most of the second level legislation was also rewritten. Most of the second level legislation was written by the regulatory authorities, some by experts from technical support organizations (TSO) and then reviewed by the regulators and governmental legislative authorities.</p>
<p><i>Stakeholders</i></p> <p>A 1.5 Who were the stakeholders (e.g. other ministries, operators, etc.) and how was their involvement achieved?</p>	<p>A 1.5 All involved ministries were consulted (environment and health primary, interior, agriculture, foreign affairs), NPP operator and TSO were invited to discuss and comment on relevant legislation. Bilateral and multilateral discussions were organised to achieve best results.</p>

A 31. General	
<p><i>Guidance</i></p> <p>A 1.6 How was guidance on the implementing legislation developed and by whom (e.g.: regulatory authorities; professional societies, trade organisations)?</p>	<p>A 1.6 Regulatory authorities</p>
<p><i>Time-scales</i></p> <p>A 1.7 What were the lead-in times for new requirements, i.e., when were they proposed, when decided, when was full compliance by operators required?</p>	<p>A 1.7</p>
<p><i>Burdens and benefits</i></p> <p>A 1.8 Did your regulatory authority perform a cost-benefit analysis of the implications of any new regulations, (regulatory analysis) and if so is there a report available (where)?</p>	<p>A 1.8 When I came to the specific answers of costs, we never had any means to analyse it, so the main purpose of your questionnaire is in our case completely defeated.</p>
<p><i>Cost of Not Acting</i></p> <p>A 1.9 Were the costs/savings/implications of not implementing ICRP 60 assessed? If so, what were they?</p>	<p>A 1.9</p>
<p><i>Actual costs</i></p> <p>ICRP 60 and Euratom Directives 96/29 and 97/43 entailed, e.g., that</p> <ul style="list-style-type: none"> -the annual limit on occupational effective dose was reduced from 50 to 20 mSv, with an option of 5-year averaging; - it was clarified that the annual limit on effective dose to members of the public is 1 mSv, not 5 mSv; - effective dose (with new weighting factors w_R and w_T) replaced the effective dose equivalent; - the concepts of dose and risk constraints were introduced; - diagnostic reference levels were introduced. <p>A 1.10 How did these new requirements arising from ICRP 60 impact on operations?</p> <p>A 1.11 Did the incorporation</p>	<p>A 1.10</p> <p>A 1.11</p>

A 31. General	
of ICRP 60 lead to any reduction of any kind of cost or effort?	

A 32. Application / scope	
Questions A 2.1 to A 2.2 are aimed primarily at regulators. We are grateful for replies from both operators and regulators to questions A 2.3 - A 2.4!	
<p><i>Scope</i></p> <p>A 2.1 Did pre-ICRP 60 legislation in your country cover all uses and users of ionising radiation, e.g.: industrial applications (including industrial radiography), medical applications (diagnostic and therapeutic), nuclear fuel cycle, research and teaching, transport, radioactive waste disposal, occupational exposure to radon (mining and non-mining), agriculture?</p> <p>A 2.2 If not, was new legislation introduced to close the previous gaps?</p> <p>A 2.3 Did the timeframe for implementation vary for the sectors described in A 2.1? If so, how?</p>	<p>A 2.1</p> <p>A 2.2</p> <p>A 2.3</p>
<p><i>Response</i></p> <p>A 2.4 Was there any resistance from those sectors (if any) which were not previously covered? If so, what were the main perceived difficulties and what was done to overcome them?</p>	<p>A 2.4</p>

A 33. Dose limits and dose distribution	
Questions A 3.1 – A 3.3 are aimed primarily at regulators. We would be grateful for replies from both regulators and operators for questions A 3.4 – A 3.10!	
<p><i>Historical limits</i></p> <p>A 3.1 What were your dose limits before you incorporated ICRP 60?</p>	<p>A 3.1</p>

A 33. Dose limits and dose distribution	
<p><i>Current limits</i></p> <p>A 3.2 What were your dose limits after implementation?</p> <p>A 3.3 Was any flexibility built into dose limits, e.g. public limits allowed up to 5 mSv in exceptional circumstances?</p> <p>A 3.4 If 5-year averaging was chosen for occupational doses, what is your experience? Were there any difficulties?</p>	<p>A 3.2</p> <p>A 3.3</p> <p>A 3.4</p>
<p><i>Transition experience</i></p> <p>A 3.5 What was your experience of establishing these lower dose limits?</p> <p>A 3.6 Did any installation need significant rebuilding to comply with added shielding requirements? If no, how was this avoided?</p> <p>A 3.7 Were there any other difficulties? If so, what were they and how were they resolved?</p>	<p>A 3.5</p> <p>A 3.6</p> <p>A 3.7</p>
<p><i>Resulting doses</i></p> <p>A 3.8 What analyses of dose distributions are available for your country, over what period?</p> <p>A 3.9 Have these dose distributions changed? How?</p> <p>3.10 If yes, what was (were) the main factor(s) influencing these changes?</p>	<p>A 3.8</p> <p>A 3.9</p> <p>A 3.10</p>

A 34. Experience with specific technical aspects	
We would appreciate answers from both regulators and operators to all of these questions!	
<p><i>Pregnant workers</i></p> <p>A 4.1 What happens when an occupationally exposed worker becomes pregnant?</p> <p>A 4.2 Did the introduction of the 2 mSv limit for the abdomen (ICRP 60) or the 1 mSv limit for the embryo /</p>	<p>A 4.1</p> <p>A 4.2</p> <p>A 4.3</p>

A 34. Experience with specific technical aspects	
<p>fetus (Euratom Directive) cause any problems or costs? A 4.3 If yes, what were they and how were they resolved?</p>	
<p><i>Constraints</i> A 4.4 What is your experience of the introduction and use of dose constraints for occupational and public exposures? A 4.5 Were there any difficulties? If yes, what were they and how were they resolved? A 4.6 Have you at all used risk constraints? If yes, what is your experience?</p>	<p>A 4.4 A 4.5 A 4.6</p>
<p><i>Radiation Dosimetry</i> A 4.7 Please describe briefly the organisation and regulatory framework for dosimetry in your country. A 4.8 Did the introduction of ICRP 60 radiation and tissue weighting factors lead to any difficulties? If yes, what were they and how were they resolved? A 4.9 Were there any costs associated with the implementation of the ICRP 60 dosimetric approach (e.g. dose coefficients, modelling, instrument calibration, etc.), if so, how much and borne by whom?</p>	<p>A 4.7 A 4.8 A 4.9</p>
<p><i>Radon</i> A 4.10 Please describe briefly the current arrangements with respect to radon, in dwellings and at the workplace. A 4.11 Did the implementation of ICRP 60 cause any new efforts or costs? If yes, what were they and how were they resolved?</p>	<p>A 4.10 A 4.11</p>

A 35. Training implications	
Question A 5.1 – A 5.2 are aimed primarily at regulators, and questions A 5.3 – A 5.5 at both regulators and operators!	
<p><i>Regulators' staff</i></p> <p>A 5.1 What methods did you use to ensure that relevant members of staff were aware of and understood the revised legislation?</p> <p>A 5.2 Were there any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?</p> <p>A 5.3 Were you involved in ensuring that stakeholders were aware of and understood the revised legislation?</p> <p>A 5.4 If so, how did you do this?</p>	<p>A 5.1</p> <p>A 5.2.</p> <p>A 5.3</p> <p>A 5.4</p>
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>A 5.5 What was the extent of training and information required? Was this an entirely new effort, or could it be integrated into existing schedules of recurring training? What were the costs of training?</p>	<p>A 5.5</p>

Part B: incorporating ICRP 103: Anticipated key impacts/provisions

B 1. General	
Questions B 1.1 to B 1.6 are aimed primarily at regulators, and questions B 1.7 - B 1.8 primarily at operators, but we welcome your replies to all queries!	
<p><i>Legislation</i></p> <p>B 1.1 Do you expect to have to change your ionising radiation protection legislation/rules if/when ICRP 103 is incorporated?</p> <p>B 1.2 If appropriate, please</p>	<p>B 1.1 As far as ICRP 103 goes, wea havent started to implement it yet..</p> <p>B 1.2</p>

B 1. General	
briefly describe the anticipated changes.	
<p><i>Organisation</i></p> <p>B 1.3 Do you expect that the incorporation of ICRP 103 will lead to any changes to the organisation and/or resources of the radiation protection regulators, compared with that reported in Section A?</p> <p>B 1.4 If appropriate, please briefly describe how consistency of approach between regulatory organisations is to be achieved?</p>	<p>B 1.3</p> <p>B 1.4</p>
<p><i>Burdens and benefits</i></p> <p>B 1.5 Does your regulatory authority expect to perform a cost-benefit analysis of the implications of any new regulations (regulatory analysis) and if so, when might a report become available (where)?</p>	<p>B 1.5</p>
<p><i>Cost of Not Acting</i></p> <p>B 1.6 Will the costs / savings / implications of not implementing Publication 103 be assessed? If so, when?</p>	<p>B 1.6</p>
<p><i>Anticipated costs</i></p> <p>ICRP 103 and the new Euratom Directive will entail, e.g.,</p> <ul style="list-style-type: none"> - amended w_R and w_T; - added emphasis on dose constraints. <p>B 1.7 How do you expect these new requirements arising from ICRP 103 to impact on operations?</p> <p>B 1.8 Do you anticipate that the incorporation of ICRP 103 may lead to any reduction of any kind of cost or effort?</p>	<p>B 1.7</p> <p>B 1.8</p>

B 2. Experience with specific technical aspects	
We would appreciate answers from both regulators and operators to all of these questions!	
<p><i>Pregnant workers</i></p> <p>B 2.1 Do you envisage that the introduction of the 1 mSv limit for the embryo / fetus (ICRP 103) will cause any problems or costs? <i>(Note: this question does not apply to EU member countries since the current Euratom BSS Directive already prescribes such a limit).</i></p> <p>B 2.2 If yes, what might they be, and how do you plan to resolve them?</p>	<p>B 2.1</p> <p>B 2.2</p>
<p><i>Constraints</i></p> <p>B 2.3 Is the added emphasis on dose constraints in ICRP 103 expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p> <p>B 2.4 Are risk constraints likely to be introduced with the implementation of ICRP 103?</p>	<p>B 2.3</p> <p>B 2.4</p>
<p><i>Dosimetry</i></p> <p>B 2.5 Are the new ICRP 103 radiation and tissue weighting factors expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.5</p>
<p><i>Radon</i></p> <p>B 2.6 Is the implementation of ICRP 103 expected to cause any new efforts or costs with respect to radon? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.6</p>
B 3. Training implications	
Questions 3.1 – 3.3 are aimed primarily at regulators, and question 3.4 at both regulators and operators!	
<p><i>Regulators' staff</i></p> <p>B 3.1 What methods do you plan to use to ensure that relevant members of staff</p>	<p>B 3.1</p> <p>B 3.2</p> <p>B 3.3</p>

B 3. Training implications	
<p>were aware of and understood the revised legislation?</p> <p>B 3.2 Do you anticipate any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?</p> <p>B 3.3 Do you expect to be involved in ensuring that stakeholders are aware of and understood the revised legislation? If so, how do you anticipate doing this?</p>	
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>B 3.4 What do you expect will be the extent of training and information required? Will this be an entirely new effort, or could it be integrated into existing schedules of recurring training? What may be the anticipated costs of training?</p>	<p>B 3.4</p>

And finally: Is there anything else that you wish to add?

[Please add any 'open' comments here!]

Dear Sir,

I'm afraid that i will not be of much help. The main reason is the following: the independence of Slovenia (1991) roughly coincided with ICRP 60 so it was necessary to produce new national legislation anyway. I have started the questionnaire but soon found that we have never actually analysed the impact of new legislation since we had to do it anyway and we did everything in accordance with EU directives and BSS (since we were striving to join EU anyway). I will send you the short answers that describe the situation in Slovenia, maybe you will find something useful.

I am sorry for the incomplete answer.

Best regards

Michel Cindro
Senior Counsellor
Slovenian Nuclear Safety Administration

Questionnaire v.2.0 - completed for [country]:SPAIN.....

**NEA Project for Obtaining Historical Information on Costs and Impacts of Incorporating ICRP Publ. 60 and Possible Resources for Incorporating ICRP Publ. 103
Part A: incorporating ICRP 60: Key impacts/provisions**

NOTE: for EU Member States: references to incorporation of ICRP 60 should be read as implementation of Directives 96/29/Euratom and 97/43/Euratom.

A 36. General	
Questions A 1.1 to A 1.9 are aimed primarily at regulators, and questions A 1.10 – A 1.11 primarily at operators, but we welcome your replies to all queries!	
Question	Your experience
<p><i>Legislation</i></p> <p>A 1.1 Please describe briefly the hierarchy, if applicable, of ionising radiation protection legislation/rules in your country, e.g. national law, national government regulations; central authority regulations; regional or local authority regulations; other (e.g., professional body) rules. Also, please briefly describe what is covered at each level.</p>	<p>A 1.1 [Please fill in your reply here!]</p> <p>National Law: Very short and general requirements included in Nuclear Energy Act.</p> <p>National Government Regulations: This is the main regulatory tool used. More than twelve Royal Decrees were released to incorporate to national regulations UE Directives related to radiation protection.</p> <p>In addition some binding technical regulations were released by the regulatory authority (CSN) who also released guidance. This two types of regulations / guidance are to further develop requirements in Royal Decrees to a very detailed level.</p>
<p><i>Organisation</i></p> <p>A1.2 Describe the different authorities, and (approximately) how many regulators are involved in making and enforcing radiation protection legislation? Also, if appropriate, please briefly describe how consistency of approach between regulatory organisations is achieved?</p>	<p>A 1.2</p> <p>The same authority in charge of making regulations are in charge of enforcement.</p> <p><u>Public, workers and environmental Radiation Protection:</u> Industry Ministry Regional Industry Authorities Consejo de Seguridad Nuclear.</p> <p><u>Patients Radiation Protection :</u> Health Ministry Regional Health Authorities.</p> <p>In every case regulations establish functions and responsibilities for each one of these authorities as well as the relationship between the different authorities. Those relationships vary from ask or receive official binding reports to an open co-operation.</p>
<p><i>ICRP 60 incorporation</i></p> <p>A 1.3 To what extent were legislation and regulations rewritten when ICRP 60 was incorporated?</p> <p>A 1.4 What was the procedure, what problems and efforts were there?</p>	<p>A 1.3</p> <p>They were fully rewritten following UE Directives.</p> <p>A 1.4</p> <p>For Public, workers and environmental Radiation Protection CSN drafted the new regulations. Industry Ministry led a working group were Draft regulations were discussed / agreed with the rest of authorities and Stakeholders (trade unions) involved.</p> <p>For Patients radiation protection Health Ministry was both in charge of Drafting and led the corresponding working group.</p>

A 36. General	
	There were no problems. Some difficulties were found derived from the need (asked by trade unions) to accommodate medical surveillance of exposed workers to general regulations on work risk prevention.
<p><i>Stakeholders</i></p> <p>A 1.5 Who were the stakeholders (e.g. other ministries, operators, etc.) and how was their involvement achieved?</p>	<p>A 1.5</p> <p>Many Ministries and bigger trade unions took part in the mentioned groups to write the new regulations. In addition operators, professional societies, ecologist organisations and even members of the public received the regulation projects for comments prior to approval.</p>
<p><i>Guidance</i></p> <p>A 1.6 How was guidance on the implementing legislation developed and by whom (e.g.: regulatory authorities; professional societies, trade organisations)?</p>	<p>A 1.6</p> <p>For Public, workers and environmental Radiation Protection: CSN through its planned program to develop regulations and guidance.</p> <p>For Patients radiation protection: Health Authorities and Professional Societies.</p>
<p><i>Time-scales</i></p> <p>A 1.7 What were the lead-in times for new requirements, i.e., when were they proposed, when decided, when was full compliance by operators required?</p>	<p>A 1.7</p> <p>As Spain belongs to UE time scales to translate no national regulations were set up in the corresponding Directives EURATOM 96/29 y EURATOM 97/43.</p> <p>The main regulation translating to national regulations RP requirements according to ICRP 60 was released July 2001. A time period of one year was set for operators to develop RP Manuals and procedures.</p> <p>For patients RP Quality control requirements regulations on Nuclear Medicine, Radiotherapy and X-ray diagnosis were released in 1997, 1998 and 1998 respectively. Finally a regulation related to Justifications of medical exposures was released in 2001.</p>
<p><i>Burdens and benefits</i></p> <p>A 1.8 Did your regulatory authority perform a cost-benefit analysis of the implications of any new regulations, (regulatory analysis) and if so is there a report available (where)?</p>	<p>A 1.8</p> <p><i>No they did'nt.</i></p>

A 36. General	
<p><i>Cost of Not Acting</i></p> <p>A 1.9 Were the costs/savings/implications of not implementing ICRP 60 assessed? If so, what were they?</p>	<p>A 1.9 No they weren't assessed.</p>
<p><i>Actual costs</i></p> <p>ICRP 60 and Euratom Directives 96/29 and 97/43 entailed, e.g., that</p> <ul style="list-style-type: none"> -the annual limit on occupational effective dose was reduced from 50 to 20 mSv, with an option of 5-year averaging; - it was clarified that the annual limit on effective dose to members of the public is 1 mSv, not 5 mSv; - effective dose (with new weighting factors w_R and w_T) replaced the effective dose equivalent; - the concepts of dose and risk constraints were introduced; - diagnostic reference levels were introduced. <p>A 1.10 How did these new requirements arising from ICRP 60 impact on operations?</p> <p>A 1.11 Did the incorporation of ICRP 60 lead to any reduction of any kind of cost or effort?</p>	<p>A 1.10 New Dose Limits, constraints and diagnostic reference levels were incorporated to operations without specific impact. From the time the UE directives were released operators started to use the new values as a trial exercise to be ready when they were incorporated to national regulations.</p> <p>A 1.11 There has not been any analysis related to this, no evidence of any kind of cost or effort exists. All operators and services companies (dosimetry services...) had (at least) costs related to updating RP manuals and procedures to the new regulations as required by the competent authorities. .</p>

A 37. Application / scope	
<p>Questions A 2.1 to A 2.2 are aimed primarily at regulators. We are grateful for replies from both operators and regulators to questions A 2.3 - A 2.4!</p>	
<p><i>Scope</i></p> <p>A 2.1 Did pre-ICRP 60 legislation in your country cover all uses and users of ionising radiation, e.g.: industrial applications (including industrial radiography), medical applications (diagnostic and therapeutic), nuclear fuel cycle, research and teaching, transport, radioactive waste disposal, occupational exposure to radon (mining and non-mining), agriculture?</p>	<p>A 2.1 Yes, except exposures to natural radiation.</p> <p>A 2.2 Exposures to natural radiation.</p> <p>A 2.3 Yes. For the case of exposures to natural radiation first steps were to identify activities and facilities where they take place, second determine which of them need for a radiation program, third decide a RP program tailored to each specific activity to be required. All this process delayed the effective implementation of the new requirements.</p>

A 37. Application / scope	
<p>A 2.2 If not, was new legislation introduced to close the previous gaps?</p> <p>A 2.3 Did the timeframe for implementation vary for the sectors described in A 2.1? If so, how?</p>	
<p><i>Response</i></p> <p>A 2.4 Was there any resistance from those sectors (if any) which were not previously covered? If so, what were the main perceived difficulties and what was done to overcome them?</p>	<p>A 2.4</p> <p>No there was not any special resistance.</p>

A 38. Dose limits and dose distribution	
<p>Questions A 3.1 – A 3.3 are aimed primarily at regulators. We would be grateful for replies from both regulators and operators for questions A 3.4 – A 3.10!</p>	
<p><i>Historical limits</i></p> <p>A 3.1 What were your dose limits before you incorporated ICRP 60?</p>	<p>A 3.1</p> <p>Workers: 50 mSv/y.</p> <p>Members of the Public: 5 mSv/y.</p>
<p><i>Current limits</i></p> <p>A 3.2 What were your dose limits after implementation?</p> <p>A 3.3 Was any flexibility built into dose limits, e.g. public limits allowed up to 5 mSv in exceptional circumstances?</p> <p>A 3.4 If 5-year averaging was chosen for occupational doses, what is your experience? Were there any difficulties?</p>	<p>A 3.2</p> <p>Workers: 100 mSv averaged on 5 years with a maximum of 50 mSv/y.</p> <p>Members of the Public: 1 mSv/y.</p> <p>A 3.3</p> <p>No there was not.</p> <p>A 3.4</p> <p>Our experience has been that having a 5 years averaged limit in addition to the year limits introduces a lot of work for workers dose tracking and follow up.</p> <p>Few cases of exceeding the five year limit have been reported were the limit (100 mSv) had not been exceeded for the current year. On the other hand most practices in Spain have annual doses well below 20 mSv, thus from a practical point of view we find it interesting (as many European countries did) setting up a single dose limit of 20 mSv/y.</p>
<p><i>Transition experience</i></p> <p>A 3.5 What was your experience of establishing these lower dose limits?</p> <p>A 3.6 Did any installation need significant rebuilding to</p>	<p>A 3.5</p> <p>Good, as I said before we were applying in practice the new limits before the new regulations were released.</p> <p>Annual dose at Spanish practices were well below the new limits long in advance to the time they entered into force.</p>

A 38. Dose limits and dose distribution	
<p>comply with added shielding requirements? If no, how was this avoided?</p> <p>A 3.7 Were there any other difficulties? If so, what were they and how were they resolved?</p>	<p>A 3.6 Not they didn't. As i told doses were below the new limits only small shielding rearrangements were required.</p> <p>A 3.7 No there weren't anu other special difficulties.</p>
<p><i>Resulting doses</i></p> <p>A 3.8 What analyses of dose distributions are available for your country, over what period?</p> <p>A 3.9 Have these dose distributions changed? How?</p> <p>3.10 If yes, what was (were) the main factor(s) influencing these changes?</p>	<p>A 3.8 From a very long time ago the Spanish regulatory body carries out yearly analysis of dose results by sectors of practices.</p> <p>A 3.9 Some of them experienced additional reductions. Mainly practices having before the new regulations doses over 10 mSv/y reduced them to values under 10 mSv/y.</p> <p>A 3.10 Regulatory control (pressure) to take advantage for optimization opportunities.</p>

A 39. Experience with specific technical aspects	
<p>We would appreciate answers from both regulators and operators to all of these questions!</p>	
<p><i>Pregnant workers</i></p> <p>A 4.1 What happens when an occupationally exposed worker becomes pregnant?</p> <p>A 4.2 Did the introduction of the 2 mSv limit for the abdomen (ICRP 60) or the 1 mSv limit for the embryo / fetus (Euratom Directive) cause any problems or costs?</p> <p>A 4.3 If yes, what were they and how were they resolved?</p>	<p>A 4.1 She may (voluntary basis) declare her pregnancy to the Service in charge of RP. If she do so she receives a new dosimeter to be placed on her abdomen to monthly survey doses to the fetus with a limit of 1 mSv to the time of the birth (2 mSv at the dosimeter is assumed equivalent to 1 msV to the fetus).</p> <p>Information for women, practitioners and RP staff has been developed by CSN on implications and how to manage pregnancy of exposed workers.</p> <p>A 4.2 No problems. Additional costs for a new dosimeter during pregnancy.</p> <p>A 4.3 As mentioned, additional dosimetry required during pregnancy.</p>
<p><i>Constraints</i></p> <p>A 4.4 What is your experience of the introduction and use of dose constraints for occupational and public exposures?</p> <p>A 4.5 Were there any difficulties? If yes, what were they and how were they resolved?</p> <p>A 4.6 Have you at all used risk constraints? If yes, what</p>	<p>A 4.4 We did not introduce either use dose constraints for occupational and public exposures.</p> <p>A 4.5 Traditionally in Spain we use reference levels, proposed by licensees and accepted by regulatory authorities.</p> <p>A 4.6 A constraint for dose to population from a single nuclear facility was used (100 μSv/y). It is set up by regulatory authorities in the conditions for operating permit, no problem were identified for its implementation.</p>

A 39. Experience with specific technical aspects	
is your experience?	
<p><i>Radiation Dosimetry</i></p> <p>A 4.7 Please describe briefly the organisation and regulatory framework for dosimetry in your country.</p> <p>A 4.8 Did the introduction of ICRP 60 radiation and tissue weighting factors lead to any difficulties? If yes, what were they and how were they resolved?</p> <p>A 4.9 Were there any costs associated with the implementation of the ICRP 60 dosimetric approach (e.g. dose coefficients, modelling, instrument calibration, etc.), if so, how much and borne by whom?</p>	<p>A 4.7</p> <p>There are up to 22 private companies providing external dosimetry for practices. They must, and they are authorised by CSN.</p> <p>Same situation for internal dosimetry. There are nine companies authorised with Body counters and two companies authorised for excreta dosimetry.</p> <p>There are four labs (non authorised) capable for providing biologic dosimetry.</p> <p>A 4.8</p> <p>No problems were reported. Procedures and authorization for all services were updated.</p> <p>A 4.9</p> <p>Some joint development (services and regulatory body together) was necessary to introduce the new modelling in ICRP 66 for internal dosimetry (measurement, dose calculation and calibration).</p>
<p><i>Radon</i></p> <p>A 4.10 Please describe briefly the current arrangements with respect to radon, in dwellings and at the workplace.</p> <p>A 4.11 Did the implementation of ICRP 60 cause any new efforts or costs? If yes, what were they and how were they resolved?</p>	<p>A 4.10</p> <p>Dwellings: a lot of measurements were performed by the regulatory body. Recommendations for building were released.</p> <p>Workplaces: a technical regulation (binding) is about to be released by regulatory body setting up the concentration levels above which measures must be taken and defining the specific measures for remediation and protection to be taken.</p> <p>A 4.11</p> <p>A lot of work was carried out for Radon measurements and to develop building techniques and materials.</p>

A 40. Training implications	
Question A 5.1 – A 5.2 are aimed primarily at regulators, and questions A 5.3 – A 5.5 at both regulators and operators!	
<p><i>Regulators' staff</i></p> <p>A 5.1 What methods did you use to ensure that relevant members of staff were aware of and understood the revised legislation?</p> <p>A 5.2 Were there any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping /</p>	<p>A 5.1</p> <p>Internal training was provided by those staff members who had active role on development of new European and national regulations.</p> <p>A 5.2.</p> <p>No they weren't</p> <p>A 5.3</p> <p>Yes we, as Regulatory Body, were involved.</p> <p>A 5.4</p> <p>Joint (regulator + licensees)working groups were created for large facilities (nuclear fuell cycle facilities and NPP) to develop new radiation</p>

A 40. Training implications	
<p>reporting? If so, briefly describe?</p> <p>A 5.3 Were you involved in ensuring that stakeholders were aware of and understood the revised legislation?</p> <p>A 5.4 If so, how did you do this?</p>	<p>protection manuals and procedures.</p> <p>For the case of small practices joint working groups were created with professional societies. Format radiation protection manuals and procedures were written and released for free use. Other deliverables, formats and template were also produced.</p> <p>Specific guidance and instructions were released by regulatory body when required or found of interest.</p> <p>Reference to regulations and guidance developed by international organisations was also used.</p>
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>A 5.5 What was the extent of training and information required? Was this an entirely new effort, or could it be integrated into existing schedules of recurring training? What were the costs of training?</p>	<p>A 5.5</p> <p>In Spain all those working with radiations need to have a personnel license released by CSN.</p> <p>To get those licenses a training program must be followed provided by training companies recognised by CSN to do so. Training programs and materials were updated to the new regulations under requirement of the regulatory body.</p> <p>Continuous training and on the job training were used to train people at existing practices.</p> <p>Cost are difficult to calculate. By the time the new regulations were released in Spain there were around 80.000 exposed workers. Not all the people required the same training, for example people working on dosimetry needed more training (hours) than others.</p>

Part B: incorporating ICRP 103: Anticipated key impacts/provisions

B 1. General	
<p>Questions B 1.1 to B 1.6 are aimed primarily at regulators, and questions B 1.7 - B 1.8 primarily at operators, but we welcome your replies to all queries!</p>	
<p><i>Legislation</i></p> <p>B 1.1 Do you expect to have to change your ionising radiation protection legislation/rules if/when ICRP 103 is incorporated?</p> <p>B 1.2 If appropriate, please briefly describe the anticipated changes.</p>	<p>B 1.1</p> <p>Yes we do.</p> <p>B 1.2</p> <p>The dose limits (new limits for eye lenses ..), new categories of expositions and new approach for emergency and existing exposures, change from intervention levels to reference levels, introduce radiation protection of the environment.....,</p>
<p><i>Organisation</i></p> <p>B 1.3 Do you expect that the incorporation of ICRP 103 will lead to any changes to the organisation and/or resources of the radiation protection regulators, compared with that reported</p>	<p>B 1.3</p> <p>We don't expect big changes but small ones.</p> <p>B 1.4</p> <p>The same way as we are doing now.</p>

B 1. General	
<p>in Section A? B 1.4 If appropriate, please briefly describe how consistency of approach between regulatory organisations is to be achieved?</p>	
<p><i>Burdens and benefits</i> B 1.5 Does your regulatory authority expect to perform a cost-benefit analysis of the implications of any new regulations (regulatory analysis) and if so, when might a report become available (where)?</p>	<p>B 1.5 No it does not.</p>
<p><i>Cost of Not Acting</i> B 1.6 Will the costs / savings / implications of not implementing Publication 103 be assessed? If so, when?</p>	<p>B 1.6 No they won't.</p>
<p><i>Anticipated costs</i> ICRP 103 and the new Euratom Directive will entail, e.g., - amended w_R and w_T; - added emphasis on dose constraints. B 1.7 How do you expect these new requirements arising from ICRP 103 to impact on operations? B 1.8 Do you anticipate that the incorporation of ICRP 103 may lead to any reduction of any kind of cost or effort?</p>	<p>B 1.7 Impact is going to be very limited. Cost are expected far below those for ICRP 60. Some cost may come from incorporation and development of dose constraints . B 1.8 Reduction can take place if limits averaged for 5 years are eliminated.</p>

B 2. Experience with specific technical aspects	
<p>We would appreciate answers from both regulators and operators to all of these questions!</p>	
<p><i>Pregnant workers</i> B 2.1 Do you envisage that the introduction of the 1 mSv limit for the embryo / fetus (ICRP 103) will cause any problems or costs? <i>(Note: this</i></p>	<p>B 2.1 B 2.2</p>

B 2. Experience with specific technical aspects	
<p><i>question does not apply to EU member countries since the current Euratom BSS Directive already prescribes such a limit).</i></p> <p>B 2.2 If yes, what might they be, and how do you plan to resolve them?</p>	
<p><i>Constraints</i></p> <p>B 2.3 Is the added emphasis on dose constraints in ICRP 103 expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p> <p>B 2.4 Are risk constraints likely to be introduced with the implementation of ICRP 103?</p>	<p>B 2.3</p> <p>Yes it does. As I said before use of dose constraints has been very limited in Spain so far.</p> <p>We need to introduce dose constraints for occupational, emergency and existing situation and develop approaches to implement them and control their use.</p> <p>B 2.4</p> <p>I don't think so.</p>
<p><i>Dosimetry</i></p> <p>B 2.5 Are the new ICRP 103 radiation and tissue weighting factors expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.5</p> <p>No they are not. The same difficulties than for ICRP 60 are expected.</p>
<p><i>Radon</i></p> <p>B 2.6 Is the implementation of ICRP 103 expected to cause any new efforts or costs with respect to radon? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.6</p> <p>Yes it is. As lower Radon concentrations are now allowed the scope of activities and facilities will grow. The approach to be followed I think will be very similar to that introduced after ICRP 60.</p>

B 3. Training implications	
<p>Questions 3.1 – 3.3 are aimed primarily at regulators, and question 3.4 at both regulators and operators!</p>	
<p><i>Regulators' staff</i></p> <p>B 3.1 What methods do you plan to use to ensure that relevant members of staff were aware of and understood the revised legislation?</p> <p>B 3.2 Do you anticipate any issues associated with the implementation of new terminology, dose coefficients, calculation</p>	<p>B 3.1</p> <p>Internal training provided by those who took part in development of new IAEA IBSS and European Directive (recast).</p> <p>B 3.2</p> <p>No we don't. We anticipate only operational difficulties to be sorted out based on knowledge and experience.</p> <p>B 3.3</p> <p>As we did for ICRP 60 implementation, involve them in regulations development and working with them for their implementation.</p>

B 3. Training implications	
<p>methods or record keeping / reporting? If so, briefly describe?</p> <p>B 3.3 Do you expect to be involved in ensuring that stakeholders are aware of and understood the revised legislation? If so, how do you anticipate doing this?</p>	
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>B 3.4 What do you expect will be the extent of training and information required? Will this be an entirely new effort, or could it be integrated into existing schedules of recurring training? What may be the anticipated costs of training?</p>	<p>B 3.4</p> <p>No I think it won't. As the system has not been entirely changed but explained in a different (more clear and friendly) way, we think training efforts will be less than those made to introduce ICRP 60. The main uncertainty is that related to dose constraints as this tool has had very limited use in the past.</p>

And finally: Is there anything else that you wish to add?
[Please add any 'open' comments here!]

Questionnaire v.2.0 - completed for [country]:Sweden.....

**NEA Project for Obtaining Historical Information on Costs and Impacts of Incorporating ICRP Publ. 60 and Possible Resources for Incorporating ICRP Publ. 103
Part A: incorporating ICRP 60: Key impacts/provisions**

NOTE: for EU Member States: references to incorporation of ICRP 60 should be read as implementation of Directives 96/29/Euratom and 97/43/Euratom.

A 41. General	
Questions A 1.1 to A 1.9 are aimed primarily at regulators, and questions A 1.10 – A 1.11 primarily at operators, but we welcome your replies to all queries!	
Question	Your experience
<p><i>Legislation</i></p> <p>A 1.1 Please describe briefly the hierarchy, if applicable, of ionising radiation protection legislation/rules in your country, e.g. national law, national government regulations; central authority regulations; regional or local authority regulations; other (e.g., professional body) rules. Also, please briefly describe what is covered at each level.</p>	<p>A 1.1 The Radiation Protection Act [of Parliament] (SFS 1988:220 with amendments) aims ‘to protect people, animals and the environment against the harmful effects of radiation’. It lists general obligations, prescribes licensing, and permits the Government, or authority/ies so empowered by the Government, to carry out licensing and issue any further regulations as necessary, as well as exceptions from the Act or certain of its provisions, insofar as this is not in conflict with the intentions of the Act. It clarifies that nuclear installations that have been granted a licence according to the Nuclear Technology Act do not normally need an additional RP licence; instead the Government or authority so empowered by the Government may issue RP licence conditions [which would otherwise have been part of an RP licence]. The RP Act also specifies penalties for offences against its provisions.</p> <p>The [Government] Radiation Protection Ordinance (SFS 1988:293 with amendments) permits the Radiation Safety Authority (SSM), or municipality Environment & Health Protection Boards if so empowered by the SSM, to issue detailed regulations concerning the provisions of the RP Act. It also lists exceptions from the RP Act in terms of activity, specific activity, dose rate, technical specification, etc. It permits the SSM to issue exceptions in both directions from the general levels prescribed by the Ordinance, as regulations and as decisions in specific cases, as long as this is not in conflict with the intentions of the Ordinance.</p> <p>There is a considerable body of Regulations of the Radiation Safety Authority. These include general rules such as Dose Limit Regulations, Discharge Authorisations for Nuclear Installations, etc., as well as rather specific ones (e.g., on tritium in azimuth compasses) and non-technical ones (e.g., on record retention at nuclear installations), and numerous ones on non-ionising radiation.</p> <p>Thus, laws and government ordinances primarily focus on principles while numeric values are mostly given in authority regulations, which are easier to update in response to scientific progress. The regulatory system is mostly performance-based rather than prescriptive, with some room for negotiation if licensees can convince the authority of the soundness of their case. Some aspects are prescriptive for practical reasons (e.g., transport; use of equipment such as level gauges where little training is required).</p>
<p><i>Organisation</i></p> <p>A1.2 Describe the different authorities, and (approximately) how many regulators are involved in making and enforcing radiation protection legislation? Also, if</p>	<p>A 1.2 The Government offices are relatively small compared with ministries in many other countries, e.g., the Environment Ministry (under which the SSM belongs) has just some 2 civil servants directly involved in RP, while authorities/agencies are bigger. The SSM, which deals with RP and nuclear safety and security, has almost 300 employees making and enforcing regulations. The SSM delegates some enforcement to the ~290 municipal Environment & Health Protection Boards (e.g., sunbeds; radon measurements).</p> <p>Some regulations concerning radiation are issued by other authorities in</p>

A 41. General	
<p>appropriate, please briefly describe how consistency of approach between regulatory organisations is achieved?</p>	<p>consultation with the SSM. The most important case concerns indoor radon, where the Board of Health and Welfare (SoS) issues advice on radon in existing dwellings, the Board of Housing, Building and Planning (BoV) issues binding regulations on radon in new dwellings, and the Work Environment Authority (AMV) issues binding regulations on radon at workplaces including mines. Other collaborating authorities include, e.g., the Food Administration (SLV) and the Medical Products Agency (LV). All of these authorities have many employees but only a handful of people working with radiation issues. Consistency is achieved through close collaboration with the SSM and formal policy agreements.</p> <p>Some activities, such as the establishment of large installations causing radioactive discharges, are also processed in an Environmental Court (5 in Sweden). Decisions there take account of, but are not necessarily consistent with, evidence given by the SSM.</p>
<p><i>ICRP 60 incorporation</i> A 1.3 To what extent were legislation and regulations rewritten when ICRP 60 was incorporated? A 1.4 What was the procedure, what problems and efforts were there?</p>	<p>A 1.3 The RP Act and Ordinance contain few technical details of the sort that distinguish ICRP 60 from ICRP 26. They were revised in 1988; this was not primarily due to ICRP 60, but paved the way for revision of the pertinent regulations. Many ‘SSI’ (now SSM) regulations were rewritten; an actual regulation on dose limits replaced the older practice of repeating those limits in all licenses as license conditions. This came as no surprise to licensees, they were well aware of the 1987 Como statement and of the contents of drafts and had begun to work along the major lines of ICRP 60 before there were any formal regulations.</p> <p>A 1.4 As always, draft regulations were prepared by the authority (SSI/SSM) with informal consultations with licensees’ experts, then issued as formal consultation documents, then amended as appropriate and issued as final binding regulations. Considerable effort was spent on meetings at all levels with all sorts of interested parties, consultations, information documents, and other interactions. This helped, but the major reason why the transition went quite smoothly was that most licensees felt that ICRP 60 made sense. The only problem was that Sweden joined the EU only in 1995; because of this some regulations which had been drafted or updated in parallel with the development of ICRP 60 had to be revised again to ensure consistency with the Basic Safety Standards Directive.</p>
<p><i>Stakeholders</i> A 1.5 Who were the stakeholders (e.g. other ministries, operators, etc.) and how was their involvement achieved?</p>	<p>A 1.5 Licensees: Inevitably, nuclear installations and large hospitals were regarded and treated as major stakeholders. There were contacts both at the managerial level and with RP professionals within such organisations, as well as with the professional societies. Less attention was paid to small operators (although some seasoned inspectors had an astonishing knowledge of individual licensees and did phone or mail many of them to keep them abreast of developments). Regulators: Important stakeholders included the Environment Ministry (but there were few contacts with other Ministries) and the usual collaborating authorities (cf. reply 1.3). Members of the public: were of course also regarded as important stakeholders, but by today’s standards, with web pages and more inquisitive citizens, the actions around 1990 aiming directly at informing the public would probably be regarded as rather limited.</p>

A 41. General	
<p><i>Guidance</i></p> <p>A 1.6 How was guidance on the implementing legislation developed and by whom (e.g.: regulatory authorities; professional societies, trade organisations)?</p>	<p>A 1.6 There were few formal guidance documents. Primarily, guidance would be developed by the regulatory authority and the SSI/SSM produced leaflets, reports and information material. However, there is no tradition of extensive formal guidance publications. Professional societies were involved in that they arranged seminars, courses, etc., and this was encouraged by the SSI/SSM, but they did not produce formal guidance (and would not have been expected to do so). Trade organisations sometimes express opinions on regulatory issues but do not produce formal guidance.</p>
<p><i>Time-scales</i></p> <p>A 1.7 What were the lead-in times for new requirements, i.e., when were they proposed, when decided, when was full compliance by operators required?</p>	<p>A 1.7 Generally, the time-scale for a new requirement varies from 1 up to 10 years from first proposal to full compliance, depending on the nature of the requirement. In this case, the starting point is not easily defined (informal discussions about ongoing work within ICRP? the Como statement? the first informal consultations on ideas for a dose limit regulation?) but the SSM suggests that 6 years is an adequate reply. The EU BSS Directive took another 4 years to implement, with additional transition provisions for some requirements.</p>
<p><i>Burdens and benefits</i></p> <p>A 1.8 Did your regulatory authority perform a cost-benefit analysis of the implications of any new regulations, (regulatory analysis) and if so is there a report available (where)?</p>	<p>A 1.8 This is mandatory whenever any kind of new regulation or legislation is introduced, but unfortunately it has not been possible to obtain a copy of the analysis.</p>
<p><i>Cost of Not Acting</i></p> <p>A 1.9 Were the costs/savings/implications of not implementing ICRP 60 assessed? If so, what were they?</p>	<p>A 1.9 This was not an option once Sweden had joined the EU. In principle, the cost of not acting is also analysed when the costs of proposed new regulations are studied (sometimes, simply by asking operators what they think).</p>
<p><i>Actual costs</i></p> <p>ICRP 60 and Euratom Directives 96/29 and 97/43 entailed, e.g., that</p> <ul style="list-style-type: none"> -the annual limit on occupational effective dose was reduced from 50 to 20 mSv, with an option of 5-year averaging; - it was clarified that the annual limit on effective dose to members of the public is 1 mSv, not 5 mSv; - effective dose (with new weighting factors w_R and w_T) replaced the effective dose equivalent; - the concepts of dose and risk constraints were introduced; - diagnostic reference levels were introduced. <p>A 1.10 How did these new requirements arising from ICRP 60 impact on operations?</p>	<p>A 1.10 <i>Regulator</i>: The introduction of ICRP 60 was not perceived as 'expensive'. Major cost items were for education and training and for an upgrade of the nuclear operators' joint dose registry.</p> <p><i>Nuclear power plant</i>: ICRP 60 / Euratom 96/29 did not cost us very much. The contractor companies, i.e., the formal employers of the itinerant workers, had some more costs: they needed to hire additional staff to avoid exceeding 20 (100/5) mSv, and in the end of course these costs were passed on to us. However, the contractor companies want to be good employers, and we certainly felt that the relatively small amounts was money well spent. Also, we are keen to do what the regulator wants. Our owners are perfectly prepared to cover the costs of any sensible improvement. We are always consulted before new rules are implemented, and if we have any genuine concerns the regulator tries to accommodate our views. <i>Hospital (physicist)</i>: DRLs are very useful. Our hospital has reduced diagnostic doses by 350 manSv, 65% of which can be attributed to DRLs. However, the collection of data for DRL implementation takes time, and we also had to acquire suitable statistical software. The lower occupational dose limits has had a positive impact on doses to interventional radiologists.</p> <p><i>Hospital (clinic director)</i>: We started by listing problem areas and identified occupational doses in interventional radiology, for effective dose and even more for eye lens and skin dose. Our physicians required</p>

A 41. General	
<p>A 1.11 Did the incorporation of ICRP 60 lead to any reduction of any kind of cost or effort?</p>	<p>some persuasion to participate in training and reduce their doses, but in the end they all complied and the resulting improved RP is a boon. Furthermore, we had to attend to doses to members of the public, mainly by using mobile equipment more carefully and with mobile shielding where appropriate. DRLs were very useful but also quite costly (many measurements, much work, to the extent that additional staff were hired). Since the use of DRLs was sensible and mandatory, extra money was provided as required by the hospital owners.</p> <p><i>Non-destructive testing outfit:</i> No particular impact, all doses from our normal operations are well below 20 mSv in a year. The highest doses occur when we visit NPPs, but then the radiation comes from the tested object, not from our equipment. We have had 3 incidents in the last 20 years but even then no annual dose was above 20, let alone 50, mSv.</p> <p>A 1.11 <i>NPP:</i> The lifetime dose limit that was introduced in 1989 in anticipation of ICRP 60 caused us some administrative effort, so we saved some money when it was removed when the dose limits were fully aligned with Euratom 96/29.</p> <p>[All other respondents: No]</p>

A 42. Application / scope	
<p>Questions A 2.1 to A 2.2 are aimed primarily at regulators. We are grateful for replies from both operators and regulators to questions A 2.3 - A 2.4!</p>	
<p><i>Scope</i></p> <p>A 2.1 Did pre-ICRP 60 legislation in your country cover all uses and users of ionising radiation, e.g.: industrial applications (including industrial radiography), medical applications (diagnostic and therapeutic), nuclear fuel cycle, research and teaching, transport, radioactive waste disposal, occupational exposure to radon (mining and non-mining), agriculture?</p> <p>A 2.2 If not, was new legislation introduced to close the previous gaps?</p> <p>A 2.3 Did the timeframe for implementation vary for the sectors described in A 2.1? If so, how?</p>	<p>A 2.1 The 1988 RP Act covered all uses and users. When it replaced the previous, 1958, RP Act, the concern seemed to be to avoid over-regulation rather than to find any 'missing' area that would need to be added.</p> <p>A 2.2 -</p> <p>A 2.3 -</p>
<p><i>Response</i></p> <p>A 2.4 Was there any resistance from those</p>	<p>A 2.4 -</p>

A 42. Application / scope	
sectors (if any) which were not previously covered? If so, what were the main perceived difficulties and what was done to overcome them?	
A 43. Dose limits and dose distribution	
Questions A 3.1 – A 3.3 are aimed primarily at regulators. We would be grateful for replies from both regulators and operators for questions A 3.4 – A 3.10!	
<p><i>Historical limits</i></p> <p>A 3.1 What were your dose limits before you incorporated ICRP 60?</p>	<p>A 3.1 Essentially, those of ICRP 26, but as mentioned above, before 1990 dose limits were given as licence conditions rather than in a general regulation. This permitted some variation with respect to the annual limit on effective dose equivalent for members of the public, reflecting that ICRP 26 was somewhat cryptic on this topic. Thus, some licences stated that the limit was 1 mSv while others stated that it was 5 mSv.</p>
<p><i>Current limits</i></p> <p>A 3.2 What were your dose limits after implementation?</p> <p>A 3.3 Was any flexibility built into dose limits, e.g. public limits allowed up to 5 mSv in exceptional circumstances?</p> <p>A 3.4 If 5-year averaging was chosen for occupational doses, what is your experience? Were there any difficulties?</p>	<p>A 3.2 Essentially, those of ICRP 60. Initially, in addition to the ICRP limits, there was a lifetime limit on occupational effective dose of 700 mSv, corresponding to 15 mSv per year of occupational exposure, but this was discarded after a few years.</p> <p>A 3.3 Yes, the same flexibility as in ICRP 60, i.e. occupational 100 mSv in 5 consecutive calendar years with no more than 50 mSv in a single year, and public exceptionally up to 5 mSv in a 5-y period. However, nobody has ever requested the flexibility for public exposures.</p> <p>A 3.4 Nuclear operators claim that the flexibility for occupational exposure is important, not because workers need to exceed 20 mSv, but because it permits operators to plan work in the 15-20 mSv bracket without fearing a direct infraction in case something goes awry and somebody gets 21 mSv. No real formal or practical problems were encountered. Itinerant workers tended to get high doses in the first few years, but operators quickly learned to ‘budget’ their doses to be able to use staff adequately through entire 5-y periods. Much of the optimisation was very cheap and simple, like proper planning of jobs, bringing the right tools, etc. Furthermore, reduced dose rates led to reductions of other costs.</p>
<p><i>Transition experience</i></p> <p>A 3.5 What was your experience of establishing these lower dose limits?</p> <p>A 3.6 Did any installation need significant rebuilding to comply with added shielding requirements? If no, how was this avoided?</p> <p>A 3.7 Were there any other difficulties? If so, what were they and how were they resolved?</p>	<p>A 3.5 <i>Regulator:</i> The 20 (100/5) mSv limit reduced doses considerably; there used to be lots of people around 20 mSv but these are now rare exceptions. The lowered limit forced new technology and better planning, reduced source terms and reduced dose rates. Also, different operators are now balancing low collective dose vs low individual doses more similarly. There were some initial complaints about costs (of technology and training), but operators soon saw that the lower doses permitted the use of a smaller group of more experienced workers, and senior management realised that the costs were trivial compared to continuous investments in safety and modernisation. Thus, the RP investment paid off quite rapidly and led to significant savings in the long run. People do wear their dosimeters, the anecdotes to the contrary that abound internationally appear to be just cock-and-bull stories, at least in Sweden.</p> <p><i>NPP:</i> The lowered dose limit was not a problem. However, the flexibility of averaging over 5 years is very important to us. The common central dose registry for all nuclear workers provides a computerised clear overview of the 5-y averages. We advise contractors to try to keep below</p>

A 43. Dose limits and dose distribution	
	<p>20 mSv at all times, but occasionally a dose closer to 50 mSv to a particular type of specialist is optimal, even though that worker may then have to do non-radiation work for a year or more. -In spite of the rumours, our staff always use their dosimeters as prescribed, we have no problems with this.</p> <p><i>Hosp. (physicist):</i> We did have one cardiologist who needed some convincing, but now everybody uses their dosimeters as prescribed.</p> <p><i>Hosp, (clinic director):</i> The 20 (100/5) limit was rarely a problem, we had more difficulties with skin and eye lens doses.</p> <p><i>NDT:</i> We were already below the new dose limits so we had no problems.</p> <p><i>A 3.6 Regulator:</i> Improved modelling, e.g., more realistic occupancy factors, meant that usually, no significant rebuilding was necessary, but calculations to verify this are mandatory. Note that there are new and better materials for temporary shielding purposes.</p> <p><i>NPP:</i> We did add some more permanent shielding at some locations, but we regard this as an ALARA action rather than a compliance necessity.</p> <p><i>Hosp. (physicist):</i> No actual rebuilding was required but the mandatory calculations or measurements are difficult - see also 4.5 below.</p> <p><i>NDT:</i> We don't rebuild our customers' installations, but we have improved the mobile shielding equipment that we are using. However, this is done as part of our optimisation of RP, not in response to any new requirement.</p> <p>A 3.7 (No)</p>
<p><i>Resulting doses</i></p> <p>A 3.8 What analyses of dose distributions are available for your country, over what period?</p> <p>A 3.9 Have these dose distributions changed? How?</p> <p>3.10 If yes, what was (were) the main factor(s) influencing these changes?</p>	<p><i>A 3.8 Regulator:</i> There is a Central Dose Registry common to all nuclear installations and distributions are provided in annual reports on nuclear issues that can be obtained from SSM. There are several suppliers of dose meters for health care and while the regulator has reasonable access to information about doses and dose distribution, this is not systematically organised or published.</p> <p><i>A 3.9 Regulator:</i> Since 1990, there has been a major shift downwards in average dose as well as a significant reduction of the number of doses close to the dose limits. However, the trend is not a simple linear reduction. Several major refurbishments at nuclear installations were planned investments in dose as well as money, where high collective and individual doses were accepted in a particular year in order to reduce longer-term doses.</p> <p><i>NDT:</i> For those working outside the nuclear sector, doses are decreasing. However, in recent years dose trends are increasing for those who are working inside NPPs. This is because of the large refurbishments and increased effects at the plants.</p> <p><i>A 3.10 Regulator:</i> The introduction of the 20 (100/5) mSv limit was important. Rather than the actual numerical restriction, perhaps the most important factor was the added attention to RP that resulted from all the discussions, training, etc. because of the new ICRP rec/s and the Euratom BSS Directive.</p> <p><i>Hosp. (clinic director):</i> While the 20 (100/5) limit was not in itself a problem area, the discussions helped us focus on RP issues and improve. We also track patient doses much more conscientiously than in the past. RP does need constant attention, otherwise it's easily forgotten.</p> <p><i>NDT:</i> A new generation has arisen within our profession, the older people who did not always know much about RP are gone and the new</p>

A 43. Dose limits and dose distribution	
	employees are well educated. They were influenced by the spirit of ICRP 60, even though their doses were already below the new limits. It would be helpful if the regulator demanded more RP training for our staff, in line with the rules in Norway; this would help us to improve further.

A 44. Experience with specific technical aspects	
We would appreciate answers from both regulators and operators to all of these questions!	
<p><i>Pregnant workers</i></p> <p>A 4.1 What happens when an occupationally exposed worker becomes pregnant?</p> <p>A 4.2 Did the introduction of the 2 mSv limit for the abdomen (ICRP 60) or the 1 mSv limit for the embryo / fetus (Euratom Directive) cause any problems or costs?</p> <p>A 4.3 If yes, what were they and how were they resolved?</p>	<p>A 4.1 <i>Regulator</i>: The worker is expected to report her pregnancy to the employer. Once this has happened, the employer must provide an appropriate analysis. The worker has a right to be moved to non-radiation tasks during pregnancy, if there is any chance at all of exceeding the embryo/fetus dose limit.</p> <p><i>NPP</i>: We have no problems, our organisation is large enough that it is usually easy to arrange alternative work and the costs are trivial. It could be a bit more difficult for contractors and in rare cases, the pregnant worker is unwilling to do non-radiation work</p> <p><i>Hosp. (physicist)</i>: We comply with the rules and labour relations are fine, but sometimes it does cause costs because it is difficult to find suitable alternative work.</p> <p>A 4.2 <i>Regulator</i>: Similar arrangements were in place already and the new limits did not cause any major problems or costs. Some operators have had additional, more stringent internal rules, and occasionally those rules caused problems when a pregnant worker refused to be removed from work with radiation.</p> <p><i>NDT</i>: So far, we have never had a pregnant tester among our 120 testing staff, so we have no experience of any problems.</p> <p>A 4.3 <i>Hosp. (physicist; clinic director)</i>. Sometimes it is difficult to find a suitable non-radiation task for a pregnant worker, leading to extra costs.</p>
<p><i>Constraints</i></p> <p>A 4.4 What is your experience of the introduction and use of dose constraints for occupational and public exposures?</p> <p>A 4.5 Were there any difficulties? If yes, what were they and how were they resolved?</p> <p>A 4.6 Have you at all used risk constraints? If yes, what is your experience?</p>	<p>A 4.4 <i>Regulator</i>: Very positive, dose constraints are used frequently (albeit sometimes with other names) and the effect is excellent. The regulator has been keen not to set occupational dose constraints but to require operators to set (and report) such constraints.</p> <p>A 4.5 <i>Regulator</i>: At first, there was a learning curve, particularly for an older generation of RP experts, to avoid confusion with limits. However, mostly staff at operators are well educated and in touch with developments at ICRP = well prepared. There is no adversarial tradition, rather a spirit of operators and regulators collaborating towards a common goal.</p> <p><i>NPP</i>: Our experience over the last 10-15 y is very positive. Our electronic dosimeters have area-specific alarm trigger levels which help staff to keep below constraints. Monthly follow-up analyses show that problems are almost always due to workers deviating from instructions and help us to improve training and work discipline. We do not report formally individual deviations to the regulator, but annual statistics are provided and we may discuss interesting cases in our day-to-day contacts with the inspectors.</p> <p><i>Hosp. (physicist)</i>: It is difficult to assess (or measure) whether our shielding is sufficient to achieve compliance with the 0.1 mSv in a year constraint on public exposure.</p> <p><i>NDT</i>: Usually, constraints is not an issue, but occasionally, special testing</p>

A 44. Experience with specific technical aspects	
	<p>tasks at NPPs required us to think through the optimisation and apply constraints that affected the way the job was performed. Again, this is due to the radiation environment at the plant, not our own equipment.</p> <p><i>A 4.6 Regulator:</i> Hardly ever in a formal sense, although calculations performed at some irradiator installations and a few other similar establishments could be interpreted as setting risk constraints.</p> <p><i>Hosp. (clinic director):</i> Not formally, but in reality we've done the calculations for radiotherapy equipment and in nuclear medicine.</p>
<p><i>Radiation Dosimetry</i></p> <p>A 4.7 Please describe briefly the organisation and regulatory framework for dosimetry in your country.</p> <p>A 4.8 Did the introduction of ICRP 60 radiation and tissue weighting factors lead to any difficulties? If yes, what were they and how were they resolved?</p> <p>A 4.9 Were there any costs associated with the implementation of the ICRP 60 dosimetric approach (e.g. dose coefficients, modelling, instrument calibration, etc.), if so, how much and borne by whom?</p>	<p><i>A 4.7 Regulator:</i> Employers are required to provide dosimetry from an approved supplier. The Euratom Directive prescribes this for Cat. A workers only but at nuclear installations, they are used more liberally, for everybody ever entering controlled areas. Health care establishments have been more cost conscious and focused on Cat. A only, not least because many dosimeters never registered any dose.</p> <p><i>A 4.8 Regulator:</i> Problems envisaged by some metrology boffins never materialised. Survey meters as well as personal dose meters were recalibrated over a few years in connection with the normal process of recurrent calibration.</p> <p><i>NPP:</i> Recalibrations and, when required, new instrumentation were all fitted into the normal running calibration and replacement programme, so there were no real extra costs.</p> <p><i>Hosp. (clinic director):</i> We had to obtain some new types of personal dosimeters for finger and eye lens doses - the problem was to find equipment that worked in practical contexts; once we had identified them their use was financed within existing budgets.</p> <p><i>A 4.9 Hosp. (clinic director):</i> We did not really need to do anything beyond our normal calibration programme, so no problem, no extra cost.</p> <p><i>NDT:</i> The requirements on dosimetry and on dose statistics have become more stringent, but this does not seem to be because of ICRP 60.</p>
<p><i>Radon</i></p> <p>A 4.10 Please describe briefly the current arrangements with respect to radon, in dwellings and at the workplace.</p> <p>A 4.11 Did the implementation of ICRP 60 cause any new efforts or costs? If yes, what were they and how were they resolved?</p>	<p><i>A 4.10 Regulator:</i> The maximum concentration of radon in dwellings is 200 Bq/m³ (mandatory for new houses, recommended for existing houses). At workplaces above ground, the mandatory maximum concentration is 400 Bq/m³ while in mines and other underground workplaces, it is 2.5 MBq/m³ per year. There are also regulations and recommendations concerning radon in drinking water.</p> <p><i>A 4.11 Regulator:</i> The rules and regulations concerning radon have been tightened successively over a long period, not necessarily connected directly to ICRP 60. There have been several campaigns of government-subsidised favourable loans to home-owners for radon mitigation projects.</p>
A 45. Training implications	
<p>Question A 5.1 – A 5.2 are aimed primarily at regulators, and questions A 5.3 – A 5.5 at both regulators and operators!</p>	
<p><i>Regulators' staff</i></p> <p>A 5.1 What methods did you use to ensure that relevant members of staff were aware</p>	<p>A 5.1 At the time, recurrent training was regarded as a priority (also apart from ICRP 60) and significant resources were devoted to provide staff with what they needed. As a platform, there was a basic 2 h lecture on ICRP 60 with a compendium for every single employee, including all</p>

A 45. Training implications	
<p>of and understood the revised legislation?</p> <p>A 5.2 Were there any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?</p> <p>A 5.3 Were you involved in ensuring that stakeholders were aware of and understood the revised legislation?</p> <p>A 5.4 If so, how did you do this?</p>	<p>support staff. For professionals, this was followed by a 2-day course to start them reading their ICRP 60 copies. (These lectures and courses were led by Bo Lindell, ensuring insight into the deliberations of ICRP!). Then, there were seminars, discussions, participation in national and international meetings... and ‘table-top exercises’ in handling regulatory issues with ICRP 60 at hand. There were informal discussions about ICRP 60 all the time, at coffee breaks, over lunch, etc.</p> <p>A 5.2. Nothing that can be recalled now.</p> <p>A 5.3 <i>Regulator</i>: Yes, this was an important task.</p> <p><i>NPP</i>: We are always providing information to the local community and to our visitors, and at the time we included some material about ICRP 60 and the Euratom Directive.</p> <p>A 5.4 <i>Regulator</i>: See 1.6!</p>
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>A 5.5 What was the extent of training and information required? Was this an entirely new effort, or could it be integrated into existing schedules of recurring training? What were the costs of training?</p>	<p>A 5.5 <i>NPP</i>: There is a significant and mandatory programme of recurrent training of staff and contractors, and ICRP 60 and the subsequent new regulations were fitted into this programme. Thus, we did not regard this as an extra cost.</p> <p><i>Hosp. (physicist)</i>: We planned to integrate it into our normal recurring training programme, but in reality the ICRP 60 component took much more time.</p> <p><i>NDT</i>: The training was integrated into our normal programme. Actually, we would welcome regulations on more training; the cost would be acceptable.</p>

Part B: incorporating ICRP 103: Anticipated key impacts/provisions

B 1. General	
<p>Questions B 1.1 to B 1.6 are aimed primarily at regulators, and questions B 1.7 - B 1.8 primarily at operators, but we welcome your replies to all queries!</p>	
<p><i>Legislation</i></p> <p>B 1.1 Do you expect to have to change your ionising radiation protection legislation/rules if/when ICRP 103 is incorporated?</p> <p>B 1.2 If appropriate, please briefly describe the anticipated changes.</p>	<p>B 1.1 Not needed (except minor amendments to SSM regulations, of the sort that are made anyway now and then). It should be noted that protection of the environment was mentioned as one of the aims in the 1988 RP Act, so this is not a ‘new’ issue.</p> <p>B 1.2 -</p>
<p><i>Organisation</i></p> <p>B 1.3 Do you expect that the incorporation of ICRP 103 will lead to any changes to the organisation and/or</p>	<p>B 1.3 Not as a consequence of ICRP 103 (but regulatory agencies are re-organised from time to time for other reasons).</p> <p>B 1.4 Through continued collaboration.</p>

B 1. General	
<p>resources of the radiation protection regulators, compared with that reported in Section A?</p> <p>B 1.4 If appropriate, please briefly describe how consistency of approach between regulatory organisations is to be achieved?</p>	
<p><i>Burdens and benefits</i></p> <p>B 1.5 Does your regulatory authority expect to perform a cost-benefit analysis of the implications of any new regulations (regulatory analysis) and if so, when might a report become available (where)?</p>	<p>B 1.5 Yes, this is a formal requirement for any new regulation, and will be part of the consultative document that precedes every new regulation.</p>
<p><i>Cost of Not Acting</i></p> <p>B 1.6 Will the costs / savings / implications of not implementing Publication 103 be assessed? If so, when?</p>	<p>B 1.6 This is a mandatory part of the cost assessment, but is likely to be very cursory since the Euratom Directive will also be mandatory.</p>
<p><i>Anticipated costs</i></p> <p>ICRP 103 and the new Euratom Directive will entail, e.g.,</p> <ul style="list-style-type: none"> - amended w_R and w_T; - added emphasis on dose constraints. <p>B 1.7 How do you expect these new requirements arising from ICRP 103 to impact on operations?</p> <p>B 1.8 Do you anticipate that the incorporation of ICRP 103 may lead to any reduction of any kind of cost or effort?</p>	<p>B 1.7 <i>NPP</i>: ICRP 103 involves fewer changes than ICRP 60, so any costs will be smaller. As always, we will be consulted on all new regulations and the anticipated cost. We will need to consider the new weighting factors and the new phantoms for internal dosimetry. We may also have to review our emergency plans in view of ICRP 103. Mostly, this will all fit into the normal work programme.</p> <p><i>Hosp. (physicist)</i>: The only problem we anticipate is that we will now need to clarify how we measured or assessed that our shielding is sufficient, but this is really an effect of ICRP 60, not ICRP 103.</p> <p><i>Hosp. (clinic director)</i>: There will be no change at all, really.</p> <p><i>NDT</i>: No change that will affect us, so no new costs.</p> <p>B 1.8 Not yet known.</p>

B 2. Experience with specific technical aspects	
<p>We would appreciate answers from both regulators and operators to all of these questions!</p>	
<p><i>Pregnant workers</i></p> <p>B 2.1 Do you envisage that the introduction of the 1 mSv</p>	<p>B 2.1 (Not relevant, Sweden is a member of EU)</p> <p>B 2.2 -</p>

B 2. Experience with specific technical aspects	
<p>limit for the embryo / fetus (ICRP 103) will cause any problems or costs? (<i>Note: this question does not apply to EU member countries since the current Euratom BSS Directive already prescribes such a limit</i>).</p> <p>B 2.2 If yes, what might they be, and how do you plan to resolve them?</p>	
<p>Constraints</p> <p>B 2.3 Is the added emphasis on dose constraints in ICRP 103 expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p> <p>B 2.4 Are risk constraints likely to be introduced with the implementation of ICRP 103?</p>	<p>B 2.3 <i>Regulator</i>: No difficulties expected, but in theory this will require some new approaches by operators. In reality, they have already moved in this direction - they can, and do, read ICRP reports, and such developments follow naturally from the continuous dialogue between operators and regulators.</p> <p><i>NPP</i>: No problem, we are very pleased with the experience so far of working more with constraints.</p> <p><i>Hosp. (physicist)</i>: No problems envisaged.</p> <p>B 2.4 <i>Regulator</i>: Possibly by encouraging operators to set risk constraints more often.</p>
<p>Dosimetry</p> <p>B 2.5 Are the new ICRP 103 radiation and tissue weighting factors expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.5 <i>Regulator</i>: Given that ICRP 60 caused few problems in this respect, and ICRP 103 involves less dramatic changes, no difficulties are expected.</p> <p><i>Hosp. (physicist)</i>: No problem foreseen.</p>
<p>Radon</p> <p>B 2.6 Is the implementation of ICRP 103 expected to cause any new efforts or costs with respect to radon? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.6 <i>Regulator</i>: No, there may well be further developments and costs with respect to radon, but not as a result of ICRP 103.</p>

B 3. Training implications	
<p>Questions 3.1 – 3.3 are aimed primarily at regulators, and question 3.4 at both regulators and operators!</p>	
<p>Regulators' staff</p> <p>B 3.1 What methods do you plan to use to ensure that relevant members of staff were aware of and understood the revised legislation?</p> <p>B 3.2 Do you anticipate any issues associated with the</p>	<p>B 3.1 In principle, the same methods that were applied when ICRP 60 was implemented (cf. section A, 6.1). For a number of reasons, e.g., scarcity of resources, it is feared that in reality the training for this transition will be less complete, but the intention is to do the same thing.</p> <p>B 3.2 No.</p> <p>B 3.3 Yes, as with ICRP 60. Thus consultations, meetings, FAQ documents, lectures... E-mail and web sites will facilitate this work.</p>

B 3. Training implications	
<p>implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?</p> <p>B 3.3 Do you expect to be involved in ensuring that stakeholders are aware of and understood the revised legislation? If so, how do you anticipate doing this?</p>	
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>B 3.4 What do you expect will be the extent of training and information required? Will this be an entirely new effort, or could it be integrated into existing schedules of recurring training? What may be the anticipated costs of training?</p>	<p>B 3.4 <i>NPP</i>: General information will be provided within the normal recurrent training programme. Some specialists will need much more detailed information, but this is a small group. Thus, the extra costs will be trivial.</p> <p><i>Hosp. (clinic director)</i>: We will have training of course, but expect to be able to fit this into our normal training programme, by focusing specifically on ICRP 103 during one or two years,</p>

And finally: Is there anything else that you wish to add?

Regulator: Nuclear operators are usually prepared to accept sensible proposals. If we can convince them that something will increase safety and/or reduce doses, they will accept the costs. There is a clear tradition of constant improvement in collaboration with the regulator. The health care sector is also keen on collaboration in principle, but in health care, cost does become an issue more often.

Questionnaire v.2.0 - completed for [country]: **UK**

NEA Project for Obtaining Historical Information on Costs and Impacts of Incorporating ICRP Publ. 60 and Possible Resources for Incorporating ICRP Publ. 103
Part A: incorporating ICRP 60: Key impacts/provisions

NOTE: for EU Member States: references to incorporation of ICRP 60 should be read as implementation of Directives 96/29/Euratom and 97/43/Euratom.

A 46. General	
Questions A 1.1 to A 1.9 are aimed primarily at regulators, and questions A 1.10 – A 1.11 primarily at operators, but we welcome your replies to all queries!	
Question	Your experience
<p><i>Legislation</i></p> <p>A 1.1 Please describe briefly the hierarchy, if applicable, of ionising radiation protection legislation/rules in your country, e.g. national law, national government regulations; central authority regulations; regional or local authority regulations; other (e.g., professional body) rules. Also, please briefly describe what is covered at each level.</p>	<p>A 1.1 National law made by Parliament:</p> <ul style="list-style-type: none"> - primary legislation (overarching provisions, such as The Health and Safety at Work etc Act 1974 (HSWA) which set out a broad framework for all occupational health and safety); - secondary, risk, sector or topic specific, legislation (such as the Ionising Radiations Regulations (IRRs) [Refs. UK1, UK2] made under HSWA, supported where necessary by Approved Codes of Practice (quasi legal status). <p>The IRRs allow the regulatory authority (the Health and Safety Executive (HSE)) to grant exemption certificates for specific purposes.</p> <p>Non- statutory guidance may be provided by the regulatory authority or by professional/trade organisations</p>
<p><i>Organisation</i></p> <p>A1.2 Describe the different authorities, and (approximately) how many regulators are involved in making and enforcing radiation protection legislation? Also, if appropriate, please briefly describe how consistency of approach between regulatory organisations is achieved?</p>	<p>A 1.2 For implementation of the 1996 BSS Euratom Directive, over 12 different government departments and agencies were involved (Health and Safety Commission/Executive; National Radiological Protection Board; Department (Dept.) for the environment, food and rural affairs; Environment Agency/Scottish Environmental Protection Agency; Northern Ireland Depts; Gibraltar; Food Standards Agency; Health Depts; Dept. for Trade and Industry; Dept. for Transport).</p> <p>Consistency is achieved by Memoranda of Understanding/Agreement and liaison meetings at appropriate levels, where necessary.</p>
<p><i>ICRP 60 incorporation</i></p> <p>A 1.3 To what extent were legislation and regulations rewritten when ICRP 60 was incorporated?</p> <p>A 1.4 What was the procedure, what problems and efforts were there?</p>	<p>A 1.3 The move from ICRP 26 to ICRP 60, via implementation of the relevant Euratom Directives, was seen as evolution rather than revolution and there was plenty of warning of what the main changes would be so that the impact was generally relatively insignificant. For instance, the UK presaged the likely reduction of dose limits by issuing ACOP guidance on dose limitation and restriction of exposure in the light of ICRP's 1987 'Como' Statement. Nevertheless, the existing legislation had to be amended and some minor gaps (eg relating to radioactively contaminated land) filled by new legal provisions. A legal Direction was issued to the Environment Agency in relation to the public dose limit and dose constraint requirements of the BSS Directive</p> <p>A 1.4 For occupational, and to a lesser extent other, radiation protection legislation the procedure was, and still is, for draft regulations to be prepared by the regulatory authority in conjunction with stakeholder advisory groups at various levels, then to issue a formal consultative</p>

A 46. General	
	document on which any interested parties may comment, before finalising the regulations in the light of comments received. The understanding of, and opportunities to comment on, the proposals in the ConDoc were augmented by workshops and other meetings with stakeholders. This helped to remove/avoid misunderstandings and prepared employers and workers for the revised requirements. There were no insuperable, and very few significant, problems.
<p>Stakeholders</p> <p>A 1.5 Who were the stakeholders (e.g. other ministries, operators, etc.) and how was their involvement achieved?</p>	A 1.5 Stakeholders were government departments (GDs) and agencies, major operators, health authorities, trade unions, professional bodies, non-departmental government bodies (eg Equal Opportunities Commission). HSE (and others) set up working groups to develop content of IRR99 [Ref. UK2]. Representatives of organisations participating in official working groups etc, also invited colleagues (such as Health Physicists) within their organisations to comment on the drafts to assess the impact of the changes.
<p>Guidance</p> <p>A 1.6 How was guidance on the implementing legislation developed and by whom (e.g.: regulatory authorities; professional societies, trade organisations)?</p>	A 1.6 Guidance was developed by GDs/regulatory authorities and trade and professional bodies as appropriate, in conjunction with relevant stakeholders, and finalised after consultation.
<p>Time-scales</p> <p>A 1.7 What were the lead-in times for new requirements, i.e., when were they proposed, when decided, when was full compliance by operators required?</p>	A 1.7 Preliminary work on implementation of the 1996 Euratom Directive was started while negotiations were still in progress. The main implementing regulations (IRR99 [Ref. UK2]) were made on 3 December 1999 and came into force on 1 January 2000, except for the regulation on authorisation of specified practices which came into force on 13 May 2000. These regulations contained transitional provisions for some specific requirements
<p>Burdens and benefits</p> <p>A 1.8 Did your regulatory authority perform a cost-benefit analysis of the implications of any new regulations, (regulatory analysis) and if so is there a report available (where)?</p>	A 1.8 Yes [= Annex C of the main report]
<p>Cost of Not Acting</p> <p>A 1.9 Were the costs/ savings/ implications of not implementing ICRP 60 assessed? If so, what were they?</p>	A 1.9 Not an option for a member State of the EU as the ICRP recommendations were incorporated into the 1996 BSS Directive
<p>Actual costs</p> <p>ICRP 60 and Euratom Directives 96/29 and 97/43 entailed, e.g., that</p> <ul style="list-style-type: none"> -the annual limit on occupational effective dose was reduced from 50 to 20 mSv, with an option of 5-year averaging; - it was clarified that the annual limit on effective dose to members of the public is 1 mSv, not 5 mSv; - effective dose (with new weighting factors w_R and w_T) replaced the effective 	A 1.10 Many of the fundamental principles (justification, optimisation and dose limits) were already in place in IRR85 [Ref. UK1] (based on ICRP 26). The 'mantra' at the time was 'evolution not revolution' which was generally the case in practice. One organisation in the nuclear industry reports that the new regulations did not have a significant impact on the operations. Operators were already looking at dose reduction. There were a number of personnel actively involved in ensuring requirements were met, particularly changes in dosimetry requirements.

A 46. General	
<p>dose equivalent; - the concepts of dose and risk constraints were introduced; - diagnostic reference levels were introduced.</p> <p>A 1.10 How did these new requirements arising from ICRP 60 impact on operations?</p> <p>A 1.11 Did the incorporation of ICRP 60 lead to any reduction of any kind of cost or effort?</p>	<p>A 1.11 No savings or cost reduction have been identified</p>

A 47. Application / scope	
<p>Questions A 2.1 to A 2.2 are aimed primarily at regulators. We are grateful for replies from both operators and regulators to questions A 2.3 - A 2.4!</p>	
<p><i>Scope</i></p> <p>A 2.1 Did pre-ICRP 60 legislation in your country cover all uses and users of ionising radiation, e.g.: industrial applications (including industrial radiography), medical applications (diagnostic and therapeutic), nuclear fuel cycle, research and teaching, transport, radioactive waste disposal, occupational exposure to radon (mining and non-mining), agriculture?</p> <p>A 2.2 If not, was new legislation introduced to close the previous gaps?</p> <p>A 2.3 Did the timeframe for implementation vary for the sectors described in A 2.1? If so, how?</p>	<p>A 2.1 Yes</p> <p>A 2.2 n/a</p> <p>A 2.3 n/a</p>
<p><i>Response</i></p> <p>A 2.4 Was there any resistance from those sectors (if any) which were not previously covered? If so, what were the main perceived difficulties and what was done to overcome them?</p>	<p>A 2.4 n/a; Hospitals and Universities etc had already been brought into IRR85 [Ref. UK1] via Health and Safety at Work etc Act</p>

A 48. Dose limits and dose distribution	
<p>Questions A 3.1 – A 3.3 are aimed primarily at regulators. We would be grateful for replies from both regulators</p>	

A 48. Dose limits and dose distribution	
and operators for questions A 3.4 – A 3.10!	
<p><i>Historical limits</i></p> <p>A 3.1 What were your dose limits before you incorporated ICRP 60?</p>	<p>A 3.1 As ICRP 26 (via the 1980 Euratom BSS Directive) ie whole body in any calendar year:</p> <p>(a) employees - 50 mSv/y (b) trainees aged under 18 yrs - 15 mSv (c) any other persons – 5 mSv</p>
<p><i>Current limits</i></p> <p>A 3.2 What were your dose limits after implementation?</p> <p>A 3.3 Was any flexibility built into dose limits, e.g. public limits allowed up to 5 mSv in exceptional circumstances?</p> <p>A 3.4 If 5-year averaging was chosen for occupational doses, what is your experience? Were there any difficulties?</p>	<p>A 3.2 As per 1996 BSS Directive, ie limit on effective dose in any calendar year:</p> <p>(a) employees – 20 mSv (b) trainees aged under 18 yrs – 6 mSv (c) other persons – 1 mSv</p> <p>A 3.3 Flexibility for 100 mSv in any period of 5 consecutive years, max 50 mSv in any single calendar year, for employees, subject to conditions.</p> <p>A 3.4 No experience – flexibility never used.</p>
<p><i>Transition experience</i></p> <p>A 3.5 What was your experience of establishing these lower dose limits?</p> <p>A 3.6 Did any installation need significant rebuilding to comply with added shielding requirements? If no, how was this avoided?</p> <p>A 3.7 Were there any other difficulties? If so, what were they and how were they resolved?</p>	<p>A 3.5 No significant problem because of the action taken in response to the Como Statement – employers were generally already working within the revised dose limits and the primacy of ALARP had been established in the 1985 Regulations [Ref. UK1]. Public doses were already well below 1 mSv .</p> <p>The main problem reported in the medical sector was the IDR of 7.5uSv/h for radiotherapy units which remains an issue today. In at least some parts the nuclear industry a dose reduction programme was implemented, involving managers and workforce. Regular meetings examined the reduction programme. Programme involved changes in practices as well as introduction of additional shielding. Prior to this glove box workers received 50mSv per year external dose.</p> <p>A 3.6 In the medical sector some additional areas became controlled or supervised.</p> <p>A 3.7 Also in the medical sector, shielding was upgraded when new developments took place.</p>
<p><i>Resulting doses</i></p> <p>A 3.8 What analyses of dose distributions are available for your country, over what period?</p> <p>A 3.9 Have these dose distributions changed? How?</p> <p>3.10 If yes, what was (were) the main factor(s) influencing these changes?</p>	<p>A 3.8 Central Index of Dose (CID) Information, established in 1987, contains annual summaries of dose for classified persons (category A workers). Two five year analyses of dose summaries have been published, for 1986-1991 and 1990 – 96. Reports are available on HSE's website http://www.hse.gov.uk/radiation/ionising/doses/cidi.htm (HSE can supply a scanned copy of the first and second analysis and electronic results summaries for each year). Other analyses were:</p> <p>(a) public exposure (the Ionising Radiation Exposure of the UK Population reviews carried out by the UK National Radiological Protection Board (NRPB) since 1974, see http://www.hpa.org.uk/Publications/Radiation/HPARPDSeriesReports/HpaRpd001/ for 2005 review) and</p> <p>(b) reports on radioactivity in food and the environment entitled (1967 to 1994) Radioactivity in Surface and Coastal Waters of the British Isles and, post 1994, Radioactivity in Food and the Environment, see http://www.cefas.co.uk/publications/scientific-series/aquatic-environment-</p>

A 48. Dose limits and dose distribution	
	<p>reports.aspx .</p> <p>A 3.9 CIDI information showed a dramatic reduction (more than 10-fold,) over the first 6 year period, in the proportion of classified persons who had a reported annual dose in excess of 15 mSv (the principal investigation level). The number reported as having doses over 20 mSv in a year also fell by the same factor. There was a definite and sustained downward trend in both mean and effective dose for classified persons over the whole period, even taking account of uncertainties in dose assessment. For more detail see the actual reports.</p> <p>A 3.10 The main influence was the introduction, in IRR85 [Ref. UK1], of a mandatory investigation by the employer if an employee had a recorded whole body dose of more than 15 mSv (three-tenths of the whole body dose limit) for the first time in any calendar year, to determine whether exposure was being kept as low as reasonably practicable. In 1991 a 4th Part of the ACOP supporting IRR85 introduced an investigation, centred on the past and future work of the individual, triggered if an employee had a recorded dose of more than 75 mSv or more in any period of five calendar years starting from 1 January 1988. Closure of the last remaining tin mine in 1998 had a significant effect.</p>

A 49. Experience with specific technical aspects	
We would appreciate answers from both regulators and operators to all of these questions!	
<p><i>Pregnant workers</i></p> <p>A 4.1 What happens when an occupationally exposed worker becomes pregnant?</p> <p>A 4.2 Did the introduction of the 2 mSv limit for the abdomen (ICRP 60) or the 1 mSv limit for the embryo / fetus (Euratom Directive) cause any problems or costs?</p> <p>A 4.3 If yes, what were they and how were they resolved?</p>	<p>A 4.1 IRR99 [Ref. UK2] would expect a risk assessment and ALARA based approach subject to the following requirements:</p> <p>Pregnant and breast-feeding employees (5) Without prejudice to paragraph (1), a radiation employer shall ensure, that -</p> <p>(a) in relation to an employee who is pregnant, the conditions of exposure are such that, after her employer has been notified of the pregnancy, the equivalent dose to the foetus is unlikely to exceed 1 mSv during the remainder of the pregnancy; and</p> <p>(b) in relation to an employee who is breastfeeding, the conditions of exposure are restricted so as to prevent significant bodily contamination of that employee.</p> <p>Comprehensive guidance on the application of this Regulation is available</p> <p>In at least some parts of the nuclear industry pregnant workers tended to be removed from controlled areas where there was a risk of internal exposure. In other areas risk assessments were carried out and their exposure carefully monitored. So no problems, as exposure above the limit could not occur.</p> <p>A 4.2 No</p> <p>A 4.3 n/a</p>
<p><i>Constraints</i></p> <p>A 4.4 What is your experience of the introduction and use of dose constraints for occupational and public exposures?</p>	<p>A 4.4 It took a long time before the constraint philosophy was accepted as a useful concept to apply. Dose constraints for occupational exposures were useful to use in the dose reduction programme. Direct shine from Magnox stations was an issue for a while as potentially the 300 µSv constraint could be breached – but measurements confirmed that this did not occur.</p> <p>Regulatory guidance indicates that dose constraints for occupational</p>

A 49. Experience with specific technical aspects	
<p>A 4.5 Were there any difficulties? If yes, what were they and how were they resolved?</p> <p>A 4.6 Have you at all used risk constraints? If yes, what is your experience?</p>	<p>exposures are only likely to be appropriate where doses will be a significant fraction of a dose limit. Dose constraints for public exposure are most commonly associated with environmental discharges of radioactive materials and used within the permitting system.</p> <p>A 4.5 The difficulty was deciding on what to use as a constraint.</p> <p>A 4.6 Useful in design and risk assessments</p>
<p><i>Radiation Dosimetry</i></p> <p>A 4.7 Please describe briefly the organisation and regulatory framework for dosimetry in your country.</p> <p>A 4.8 Did the introduction of ICRP 60 radiation and tissue weighting factors lead to any difficulties? If yes, what were they and how were they resolved?</p> <p>A 4.9 Were there any costs associated with the implementation of the ICRP 60 dosimetric approach (e.g. dose coefficients, modelling, instrument calibration, etc.), if so, how much and borne by whom?</p>	<p>A 4.7 Employers are required to make suitable arrangements with one or more approved dosimetry service for systematically assessing doses to classified persons and making and maintaining dose records for such individuals. Approval is carried out by HSE on a five year cycle for assessing services and a seven year cycle for record keeping services. IRR99 requires services for classified workers to be approved by HSE, A statement made under the regulations specifies how services are recognised and HSE publishes detailed standards and performance tests for dosimetry services to meet.</p> <p>A 4.8 Comments included:</p> <ul style="list-style-type: none"> • We had to wait for new dose/intake data. • No difficulties except there are many published papers using the old wt factors in use as they have not been fully transformed. • The site already had arrangements for dosimetry, modelling and calibration. So impact was not significant. <p>Greatest impact was including internal exposure in the annual dose limit.</p> <p>A 4.9 Any such costs were met by dosimetry services and employers.</p>
<p><i>Radon</i></p> <p>A 4.10 Please describe briefly the current arrangements with respect to radon, in dwellings and at the workplace.</p> <p>A 4.11 Did the implementation of ICRP 60 cause any new efforts or costs? If yes, what were they and how were they resolved?</p>	<p>A 4.10 The 1999 Regulations [Ref. UK2] apply to:</p> <p>.....; b) any work (other than a practice) carried out in an atmosphere containing radon 222 gas at a concentration in air, averaged over any 24 hour period, exceeding 400 Bq m⁻³ except where the concentration of the short-lived daughters of radon 222 in air averaged over any 8 hour working period does not exceed 6.24 x 10⁻⁷Jm⁻³.</p> <p>Similar requirements were contained in IRR85 [Ref. UK1], so were not new to employers.</p> <p>HPA has recently published new radon advice (see HPA website). Radon surveys are carried out in conjunction with local authorities on a periodic basis, focussing on areas with higher radon concentrations</p> <p>A 4.11 n/a</p>

A 50. Training implications	
Question A 5.1 – A 5.2 are aimed primarily at regulators, and questions A 5.3 – A 5.5 at both regulators and operators!	
<p><i>Regulators' staff</i></p> <p>A 5.1 What methods did you use to ensure that relevant members of staff were aware of</p>	<p>A 5.1 Guidance to inspectors was prepared, also short training courses. Inspectors are well experienced with acquainting themselves with new legislation. They also attended and/or took part in familiarisation workshops and courses for employers.</p>

A 50. Training implications	
<p>and understood the revised legislation?</p> <p>A 5.2 Were there any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?</p> <p>A 5.3 Were you involved in ensuring that stakeholders were aware of and understood the revised legislation?</p> <p>A 5.4 If so, how did you do this?</p>	<p>A 5.2. There were some reported issues with dose coefficients. One was that skin dose contributed to effective dose.</p> <p>A 5.3 NRPB (now HPA) provided advice to clients of RPA service and offered training courses to RP professionals and radiation users. [Medical applications] The Regulator undertook regular meetings with the professional bodies during the negotiation of EC Directive 97/43/Euratom and held stakeholder meetings around the UK to explain the implementing regulations - IR(ME)R 2000</p> <p>A 5.4 As previously described, HSE went to considerable lengths to arrange (open) meetings with stakeholders where we could explain what the regulations really meant, and remove any misconceptions. Other regulators were involved with local liaison committees.</p>
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>A 5.5 What was the extent of training and information required? Was this an entirely new effort, or could it be integrated into existing schedules of recurring training? What were the costs of training?</p>	<p>A 5.5 Costs difficult to quantify since they involved conferences, meetings etc. Additional training was implemented to ensure operators were aware of new requirements. This was built into the current training.</p> <p>New Regulations required some additional training beyond the routine need for refresher/update but not believed to be excessive.</p>

Part B: incorporating ICRP 103: Anticipated key impacts/provisions

B 1. General	
<p>Questions B 1.1 to B 1.6 are aimed primarily at regulators, and questions B 1.7 - B 1.8 primarily at operators, but we welcome your replies to all queries!</p>	
<p><i>Legislation</i></p> <p>B 1.1 Do you expect to have to change your ionising radiation protection legislation/rules if/when ICRP 103 is incorporated?</p> <p>B 1.2 If appropriate, please briefly describe the anticipated changes.</p>	<p>B 1.1 Without a final BSS Directive it is difficult to ascertain the required changes to UK legislation/rules. On current knowledge of what the revised BSS Directive may contain, there are several new requirements, including those relating to building materials and environmental protection.</p> <p>B 1.2 Reduction of the eye dose limit could have a significant effect on the number and distribution of classified workers and on the need for emergency plans under REPPIR.</p>
<p><i>Organisation</i></p> <p>B 1.3 Do you expect that the incorporation of ICRP 103 will lead to any changes to the organisation and/or resources of the radiation protection regulators, compared with that reported in Section A?</p> <p>B 1.4 If appropriate, please</p>	<p>B 1.3 Too early to say</p> <p>B 1.4 Good liaison, as before</p>

B 1. General	
briefly describe how consistency of approach between regulatory organisations is to be achieved?	
<i>Burdens and benefits</i> B 1.5 Does your regulatory authority expect to perform a cost-benefit analysis of the implications of any new regulations (regulatory analysis) and if so, when might a report become available (where)?	B 1.5 Yes, with an input from stakeholders – already in hand. Likely to be published, as before, as an annex to the Consultative Document and thus open to comment.
<i>Cost of Not Acting</i> B 1.6 Will the costs / savings / implications of not implementing Publication 103 be assessed? If so, when?	B 1.6 n/a (implementation of the revised BSS Directive is an imperative)
<i>Anticipated costs</i> ICRP 103 and the new Euratom Directive will entail, e.g., - amended w_R and w_T ; - added emphasis on dose constraints. B 1.7 How do you expect these new requirements arising from ICRP 103 to impact on operations? B 1.8 Do you anticipate that the incorporation of ICRP 103 may lead to any reduction of any kind of cost or effort?	B 1.7 Will depend how it is implemented in UK via Euratom Directive. Not expected to be particularly significant, but still need to incorporate new dose/intakes etc B 1.8 Not yet known

B 2. Experience with specific technical aspects	
We would appreciate answers from both regulators and operators to all of these questions!	
<i>Pregnant workers</i> B 2.1 Do you envisage that the introduction of the 1 mSv limit for the embryo / fetus (ICRP 103) will cause any problems or costs? (Note: this question does not apply to EU member countries since the current Euratom BSS Directive already prescribes such a limit). B 2.2 If yes, what might they be, and how do you plan to resolve them?	B 2.1 n/a B 2.2 n/a

B 2. Experience with specific technical aspects	
<p><i>Constraints</i></p> <p>B 2.3 Is the added emphasis on dose constraints in ICRP 103 expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p> <p>B 2.4 Are risk constraints likely to be introduced with the implementation of ICRP 103?</p>	<p>B 2.3 Waste disposal – there already as part of policy</p> <p>B 2.4 [no comment]</p>
<p><i>Dosimetry</i></p> <p>B 2.5 Are the new ICRP 103 radiation and tissue weighting factors expected to lead to any difficulties? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.5 Published papers will use old factors and these will be in use until replaced.</p> <p>Work is in progress to calculate new ICRP dose coefficients using the revised radiation and tissue weighting factors, but at the same time update methodology more generally using, for example, new phantoms of the human body and updated nuclear decay data. ICRP intend in the short-term to provide a compilation of pre-103 dose coefficients for external and internal exposures to be used in the revised BSS until new coefficients are published. Effective doses from some exposures are likely to increase due to the changes eg. those involving breast dose, and others will decrease. The overall effects are complex and will not be known until calculations are complete.</p>
<p><i>Radon</i></p> <p>B 2.6 Is the implementation of ICRP 103 expected to cause any new efforts or costs with respect to radon? If yes, what are they and how do you plan to resolve them?</p>	<p>B 2.6 Not yet known</p>

B 3. Training implications	
<p>Questions 3.1 – 3.3 are aimed primarily at regulators, and question 3.4 at both regulators and operators!</p>	
<p><i>Regulators' staff</i></p> <p>B 3.1 What methods do you plan to use to ensure that relevant members of staff were aware of and understood the revised legislation?</p> <p>B 3.2 Do you anticipate any issues associated with the implementation of new terminology, dose coefficients, calculation methods or record keeping / reporting? If so, briefly describe?</p> <p>B 3.3 Do you expect to be involved in ensuring that stakeholders are aware of and</p>	<p>B 3.1 Written instructions, seminars and government and regulator guidance.</p> <p>B 3.2 "Critical Groups" are out, "representative persons" are in, this will need explaining. And that a rep. person is purely notional.</p> <p>B 3.3 Yes, as previously, including local site stakeholder groups.</p>

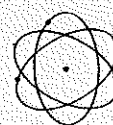
B 3. Training implications	
understood the revised legislation? If so, how do you anticipate doing this?	
<p><i>Stakeholders (primarily licensees, users, and employers)</i></p> <p>B 3.4 What do you expect will be the extent of training and information required? Will this be an entirely new effort, or could it be integrated into existing schedules of recurring training? What may be the anticipated costs of training?</p>	<p>B 3.4 Depends on the Directive. HPA/CRCE has provided update training for RP professionals and will provide user training when UK situation is known.</p>

And finally: Is there anything else that you wish to add?
[Please add any 'open' comments here!]

Livre blanc de la radioprotection

**La radioprotection à EDF
orientation et objectifs**

JUIN 1993



ÉLECTRICITÉ DE FRANCE

**Comité de
Radioprotection**

**Groupe de
Coordination en
Radioprotection**

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Nota : les orientations et objectifs sont indiqués en italique

Préface

Un livre blanc de la radioprotection, pour quoi faire ? Nos centrales nucléaires ne seraient-elles pas sûres, le personnel et la population seraient-ils mal protégés ?

Il ne viendrait à personne l'idée de s'étonner en constatant la différence entre une automobile d'aujourd'hui et un modèle des années 1960. L'expérience et les exigences croissantes de sécurité, de confort, d'économie ont conduit à des progrès spectaculaires et chaque année voit apparaître de nouveaux perfectionnements.

Il en est de même pour les centrales nucléaires. Des progrès constants ont été accomplis, je peux en témoigner. Et ce secteur a toujours été à la pointe du progrès et de la sécurité.

L'accident de Tchernobyl, en 1986, a entraîné une inquiétude bien compréhensible du public. Et la Commission Internationale de Protection Radiologique a proposé en 1991 des règles de protection plus sévères. Tout cela nous conduit à « accélérer » la marche du progrès. C'est donc dans la perspective d'une protection accrue des hommes et de l'environnement que la réflexion s'est engagée, en s'appuyant sur l'expérience acquise dans le monde, et en particulier celle tirée de notre important parc de centrales.

Un lecteur attentif pourra être déçu de ne pas trouver un objectif de date en face de chaque action projetée. Mais ce livre blanc doit être considéré comme une « loi cadre » dont les engagements sont à tenir d'ici la fin du siècle, qui est finalement très proche ; l'effort à fournir est considérable compte tenu de nos ambitions.

Je tiens à affirmer ici toute l'importance que la Direction de l'Entreprise attache à sa réalisation et j'ai toute confiance dans la compétence et le dynamisme du personnel de notre Entreprise pour mener à bien ce programme.



Rémy CARLE
Directeur Général Adjoint

Préambule

La radioprotection a pour objet la protection de l'homme contre les rayonnements ionisants ; elle concerne l'ensemble des activités liées au fonctionnement normal des installations nucléaires et également les situations d'accident ; mais celles-ci sont très peu probables en raison des règles de sûreté appliquées en France.

La radioprotection à EDF s'est d'abord attachée à la surveillance des travailleurs et aux contrôles réglementaires d'environnement. Elle a vu son champ s'élargir considérablement. Elle a pris une dimension pluridisciplinaire évidente : elle touche à de très nombreux domaines, de la conception au démantèlement des installations, dans des conditions normales ou d'accident, sous toutes sortes d'aspects tant théoriques que pratiques : techniques, réglementaires, médicaux, juridiques, sociaux.

Le cumul annuel des doses individuelles reçues par les travailleurs intervenant dans les centrales nucléaires d'EDF a depuis 1989 tendance à croître, plus particulièrement pour les travailleurs d'entreprises extérieures intervenant pour les travaux d'entretien ; ceci est dû essentiellement au vieillissement du parc qui alourdit ces travaux. Les comparaisons internationales, longtemps en notre faveur, ne sont plus toujours à notre avantage ; certaines installations étrangères de construction récente affichent des résultats meilleurs que les nôtres qu'il convient d'analyser.

Au plan des normes de radioprotection, de nouvelles valeurs plus faibles que celles en vigueur viennent d'être recommandées par la Commission Internationale de Protection Radiologique (CIPR 60 - décembre 1990). La Commission des Communautés Européennes a décidé de reprendre ces valeurs dans les normes de base EURATOM.

Les questions liées à la radioprotection sont régulièrement évoquées par les médias : les sujets sont multiples, qu'il s'agisse du stockage de déchets, de rejets - même minimes - d'effluents radioactifs, de transport de matières radioactives, de contamination de personnel, de surveillance dosimétrique des travailleurs d'entreprises extérieures, etc.

Dans ce contexte national et international, notre Entreprise doit affirmer sa volonté de maintenir notre industrie nucléaire au rang des meilleures. Compte tenu des enjeux techniques, économiques, politiques et sociaux, la politique d'EDF en matière de radioprotection mérite d'être clairement définie.

L'objectif du présent document est donc d'examiner la situation actuelle, d'en évaluer les tendances, d'exposer les éléments de la politique qu'EDF compte suivre à moyen terme (1995-2000) pour assurer une protection optimale des travailleurs et du public dans une perspective globale de l'intérêt de l'Entreprise.

Après une présentation rapide de l'organisation de la radioprotection à EDF, les différents aspects de cette radioprotection seront évoqués :

- tout d'abord les questions de radiobiologie liées aux effets des rayonnements, et les questions médicales associées,
- ensuite les divers aspects de la radioprotection tout au long de la vie des centrales nucléaires, pour assurer la protection des travailleurs, du public et de l'environnement,
- puis les thèmes de l'information et de la formation, pour terminer par les situations d'urgence.

Les engagements et orientations contenus dans ce Livre Blanc - pour lequel toutes les Directions concernées ont été consultées - font désormais partie intégrante de la Stratégie de l'Entreprise. Leur mise en œuvre nécessite maintenant une analyse détaillée débouchant sur la définition des moyens à mettre en place et sur le calendrier des actions. Mais ceci n'est pas le but du présent document et fera l'objet d'études spécifiques.



Lucien BERTRON

Directeur Délégué d'EDF Production Transport
Président du Groupe de Coordination en Radioprotection

A

ORGANISATION GENERALE DE LA RADIOPROTECTION A EDF

I - 30 ANS DE RADIOPROTECTION DANS UN CONTEXTE EVOLUTIF

Avec le démarrage des premières tranches nucléaires uranium naturel-graphite-gaz (UNGG) à Chinon (Chinon A1 dès 1961), s'est mise en place au sein d'EDF une structure nationale de radioprotection, le Service Général de Radioprotection (SGR). Ce service a ainsi supervisé, sur le plan de la radioprotection, la mise en service des 3 tranches de Chinon A, puis du premier réacteur à eau sous pression (REP) de Chooz A (1967).

Avec la mise en service des unités UNGG de 500 MW de Saint-Laurent-des-Eaux (Saint-Laurent A1 couplée en mars 1969), la Direction Générale a décidé la création du Comité de Radioprotection, chargé de proposer une politique générale en matière de radioprotection. Le SGR cédait son activité opérationnelle au Département de Radioprotection, la radiotoxicologie* étant confiée au Laboratoire d'Analyses Médicales (LAM), rattaché au Service Général de Médecine du Travail (SGMT). La surveillance de l'environnement, quant à elle, était laissée aux centrales chargées par ailleurs des mesures de protection du personnel dans son travail quotidien. Les missions du Comité de Radioprotection ont en outre été étendues en 1975 (notamment aux aspects liés à la recherche), tandis que sa composition était élargie et portée au niveau des Directeurs.

Les années 1970 ont vu le début de la réalisation du vaste programme nucléaire de tranches REP (mise en service de Fessenheim en 1977), dans un contexte de développement mondial du nucléaire après le « choc pétrolier » de 1973.

L'accident de Three Mile Island en 1979 a brisé cet élan. Plusieurs pays ont pris dès lors des décisions d'arrêt - au moins momentanément - de leur programme nucléaire. En France, le nucléaire restait malgré tout bien accepté par une opinion publique consciente des intérêts énergétiques nationaux (deuxième choc pétrolier en 1979).

Tchernobyl, en 1986, a porté un coup sérieux à l'industrie nucléaire et a encouragé la défiance du public à l'égard des techniques nucléaires. Les associations antinucléaires voient leur audience s'accroître et se présentent comme seuls informateurs indépendants, malgré les efforts de « transparence » des exploitants concrétisés par la publication des résultats de mesures dans l'environnement et une large information sur le fonctionnement des installations.

Depuis Tchernobyl on assiste en outre à un développement rapide du cadre réglementaire tant national qu'international (règlements CCE, publications AIEA, conventions internationales d'information en cas d'accident, révision des normes de radioprotection par la CIPR puis la CCE, ...), et de son évolution dans un sens plus restrictif.

Au sein de l'Entreprise, on est pendant le même temps passé de la phase des grands chantiers à une phase d'exploitation de plus de cinquante tranches ; la Direction d'EDF Production Transport est ainsi devenue la plus concernée par les questions nucléaires, et en particulier tout ce qui a trait à la radioprotection.

Les activités en matière de radioprotection ont également largement évolué au sein de l'Entreprise. Le terme « radioprotection » doit désormais être pris dans un sens large : la radioprotection traite en priorité de la protection des travailleurs, qu'elle prend en compte dès la

conception des installations, puis à tous les stades de leur exploitation - y compris l'évacuation des effluents et des déchets radioactifs - jusqu'à leur démantèlement final, avec tous les aspects réglementaires, techniques et médicaux liés à ces activités. Elle couvre également, à des degrés divers, d'autres activités telles que la protection des populations et la surveillance de l'environnement, la radiopathologie*, la radiobiologie*, la radiotoxicologie et la radiécologie* (chaînes alimentaires), la métrologie* des rayonnements, les plans d'urgence techniques et sanitaires, la formation, l'information, etc., avec là encore des aspects réglementaires et juridiques.

II — L'ORGANISATION ACTUELLE D'EDF

Compte tenu de la diversité des activités impliquées, les acteurs sont nombreux.

Les acteurs « sur le terrain » sont les exploitants des centrales nucléaires et le personnel qui en assure la maintenance ; ils mettent en œuvre les méthodes et moyens d'exploitation, d'organisation, de protection, etc. élaborés avec l'aide des Services centraux d'EDF. Ils s'appuient sur les médecins du travail affectés aux sites.

Au niveau central, on peut citer notamment les responsabilités :

■ de la Direction de l'Équipement :

⇒ conception des systèmes et installations, aide à l'exploitant, analyse de l'expérience d'exploitation, développement de logiciels de simulation, réduction des doses...

■ de la **Direction des Etudes et Recherches** :

⇒ modélisation (dispersion des effluents), problèmes d'environnement, réduction des doses, options de l'aval du cycle.

■ de la **Direction EDF Production Transport (DEPT)** :

⇒ règles d'application de la politique de radioprotection à l'exploitation et à la maintenance du parc nucléaire, gestion des combustibles, des effluents et des déchets radioactifs, plans d'urgence, démantèlement.

■ du **Service Général de la Médecine du Travail** :

⇒ doctrine, coordination de l'action des médecins du travail des sites : surveillance des travailleurs exposés, étude des conditions de travail, organisation des secours médicaux.

■ du **Service Prévention Sécurité** :

⇒ contrôles et audits sur la radioprotection des travailleurs.

Trois organismes ont plus particulièrement vocation de coordination interne dans l'élaboration de la politique d'EDF et son application pratique dans les Unités :

● Le **Comité de Radioprotection** examine les aspects généraux de la radioprotection prise dans son ensemble, c'est-à-dire tous les aspects liés à la protection de l'homme contre les rayonnements ionisants. Il s'intéresse plus particulièrement aux aspects médicaux (biologie, effets des rayonnements), aux normes de radioprotection et aux doses reçues par le personnel. Il définit les orientations générales.

● Le **Département Sécurité — Radioprotection — Environnement (DSRE)**, Département d'expertise et d'appui dans la nouvelle structure de la DEPT, est la cheville ouvrière de la radioprotection de cette Direction. Il est responsable de la définition des conditions d'application de la réglementation et de la politique d'EDF en matière de radioprotection. Il est chargé en particulier :

— de l'élaboration des règles (doctrines) applicables dans les centres de production nucléaire,

— du développement des techniques d'amélioration de la radioprotection ("ALARA"), en s'appuyant sur un retour d'expérience permanent,

— de la gestion nationale de la dosimétrie réglementaire* des agents EDF,

— de la définition des programmes-types de formation en radioprotection (et de sécurité en général),

— du suivi des problèmes liés à l'environnement nucléaire et aux déchets radioactifs.

Le DSRE est donc étroitement impliqué dans toutes les actions de radioprotection.

● Le **Groupe de Coordination en Radioprotection (GCR)**, de création récente (février 90), a pour mission de coordonner l'action des différents acteurs au sein de l'Entreprise, d'analyser les contraintes extérieures (réglementaires ou autres) pour déceler les incidences sur le fonctionnement interne, de proposer des solutions pratiques aux problèmes posés. Le GCR complète ainsi l'action du Comité en s'attachant aux aspects opérationnels de la radioprotection.

III — UNE POLITIQUE D'OUVERTURE

En présence d'un environnement national et international incertain et inquiet, EDF a décidé de pratiquer une large politique d'ouverture,

au plan national, vers :

— les Pouvoirs Publics, pour apporter la contribution d'EDF aux évolutions techniques et réglementaires, à l'amélioration des plans d'urgence, etc.

— le monde médical, pour l'informer et lui donner les moyens de formation spécifique aux risques nucléaires.

— le monde industriel, pour être au fait des dernières techniques(1).

— le monde de la recherche (notamment en biologie) pour suivre le développement des connaissances, et orienter certaines recherches (en particulier celles qui sont menées au CEA).

— le monde de la normalisation.

— le public, les mondes scolaire et universitaire, pour répondre à leurs besoins d'information, voire de formation.

— les groupements scientifiques, juridiques, techniques, etc., permettant les échanges d'idées (SFEN, SFRP, ...).

au plan international, vers :

— les exploitants nucléaires des autres pays, pour partager l'expérience et améliorer la protection des travailleurs.

— les instances communautaires européennes, afin de participer aux discussions sur les réglementations en préparation.

— les diverses Organisations internationales d'envergure : AIEA, OCDE, OMS, CIPR, IRPA, AIDN, etc. pour déceler les évolutions à long terme, et faire connaître nos positions.

etc.

Cette volonté d'ouverture et de participation caractérise la politique d'EDF en matière de radioprotection, dans ses diverses composantes faisant l'objet des chapitres suivants.

(1) Noter les relations privilégiées avec les partenaires du groupe CEA (CEA, IPSN, COGEMA), matérialisées par l'existence d'un « Comité de Radioprotection Opérationnelle EDF-Groupe CEA » où sont discutés des sujets d'intérêt commun.

B

FONDEMENTS MEDICAUX ET BIOLOGIQUES DE LA RADIOPROTECTION

Les risques liés à l'irradiation sont fonction des doses reçues ; il est donc indispensable d'imposer des limites à l'exposition humaine aux rayonnements ionisants.

Les effets sont connus directement par l'observation de personnes exposées lors d'accidents ou des explosions d'Hiroshima et Nagasaki, à l'occasion de pratiques médicales (radiothérapie, radiodiagnostic, médecine nucléaire) ou durant leur vie professionnelle. Ils sont aussi connus indirectement par l'expérimentation animale et les expériences in vitro.

Les résultats accumulés en radiobiologie permettent d'en mieux comprendre les mécanismes. Cependant **l'appréciation de leur importance réelle** (c'est-à-dire quantitative) **n'est pas satisfaisante**, même si la masse des informations scientifiques accumulées est considérable. Nous verrons plus loin pourquoi les incertitudes sont, dans l'état actuel de nos connaissances, inévitables.

1 — EFFETS DES RAYONNEMENTS IONISANTS

Les effets sont de deux types :

1 — Effets à seuil (appelés encore « déterministes* » ou « obligatoires »)

Ils n'apparaissent qu'au-dessus d'une certaine dose, appelée seuil, à peu près constante pour un effet donné pour tous les individus mais variable suivant l'effet étudié. Lorsque cette dose seuil est dépassée leur survenue est inéluctable et la gravité de l'effet augmente avec l'importance de la dose. C'est le cas par exemple des lésions cutanées. Il suffit de placer les limites au-dessous de ce seuil pour les éviter. Les effets à seuil ne peu-

vent donc survenir lors du fonctionnement normal des installations nucléaires, mais ils sont évidemment à craindre en cas d'accident d'irradiation.

2 — Effets réputés sans seuil (appelés encore « non déterministes » ou « stochastiques* »)

Pour d'autres effets, essentiellement les cancers et les effets génétiques, on ignore s'il y a un niveau de dose au-dessous duquel on peut assurer qu'ils ne peuvent survenir.

Leur apparition semble soumise aux lois du hasard. En effet c'est leur fréquence dans une population qui varie en fonction de la dose et quelle que soit l'importance de la dose ils n'apparaissent pas obligatoirement. Inversement il est impossible de démontrer qu'il y a une dose seuil au-dessous de laquelle le risque peut être considéré comme nul.

Si l'effet se manifeste, sa gravité est indépendante de la dose reçue (on a ou on n'a pas de cancer).

Rien ne distingue un cancer ou une mutation génétique radioinduits de cancers ou de mutations spontanés ou liés à d'autres causes. Il est donc nécessaire de recourir à des études statistiques pour mettre en évidence un excès de cancer dans une population exposée comparée avec une population témoin. On fait donc appel, dans cette optique, aux enquêtes épidémiologiques*.

Ces enquêtes sont toujours très longues car le temps nécessaire pour l'apparition d'un cancer radioinduit (ou d'un effet génétique) se compte en années : plus de 2 ans pour les leucémies, 10 à plus de 50 ans pour les tumeurs solides (une ou plusieurs générations pour les mutations).

Le nombre de personnes suivies doit être important car l'excès de cancers radioinduits est toujours faible même aux fortes doses : quelques pour cent au maximum pour une dose de 1 Gy alors que le bruit de fond des cancers « spontanés » est élevé (près de 25 % en France) et varie notablement d'une population à l'autre.

Lorsque la dose est plus faible, la probabilité d'apparition des cancers radioinduits décroît et compte tenu des exigences statistiques, il faudrait, pour mettre en évidence un excès de cancers, engager des études épidémiologiques sur un nombre si élevé de personnes que ces études deviennent rapidement irréalisables.

Ces difficultés ne sont pas propres aux rayonnements ionisants ; les mêmes sont observées pour tout génotoxique* chimique. C'est donc un problème méthodologique général.

3 — Problème des faibles doses

Malgré l'importance des recherches dans ce domaine, on ne peut pas affirmer que les faibles doses ont, ou n'ont pas, un effet et, si elles en ont, on ne sait pas en préciser la valeur numérique. Par faibles doses on entend des doses inférieures à 0,3 voire 0,5 Gy pour certains experts, en irradiation γ ; il s'agit ainsi de doses se situant au-dessus des limites réglementaires, donc supérieures à celles que reçoit effectivement le personnel d'EDF ou celui des entreprises intervenantes et, a fortiori, la population pendant le fonctionnement normal des installations.

On bute sur ce problème depuis 20 ans sans progresser de façon significative, ce qui met l'industrie électronucléaire dans une situation très inconfortable.

■ Contrairement à ce qu'on espérait il y a dix ou quinze ans, les recherches en radiobiologie et en biologie moléculaire, en particulier l'étude des mécanismes d'action des rayonnements ionisants, n'ont pas permis de répondre à cette question.

■ L'épidémiologie*, dont l'intérêt est certain pour les doses relativement élevées, n'a pas apporté de réponse pour les faibles doses. On peut considérer, à tort ou à raison, devant des résultats apparemment négatifs ou tout au moins contradictoires, que l'absence de réponse tient aux limites de ces enquêtes : durée trop courte, populations témoins critiquables, non prise en compte de multiples autres facteurs qui ont parfois plus de poids que les doses d'irradiation étudiées ; mais la difficulté principale réside, comme on l'a déjà indiqué ci-dessus, dans la taille insuffisante des populations étudiées. Les résultats sont très souvent d'interprétation discutable.

■ L'impossibilité de répondre à la question de la réalité et, a fortiori, de l'importance des effets des faibles doses a amené les experts à extrapoler à partir des fortes doses, en admettant par sécurité qu'il n'y a pas de seuil et que la relation dose/effet est linéaire, c'est-à-dire que le risque est proportionnel à la dose, si infime soit-elle.

Les experts ont choisi ces hypothèses de prudence non pour déterminer l'effet le plus probable mais pour déterminer sa limite supérieure. Les calculs ont été faits en introduisant un certain nombre d'hypothèses simplificatrices (prise en compte partielle du rôle du débit de dose et de l'étalement de la dose dans le temps, utilisation sans restriction de la notion de dose collective, choix des modèles d'extrapolation pour « évaluer » le nombre de cancers sur la vie entière, etc.) qui, d'après de nombreux experts, majoreraient l'importance réelle des risques (voir rapport de l'Académie des Sciences de Paris de 1989). **Ces évaluations dont les résultats sont d'ailleurs incontrôlables sont souvent présentées à tort comme représentant les résultats de calculs rigoureux de l'importance des risques.**

C'est à partir de ces évaluations que sont établies les réglementations ; elles sont choisies afin que l'importance « supposée » des risques soit à un niveau voisin, pour les travailleurs, de ceux d'autres activités économiques réputées particulièrement sûres ou, pour la population, des risques de la vie courante.

II — LES ORIENTATIONS DE LA POLITIQUE D'EDF

1 — Domaine des faibles doses

■ EDF n'a pas de laboratoire ou de service de recherches biologiques dans ce domaine. Ce n'est évidemment pas son rôle. Par contre l'Entreprise a besoin de suivre de très près tout ce qui se fait en radiobiologie afin d'être informée des études qui permettraient de mieux comprendre le problème des faibles doses et d'apprécier si ces résultats amèneront les experts à modifier les modèles choisis pour évaluer ces effets. Mais, comme indiqué plus haut, **il n'y a pas eu au cours des dernières années de progrès importants qui laissent espérer, dans un avenir proche, une réponse à cette question essentielle** : ce n'est donc pas actuellement une priorité pour EDF.

Par contre, EDF a **besoin d'avoir des experts propres à l'Entreprise** pour suivre cette question car le jour où une voie de recherche prometteuse apparaîtra, il sera nécessaire d'aider cette recherche de façon prioritaire.

■ EDF **doit s'intéresser aussi aux travaux de modélisation pour l'évaluation prospective des risques**, afin d'être capable d'en faire l'étude critique : suivant les modèles choisis, l'importance hypothétique des risques peut varier de bien plus d'un ordre de grandeur, ce qui a des conséquences importantes pour la réglementation.

■ Les difficultés des études épidémiologiques ont été soulignées précédemment : **il se pose des problèmes de méthodologie et d'interprétation statistique à propos desquels EDF a tout intérêt à provoquer des recherches.** Ceci n'empêche pas qu'EDF ait un champ d'investigation épidémiologique privilégié, celui de la surveillance de son personnel. Les coopérations internationales peuvent aider à résoudre le problème de la taille de l'échantillon.

■ EDF doit **affiner la qualité des informations sur les doses reçues par son personnel.** En particulier il est nécessaire d'**intégrer dans le fichier dosimétrique informatisé les doses antérieures à 1987** afin d'être en mesure d'effectuer des enquêtes épidémiologiques sur le personnel et de participer à des enquêtes internationales.

Un effort doit également être fait sur la connaissance des doses reçues par la population, tant en irradiation externe qu'en irradiation interne. Ces doses ne sont pas mesurées, mais calculées.

■ Ceci justifie également **un effort de recherche en radioécologie***, à propos des chaînes alimentaires, de la façon dont l'être humain est contaminé dans le milieu naturel et à propos des méthodes de calcul de l'irradiation interne. La surveillance radioécologique autour des centrales prend une importance de plus en plus grande (Cf. chap. D III).

2 — Cas des effets à seuil

Ils ne peuvent survenir qu'en cas d'accident et ce sont les travailleurs des centrales et non la population qui seraient les plus concernés par ce type d'effet.

Quels que soient les progrès faits en matière de sûreté, il faut a priori considérer que **l'accident est toujours possible** ; bien entendu son importance et ses conséquences peuvent être extrêmement variables.

■ Des progrès importants ont été faits avec la préparation du Plan d'Urgence Interne (PUI) sanitaire ; ce plan définit en particulier des scénarios enveloppes qui permettent de mieux apprécier ce que pourrait être un accident de grande dimension dans une centrale.

EDF a juridiquement une obligation de moyens, c'est-à-dire l'obligation de s'assurer qu'en cas d'accident elle pourra disposer des moyens nécessaires pour y faire face.

Pour chaque scénario « enveloppe », ont été définis les moyens humains et techniques qui seraient nécessaires tant au niveau des premiers secours qu'au niveau des hospitalisations et des évacuations. Un effort très important a été fait dans les centres nucléaires de production d'électricité, en particulier par leurs services médicaux, pour la mise en place de ces moyens.

Les problèmes posés par les accidents sont traités au chapitre G « situations d'urgence ».

■ Le deuxième volet de l'action engagée concerne le développement de moyens de recherche en radiobiologie*, en radiopathologie* et en métrologie* ; les recherches sur ces thèmes se sont amenuisées de façon très importante dans notre pays au cours des dernières années. On constate aujourd'hui que la France n'y a plus qu'une place secondaire au plan international. Tchernobyl a montré qu'il y avait bien des domaines où des recherches sont encore à faire.

EDF a souhaité avoir un partenaire dont la préoccupation essentielle soit la

recherche en matière d'effets des rayonnements ionisants car beaucoup de laboratoires, plus intéressés par d'autres recherches, ont délaissé progressivement ce domaine. **Ce partenaire est naturellement l'IPSN**, dont la vocation en matière de recherches de cette nature est clairement affirmée dans les textes qui définissent ses activités.

Une coopération s'est donc établie avec l'IPSN pour la mise en place, grâce à un plan pluriannuel (la première étape est de 5 ans, à partir de 1992) sous la responsabilité de celui-ci,

de laboratoires de recherche concernant dans un premier temps la dosimétrie biologique* et la physiopathologie* des irradiations aiguës fortes et moyennes ; dans un deuxième temps EDF souhaite que l'IPSN remette à niveau un certain nombre de « laboratoires » car, en cas d'accident, il faut absolument disposer de moyens pour la mesure des doses d'irradiation externe ou de contamination interne et la reconstitution des faits afin d'évaluer le mieux possible les doses reçues.

3 — Autres recherches générales en radiobiologie

EDF, par l'intermédiaire du Conseil Scientifique commun à la Direction des Etudes et Recherches et au Comité de Radioprotection, subventionne depuis plus de quinze ans les activités de divers laboratoires de recherche sur des sujets très divers qui peuvent avoir un intérêt en matière de radiobiologie. Le but est essentiellement d'aider les études qui concernent la radioprotection, donc EDF, et non de faire du mécénat.

NORMES DE BASE COMMUNAUTAIRES EN RADIOPROTECTION

Révision des Normes de base de Radioprotection d'EURATOM

Situation au 1.1.93. Parution prévisible : 1994 — Transposition en droit français : 1996 ?

ASPECTS CONCERNANT PLUS PARTICULIEREMENT EDF

1-LIMITES DE DOSES

La limite de dose annuelle pour les travailleurs reste fixée à 50 mSv ; mais une nouvelle limite de 100 mSv sur 5 ans est introduite, soit 20 mSv/an en moyenne. Cette limite concerne actuellement environ 1 % du personnel EDF et 6 % des travailleurs d'entreprises extérieures travaillant sur les sites EDF. Pour le public, la limite est fixée à 1 mSv/an.

2-LIMITES ANNUELLES D'INCORPORATION (LAI)*

Contrairement à la précédente, la nouvelle Directive ne fixe pas de valeurs de LAI et laisse provisoirement ce soin aux Etats. Les valeurs de la CIPR 61 ne sont pas reprises pour l'instant, car le modèle de calcul des doses à partir des activités inhalées (« modèle pulmonaire ») est en cours de révision ; on peut supposer qu'un tableau de LAI standards sera fourni ultérieurement. Les Etats garderont la possibilité d'approuver des valeurs différentes sur dossier justificatif se référant aux limites de dose primaires (cas des usines de fabrication de combustible où il n'y a pas de très fines particules inhalables)

3-LIMITES D'EXEMPTION

La Directive 80/836 mentionnait des seuils uniformes de 100 Bq/g (radioéléments artificiels) et 500 Bq/g (radioéléments naturels), au-dessous desquels les activités n'étaient pas soumises à autorisation. Ces valeurs sont remplacées par des valeurs spécifiques, pour chaque radioélément, d'activité totale ou d'activité massique au-dessus desquelles il faut autorisation ou déclaration. Les activités massiques de certains éléments sont très basses (1 Bq/g par ex. pour ^{60}Co).

Il semble qu'on s'oriente vers une situation dans laquelle le tableau de l'annexe I ne serait applicable qu'aux « petits utilisateurs » de radioéléments, les installations nucléaires étant de toute façon soumises à d'autres régimes d'autorisation.

Les valeurs du tableau I ne sont par ailleurs pas à prendre comme valeurs « de minimis ». En pratique, pour les centrales nucléaires, l'élimination des déchets très faiblement radioactifs sera à étudier au cas par cas ; la réglementation des ICPE devrait être révisée dans ce sens (Cf. aussi art. 45.c).

4-RESULTATS DOSIMETRIQUES

L'article 28 stipule que les résultats de la surveillance individuelle sont mis à la disposition (outre les médecins du travail), des autorités compétentes et de la hiérarchie.

5-FEMMES ENCEINTES

Dès la déclaration de la grossesse, la dose maximale au fœtus pendant le reste de la grossesse ne doit pas dépasser 1 mSv. A noter que la CIPR 60 mentionnait 2 mSv à l'abdomen, valeur plus facilement contrôlable. En pratique, les femmes enceintes ne devront pas être admises à travailler en zone contrôlée.

6-POINTS DIVERS

6.1 La Directive s'applique directement aux mines d'uranium (limite de dose appliquée aux doses dues au rayonnement naturel). Pour les autres mines souterraines, la surveillance de l'exposition à l'irradiation naturelle (radon) devra être faite — art. 41a — ceci inclut les mines de charbon.

6.2 Les Etats doivent faire des estimations périodiques des doses encourues par les populations voisines d'installations nucléaires (art. 46), en prenant en compte toutes les sources possibles et les chemins de transmission de la contamination.

6.3 L'établissement des plans d'urgence doit se faire en concertation avec les pays voisins pour les centrales proches des frontières (art. 50).

6.4 Les autorités compétentes sont responsables de « l'examen et l'approbation des projets d'élimination des déchets radioactifs » (art. 49).

CONCLUSIONS

Dans tous les domaines de recherche concernant la radiobiologie et la radiopathologie, **EDF doit constamment se tenir au courant de ce qui se passe et il faut que l'Entreprise dispose d'experts, en particulier au Comité de Radioprotection, capables de suivre l'évolution de ces problèmes et les progrès accomplis.** Ces experts s'appuient sur des conseillers extérieurs, français ou étrangers, et sur un Conseil Scientifique.

Par ailleurs il y a certains domaines où **EDF, par les données et les moyens dont elle dispose, peut apporter des résultats utiles à la communauté scientifique** : dosimétrie, métrologie, radioécologie, épidémiologie du personnel.

Ce n'est que s'il y a de nouveau en France une recherche en radiobiologie et en radiopathologie de haut niveau que notre pays participera au progrès scientifique et que, par voie de conséquence,

il sera écouté dans les Commissions et Structures internationales chargées de définir les règles en matière de radioprotection. C'est une des raisons pour lesquelles il est nécessaire qu'**EDF apporte son soutien aux efforts qui sont faits pour développer certains laboratoires et former des chercheurs en radiobiologie, en radiopathologie** et dans des domaines proches de la radioprotection (DEA de radiobiologie, bourses de doctorat, etc.).

C

PROTECTION DES TRAVAILLEURS

Electricité de France a toujours été soucieuse d'assurer une bonne protection des travailleurs employés dans ses centrales nucléaires. Les doses collectives moyennes enregistrées dans les centrales se situaient jusqu'à un passé récent parmi les meilleurs résultats mondiaux. Mais, depuis 1989, on assiste à une augmentation de la dose collective moyenne par unité de production. Dans le même temps, certaines tranches étrangères affichent des doses collectives annuelles beaucoup plus basses ; il convient d'en analyser les raisons. Ce constat incite à réexaminer les conséquences qu'entraînent les besoins croissants d'entretien des centrales. Il implique aussi une prise de conscience et un effort supplémentaire de l'ensemble du personnel.

Au plan international, la réduction des doses individuelles est à l'ordre du jour, avec la prise en compte des dernières

recommandations de la Commission Internationale de Protection Radiologique (CIPR 60) dans la réglementation communautaire en cours de révision. Ces recommandations étendent par ailleurs le champ d'application de la radioprotection.

CIPR 60	
Limites de dose recommandées :	
pour les travailleurs	
— limite annuelle :	50 mSv
— limite sur 5 ans :	100 mSv
	soit 20 mSv/an en moyenne
	sur la base d'une « dose-vie » de 1 Sv
pour le public	
— limite annuelle moyenne :	1 mSv
	(moyenne sur 5 ans)

Enfin, la qualité de la surveillance médicale et radiologique des travailleurs d'entreprises extérieures, qui assurent 80 % des travaux de maintenance des centrales pendant les arrêts annuels, a donné lieu à divers débats, et il est certain que des améliorations doivent être recherchées.

Devant cette situation générale, EDF entend poursuivre ses efforts pour améliorer la radioprotection des travailleurs.

Les principaux aspects de cette politique font l'objet des 4 sections ci-après :

C I : Dosimétrie individuelle (connaissance des doses)

C II : Surveillance médicale des travailleurs

C III : Travailleurs d'entreprises extérieures (actions spécifiques pour améliorer leur protection radiologique)

C IV : Réduction des doses.

C I — DOSIMETRIE INDIVIDUELLE

Toute action visant à réduire les doses reçues par le personnel doit commencer par une bonne connaissance des doses individuelles. Les doses reçues par les intervenants peuvent résulter d'une contamination interne ou d'une exposition externe aux rayonnements.

La politique connue à EDF sous le nom de « centrale propre »*, fait que les cas de contamination interne sont rares et de faible gravité ; globalement, la dose collective cumulée due à ce type d'exposition est très inférieure à 1/1000e des doses collectives enregistrées. Ce n'est donc pas un sujet de préoccupation pour notre Entreprise. Ceci n'exclut évidemment pas l'attention qui est apportée à la surveillance du per-

sonnel, qui est soumis à des contrôles systématiques réguliers. Mais le risque de contamination interne est lié à des situations d'incident qu'une bonne organisation du travail permet d'éviter au maximum.

L'essentiel des doses reçues étant ainsi imputable à l'irradiation externe, on s'attachera donc dans la suite de ce chapitre aux aspects liés à la **dosimétrie externe**.

I — LES POINTS FAIBLES DE LA DOSIMÉTRIE EXTERNE :

A un moment où la CIPR recommande de réduire les doses maximales acceptables pour les travailleurs à 100 mSv

sur 5 ans (soit 20 mSv en moyenne annuelle), et où les travailleurs sont amenés à circuler librement en Europe, il faut progresser dans le domaine de la dosimétrie.

On relève en effet diverses insuffisances ou difficultés sur plusieurs points :

1) La comptabilisation des doses

Le calcul des doses est en soi une opération délicate, car il prend en compte de très nombreux paramètres physiques et biologiques. De nouvelles méthodes de calcul sont préconisées au plan international. Il faut que les moyens de mesure (ou plutôt d'estimation), par définition imparfaits, tiennent compte de ces

règles. Mais surtout, les matériels de mesure ont des seuils et des sensibilités différentes ; et les méthodes de mesure et la façon de **comptabiliser** les doses diffèrent d'un pays à l'autre. Il y a là matière à progrès tant dans les méthodes que les techniques, et en tout cas à harmonisation au niveau européen.

2) Les moyens de mesure

La dosimétrie réglementaire en France est faite au moyen de dosimètres photographiques individuels (films). Mais l'exploitant est conduit à effectuer une dosimétrie « opérationnelle » utilisant des dosimètres électroniques à lecture directe, à des fins d'optimisation de la radioprotection qui demande une connaissance rapide des doses, les résultats des films n'étant connus que plus d'un mois plus tard.

Cette dualité de moyens est une bonne chose en soi ; car bien que les objectifs en soient différents, ces 2 systèmes sont complémentaires et peuvent pallier leurs défaillances réciproques. Une difficulté subsiste pour la bonne utilisation de cette complémentarité : elle réside dans le secret médical que les ministères de la Santé et du Travail continuent à attacher aux résultats de la dosimétrie individuelle.

3) Le cas des travailleurs extérieurs

La connaissance des doses individuelles des travailleurs d'entreprises extérieures intervenant dans les installations d'EDF est limitée à leur temps de séjour dans celles-ci. Les doses reçues hors EDF ne sont en général pas connues, car elles résultent de la dosimétrie réglementaire avec la restriction rappelée ci-dessus. Cette situation n'est pas satisfaisante, car elle ne permet pas d'assurer correctement la surveillance dosimétrique de ce type de travailleurs.

4) Les doses dues aux neutrons

Celles-ci font seulement l'objet d'estimations à partir des mesures de niveaux d'irradiation ambiante. Ces doses sont faibles ; elles ne représentent qu'une faible partie des doses collectives (environ 2 %) et concernent un effectif limité, environ 3 % du personnel « catégorie A » des sites nucléaires. Mais certains postes peuvent être plus exposés, les neutrons pouvant alors contribuer jusqu'à 30 % aux doses individuelles. Il apparaît donc souhaitable de disposer de dosimètres individuels pour les neutrons.

5) Les chantiers spéciaux

En outre, les risques d'expositions localisées, pour certains types de chantiers, demanderaient à être mieux appréhendés (doses « extrémités » notamment).

II — RÉGLEMENTATION

Au plan réglementaire, deux textes importants sont à noter au niveau européen :

■ La Directive CEE 90/641 du 04.12.1990 concernant la protection opérationnelle des travailleurs extérieurs exposés à un risque de rayonnements ionisants au cours de leur intervention en zone contrôlée. L'application de cette Directive devrait conduire à un partage de responsabilités entre exploitant et employeur -actuellement légalement seul responsable- avant la fin de 1993. Cette Directive préconise à terme un réseau européen informatisé pour la surveillance radiologique (art. 4-2).

■ La Directive « Normes de Base en radioprotection », dont le texte de 1980/1984 est en cours de révision, tiendra compte des nouvelles recommandations de la CIPR 60, en particulier pour les limites de doses individuelles. On notera que le projet final prévoit explicitement la transmission des résultats dosimétriques aux responsables de la radioprotection de l'exploitant. Cette Directive pourrait être publiée à mi-94, pour application dans les Etats membres dès 1996.

Il faut noter enfin, parmi les recommandations de l'Office parlementaire d'évaluation des choix scientifiques et technologiques (rapport BIRRAUX de décembre 1991), celle (n° 9) relative à la dosimétrie :

« des études sont engagées par le ministère de la Santé et le SCPRI sur la faisabilité d'un système électronique de dosimétrie fiable, permettant une centralisation des données et comprenant l'équipement en terminaux des médecins du travail des exploitants et des entreprises sous-traitantes... ».

III — DÉVELOPPEMENTS ET NOUVELLES ORIENTATIONS :

Dans ce contexte, EDF considère qu'il est nécessaire d'améliorer les méthodes et les procédures en matière de dosimétrie :

■ **EDF a engagé avec le groupe CEA une réflexion sur l'harmonisation des méthodes de comptabilisation des doses.** Une action commune a été engagée auprès des Communautés

européennes (DG XI) pour développer cette harmonisation. De façon générale, **EDF sera présente sur la scène internationale, dans les instances où s'élabore la politique à moyen et long terme**, pour agir dans l'intérêt de la protection sanitaire des travailleurs.

■ **L'amélioration de la dosimétrie passe également par une adéquation des méthodes de mesure aux nouvelles normes métrologiques** (CIUR, CIPR, ISO). Ce problème général est de portée internationale. **Ceci implique de disposer**, soit au sein d'EDF même, soit à défaut en s'assurant des concours extérieurs (CEA, CNRS, etc.), **de spécialistes de physique nucléaire appliquée à la métrologie. Il faudra donc consentir des efforts particuliers de formation d'experts** ; ce point important sera examiné plus en détail au chapitre F.

■ Pour le suivi dosimétrique, **EDF souhaite**, dans l'esprit du rapport BIRRAUX (mais sans se limiter aux médecins), et également dans celui de la recommandation du Conseil Supérieur de la Santé et de l'Information Nucléaire (CSSIN) du 17.01.1992 et de la Directive EURATOM 90/641 sus-mentionnée, **collaborer avec les Pouvoirs Publics à la réalisation d'un système unique de contrôle des doses. Les moyens électroniques en cours de développement peuvent apporter une solution**, en permettant à la fois :

— la dosimétrie réglementaire, avec un cumul des doses, en vue d'éventuelles études épidémiologiques, plus représentatif que celui que l'on peut obtenir avec des films.

— la dosimétrie journalière ou par opération associée à des fonctions d'alerte.

EDF considère que la mise en place d'un tel système constituerait un net progrès en facilitant la collecte et la centralisation des mesures, et en mettant fin aux ambiguïtés actuelles. Pour plus de sécurité dans la collecte des mesures et pallier ainsi un incident sur le dosimètre électronique, il serait toujours possible d'associer un moyen dosimétrique complémentaire de secours à lecture différée, par exemple un dosimètre thermo-luminescent.

La réalisation d'un tel système reste subordonnée à la définition des conditions d'accès aux données dosimétriques, pour lesquelles une certaine confidentialité -sans aller jusqu'au secret médical pour la dosimétrie externe- est nécessaire pour la protection de l'emploi des travailleurs.

■ En ce qui concerne la **dosimétrie des neutrons** il n'existe pas encore de dosimètres individuels satisfaisants car les plages de mesures ne sont pas suffisantes et la lecture est différée.

EDF s'engage à poursuivre la recherche de moyens appropriés et à favoriser le développement industriel des dosimètres « neutrons » indivi-

duels à lecture directe. Toutefois, dans la gamme des dosimètres électroniques de ce type, on ne peut espérer pouvoir disposer de matériels fiables et faciles d'emploi avant un délai de 5 ans au minimum.

■ **Un effort particulier sera fait pour améliorer la connaissance des doses « extrémités »**, par une analyse

détaillée des opérations présentant ce type de risque ; **le port des dosimètres spéciaux adaptés à ces travaux sera systématisé.**

■ La dosimétrie des travailleurs extérieurs fait l'objet d'un chapitre spécial compte tenu de son importance.

C II — SURVEILLANCE MÉDICALE DES TRAVAILLEURS DE L'ENTREPRISE

La surveillance médicale des travailleurs appartenant à EDF relève d'une action bien organisée ; en effet chaque centrale dispose d'un service médical du travail dont les médecins connaissent l'installation et ses spécificités. Ils sont en relation avec l'ensemble des partenaires de l'Entreprise (CHSCT, hiérarchie, SGMT, etc.).

Les principales difficultés sont liées à la présence de travailleurs d'entreprises extérieures, essentiellement pendant les arrêts de tranche pour révision ; elles sont examinées au chapitre C III suivant.

Le législateur a voulu l'indépendance technique des médecins du travail par rapport aux employeurs, et le fonctionnement des services médicaux du travail est régi par un ensemble de règlements très complet. Les examens à pratiquer - y compris ceux de la surveillance spéciale des travailleurs exposés aux rayonnements ionisants - ont été précisés récemment dans l'arrêté du 28.08.1991. A noter que chaque travailleur « directement affecté à des travaux sous rayonnements » (« catégorie A ») à EDF est soumis chaque année à 2 examens médicaux, et à un contrôle pluriannuel de la contamination interne.

I — RÔLE PARTICULIER DES MÉDECINS DU TRAVAIL

Le Code du Travail permet au médecin de disposer d'un tiers de son temps pour des actions sur le milieu du travail en complément de son activité clinique. C'est dans le développement de certains aspects de ce « tiers temps » que certaines améliorations sont possibles, notamment pour :

- l'étude des postes de travail,
- l'épidémiologie.

1 — Analyse des conditions de travail

Les médecins devraient disposer de fiches relatives aux postes de travail. Ces fiches doivent être établies et tenues

régulièrement à jour par le « Service compétent » au titre de la réglementation sur le suivi médical spécial.

Les médecins peuvent éprouver des difficultés à suivre certains chantiers par manque d'information en temps réel. Le rapprochement de la hiérarchie des centrales facilite la tâche des médecins dans l'analyse des situations de travail dont l'approche est pluridisciplinaire et leur permet ainsi de participer aux réflexions sur les améliorations à apporter. De façon générale, **il est souhaitable que la Direction de la centrale associe le plus directement possible le médecin du travail à la vie de l'unité** ; celui-ci, tout en restant parfaitement indépendant, est alors mieux informé et donc mieux à même de conseiller l'équipe de direction, le CHSCT, les salariés eux-mêmes.

2 — Épidémiologie

Les médecins du travail sont chargés du suivi permanent des doses cumulées reçues par le personnel exposé ou ayant été exposé à un moment de sa carrière.

Ils sont à même d'être directement associés aux études épidémiologiques globales relatives au personnel travaillant dans les installations nucléaires, car ces études nécessitent un suivi médical de longue durée des travailleurs (même après cessation du travail en milieu nucléaire conformément aux Normes de Base EURATOM). Ils peuvent en outre prendre l'initiative d'enquêtes locales.

II — CLASSEMENT DES TRAVAILLEURS

Le classement des agents en catégorie A ou B, prévu dans la réglementation française, dépend de leur niveau potentiel d'exposition pendant leur travail habituel. Doivent être actuellement classés en catégorie A tous les travailleurs susceptibles de recevoir plus de 15 mSv/an ; cette valeur est ramenée à 6 mSv dans le projet de révision des Normes de Base en radioprotection établi par EURATOM.

EDF a décidé de classer en catégorie A tous les agents intervenant habituellement en zone contrôlée, de façon

TABLEAU 6 DES MALADIES PROFESSIONNELLES (Extrait)

Affections provoquées par les rayonnements ionisants			
Date de création : 4 janvier 1931		Dernière mise à jour : 26 juin 1984	
Désignation des maladies	Délai de prise en charge	Désignation des maladies	Délai de prise en charge
Anémie, leucopénie, thrombopénie ou syndrome hémorragique consécutifs à une irradiation aiguë	30 jours	Radiodermites chroniques	10 ans
Anémie, leucopénie, thrombopénie ou syndrome hémorragique consécutifs à une irradiation chronique	1 an	Radio-épithélite aiguë des muqueuses	60 jours
Biéphanthérite ou conjonctivite	7 jours	Radiolésions chroniques des muqueuses	5 ans
Kératite	1 an	Radionécrose osseuse	30 ans
Cataracte	10 ans	Leucémies	30 ans
Radiodermites aiguës	60 jours	Cancer broncho-pulmonaire primitif par inhalation	30 ans
		Sarcome osseux	50 ans

à leur assurer le même suivi médical. Le classement en catégorie B est donc rare.

En ce qui concerne les intervenants non affectés à une INB et actuellement « non classés », mais appelés à pénétrer régulièrement en zone contrôlée sur différents sites, il a été décidé de les affecter aux catégories A ou B, suivant la fréquence de leurs inter-

ventions, pour leur assurer la surveillance médicale adéquate.

III — HARMONISATION EUROPÉENNE

Il n'y a actuellement pas d'harmonisation européenne; plusieurs thèmes sont concernés :

• formation des médecins, reconnaissance des diplômes : la formation des médecins du travail varie très largement d'un pays à un autre.

Toutefois, dans le domaine de la radioprotection propre aux centrales nucléaires, des connaissances particulières sont nécessaires et une formation spécifique complémentaire ainsi qu'une réactualisation régulière sont souhaitées.

**CARTE PROFESSIONNELLE
-SUIVI MÉDICAL-**
(décrets du 2 octobre 1986 et du 6 mai 1988)

CATÉGORIE A
**(PERSONNE DIRECTEMENT AFFECTÉE
A DES TRAVAUX SOUS RAYONNEMENTS IONISANTS
DANS L'INDUSTRIE)**

NUMÉRO D'ORDRE NATIONAL : **60469**

Date d'expiration de la présente carte : _____

Les données figurant sur cette carte sont destinées à votre Médecin du Travail et au SCPRI; seules celles du volet adressé au SCPRI feront l'objet d'un traitement informatisé.
(Dispositions conformes à la loi du 6 janvier 1978 relative à l'informatique et aux libertés).

- SCPRI - BP n° 35 - 76110 Le Vésinet Volet 1

Volet à remplir et à détacher par le médecin du travail et à adresser au SCPRI (voir au verso)

NOM : _____

NOM DE JEUNE FILLE : _____

PRÉNOMS : _____
(en totalité)

N° de S.S. : _____
(10 premiers chiffres)

EMPLOI : _____

SURVEILLANCE : DI RT RESTRICTION(S) Oui Non

SIGNATURE DU TITULAIRE : _____
attestant qu'il ne dispose d'aucune autre carte de suivi médical

CARTE DÉLIVRÉE LE : _____ EXPIRATION LE : _____

NUMÉRO D'ORDRE NATIONAL : **60469**

PAR le Dr : _____

MÉDECIN DU TRAVAIL DE : _____
(nom de l'entreprise, adresse, téléphone)

Signature du Médecin du Travail : _____ Cachet : _____

Volet 5

NOM : _____

NOM DE JEUNE FILLE : _____

PRÉNOMS : _____
(en totalité)

N° de S.S. : _____
(10 premiers chiffres)

EMPLOI : _____

CARTE DÉLIVRÉE LE : _____

SURVEILLANCE : DI RT RESTRICTION(S) Oui Non

PAR le Dr : _____

MÉDECIN DU TRAVAIL DE : _____
(nom de l'entreprise, adresse, téléphone)

Photo d'identité

Cachet : _____

Signature du Médecin du Travail _____

VALIDATIONS SEMESTRIELLES OBLIGATOIRES
(à partir du 2^{ème} semestre)

DATES LIMITES	SURVEILLANCE (1)	RESTRICTIONS (2)	SIGNATURE DU MÉDECIN DU TRAVAIL ET CACHET
Validée du _____ au _____	DI		
Validée du _____ au _____	RT		
Validée du _____ au _____	DI		
Validée du _____ au _____	RT		
Validée du _____ au _____	DI		
Validée du _____ au _____	RT		
Validée du _____ au _____	DI		
Validée du _____ au _____	RT		
Validée du _____ au _____	DI		
Validée du _____ au _____	RT		

Volet 2

(1) Rayer la mention éventuellement inutile.
(2) Répondre par oui ou non.

DI = dosimétrie individuelle.
RT = radiotoxicologie. Volet 3

Se pose en outre le problème de la reconnaissance des diplômes et de leur équivalence au plan européen.

• **surveillance médicale et contrôle d'exposition**, notamment en ce qui concerne les moyens de dosimétrie individuelle légale.

• **maladies professionnelles** : la réglementation française en matière de reconnaissance des maladies professionnelles est basée sur la présomption d'origine. Par suite, le simple fait d'avoir été exposé aux rayonnements ionisants

donne automatiquement droit -quelle que soit la dose, aussi faible soit-elle- à indemnisation si la maladie développée est classée au « tableau 6 » (voir encart page 13), alors que d'autres maladies qui pourraient être radioinduites ne sont pas reconnues. Cette situation, qui va certes dans le sens de la protection sociale maximum des travailleurs, posera à terme des problèmes difficiles à résoudre : le vieillissement des travailleurs « exposés » s'accompagnera inévitablement de l'apparition des mêmes cancers qui frappent environ 1/4

de la population. Il faudra sans aucun doute faire évoluer la réglementation. *L'approche statistique des risques*, sur les bases des documents UNSCEAR 88, bien que critiquable sur certains aspects, *est plus logique. Des propositions seront faites en ce sens, dans un souci d'harmonisation au niveau européen.*

Diverses actions sont donc à entreprendre auprès de la CCE pour tendre vers l'harmonisation rendue nécessaire par l'ouverture des frontières en 1993.

C III — TRAVAILLEURS D'ENTREPRISES EXTERIEURES

Si la surveillance médicale et le suivi dosimétrique du personnel d'EDF ne semblent pas poser de problème important, il n'en est pas de même pour les agents d'entreprises prestataires de services dits « travailleurs extérieurs ». Encore faut-il distinguer dans cette catégorie les employés de grosses entreprises bien organisées des travailleurs de petites entreprises et surtout de ceux fournis par des sociétés de travail temporaire.

1 — PROBLEMES RENCONTRÉS AVEC LES TRAVAILLEURS EXTERIEURS

Le nombre de « travailleurs extérieurs » amenés à travailler en zone contrôlée est annuellement de l'ordre de 20 000 suivant les estimations actuelles. Ils reçoivent environ 80 % des doses reçues par l'ensemble du personnel intervenant dans les centrales nucléaires, et c'est dans cette population que l'on observe le plus grand nombre de sujets recevant actuellement des doses annuelles supérieures à 20 mSv.

Le suivi des travailleurs extérieurs n'est pas actuellement satisfaisant, tant au plan médical qu'au plan des doses reçues.

1 — **suivi médical** : ces travailleurs étant très mobiles et changeant de surcroît fréquemment d'entreprise, ils ne sont généralement pas suivis par un médecin unique ; le médecin a des difficultés à obtenir le dossier médical de l'intéressé, et même le cas échéant à savoir s'il en a déjà un ; cette question devrait être résolue à terme par la carte individuelle de suivi médical instaurée par l'arrêté du 31 juillet 1991.

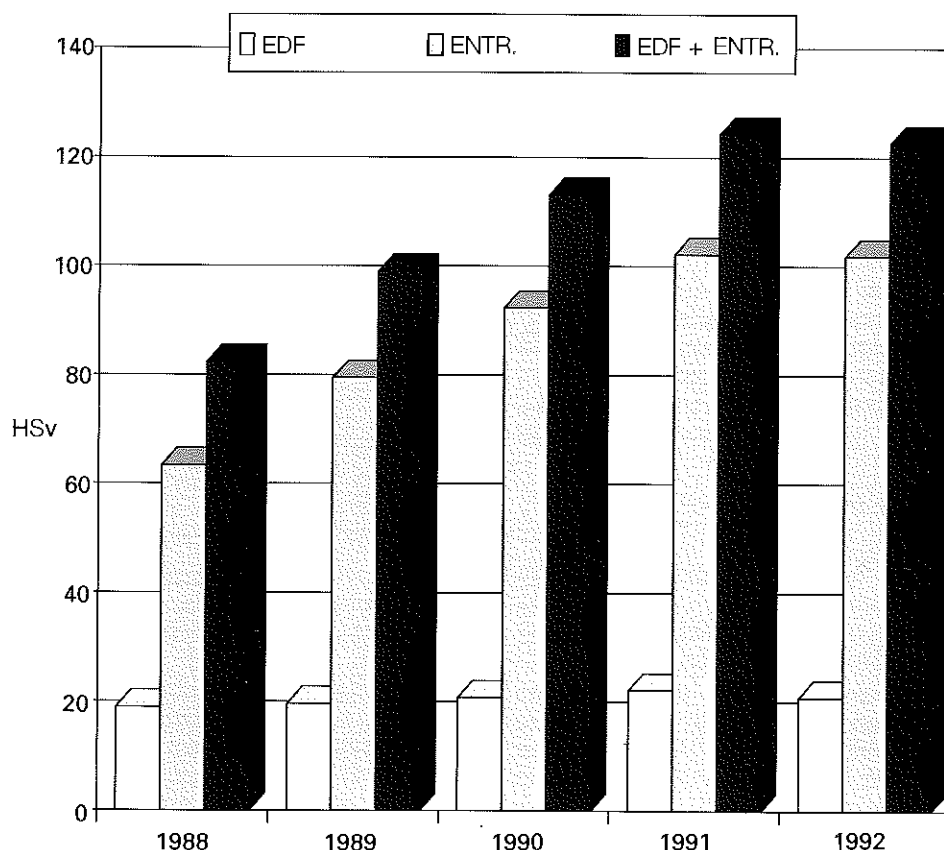
2 — **suivi dosimétrique** : les travailleurs arrivant sur les sites EDF sont en général munis d'un carnet individuel de travailleur « catégorie A », sur lequel

devraient figurer les doses reçues antérieurement. Mais ces carnets sont souvent mal remplis, incomplets. Ceci indépendamment de fraudes qui pourraient être le fait aussi bien de l'employeur que du travailleur et qu'il est difficile de déceler. Quant à la dosimétrie réglementaire « film », elle n'est pas connue des exploitants par suite du secret médical. D'ailleurs, même pour les médecins qui devraient en principe avoir accès aux résultats dosimétriques, la connaissance des doses des travailleurs migrants est très difficile, essentiellement en raison

d'une mauvaise organisation de la collecte et de la gestion des données à l'échelon national.

3 — le problème posé par les travailleurs extérieurs ne se limite pas à ces questions de suivi ; le problème de fond est en effet leur emploi dans des travaux où les doses reçues sont les plus importantes, qu'il s'agisse d'emplois très spécialisés et rares - par exemple les soudeurs sur circuit primaire - ou d'emplois liés à l'assainissement - nettoyeurs, décontamineurs.

RÉPARTITION DES DOSES TOTALES ANNUELLES





VOLET 1B

NOM : _____
 PRENOM : _____
CARNET D'ACCES N° _____

FORMATION

FORMATION QUALITE SURETE
 QSP - N° D'ATTESTATION : _____

FORMATION PREVENTION DES RISQUES

OBJET	DATE	VISA ENTREPRISE

VOLET 2A

NOM : _____
 PRENOM : _____
CARNET D'ACCES N° _____

EMPLOYEUR* : _____

ADRESSE : _____

TEL : _____
 CODE SIRET : _____

ENTREPRISE UTILISATRICE : _____

ADRESSE : _____

TEL : _____
 CODE SIRET : _____

(* Etablissement ou agence gestionnaire des I)

CACHET

VOLET 3C

NOM : _____
 PRENOM : _____
CARNET D'ACCES N° _____

RESTITUTION DOSIMETRE OPERATIONNELLE (msv)

	DOSINAT	GLOBAL
→ 60 derniers mois		
→ 12 derniers mois		
→ 3 derniers mois		
→ dernier mois		

Mise à jour le : _____

VOLET 3A

NOM : _____
 PRENOM : _____
CARNET D'ACCES N° _____

RELEVÉ MANUEL DE DOSIMETRE OPERATIONNELLE

MOS : _____ ANNEE : _____

JOUR	SITE	RELEVÉS SUCCESSIFS	TOTAL (mSv)
1			
2			
3			
4			

EDF-GDF, S.O.A.M.T. *

CARNET D'EXAMENS ANTHROPOGAMMAMÉTRIQUES

NOM-PRENOM : _____ N° INSEE : _____

DATE NAISSANCE : _____

Date	Type de l'examen	Résultat	Observations	Carnet du Service de Médecine du Travail EDF-GDF
	<input type="checkbox"/> S <input type="checkbox"/> P <input type="checkbox"/> D	<input type="checkbox"/> <S <input type="checkbox"/> >S		
	<input type="checkbox"/> S <input type="checkbox"/> P <input type="checkbox"/> D	<input type="checkbox"/> <S <input type="checkbox"/> >S		
	<input type="checkbox"/> S <input type="checkbox"/> P <input type="checkbox"/> D	<input type="checkbox"/> <S <input type="checkbox"/> >S		
	<input type="checkbox"/> S <input type="checkbox"/> P <input type="checkbox"/> D	<input type="checkbox"/> <S <input type="checkbox"/> >S		
	<input type="checkbox"/> S <input type="checkbox"/> P <input type="checkbox"/> D	<input type="checkbox"/> <S <input type="checkbox"/> >S		

S: Entée P: Permanent D: Dérivée

S: 1/120 OMA seul 99% par le SCPI ou l'histogramme d'interprétation du spectre

POUR LA MAJORITÉ DES CAS, LES ACTIVITÉS INFÉRIEURES À "S" SONT NÉGLIGEABLES SUR LE PLAN BIOLOGIQUE POUR UNE INCORPORATION DATANT DE MOINS DE QUELQUES SEMAINES.

Cette structure d'emploi demande des mesures particulières si l'on veut pouvoir assurer la réalisation de ces travaux nécessaires tout en garantissant les conditions de travail de ce type de travailleurs ; on risque en effet d'assister à une « gestion de l'emploi par la dose », ce qui pose des problèmes d'éthique.

II — ATTITUDE D'EDF DEVANT CETTE SITUATION

La politique clairement affichée par EDF est d'assurer aux travailleurs extérieurs le même niveau de protection qu'à ses propres agents.

Cette préoccupation est également celle de la CCE dans la Directive du 04.12.1990 sur la « protection opérationnelle des travailleurs extérieurs exposés aux rayonnements ionisants... » (90/641 EURATOM) mentionnée précédemment.

L'application de cette politique comporte plusieurs volets :

- suivi dosimétrique
- suivi médical
- amélioration des postes de travail
- relations contractuelles avec les entreprises

1 — Amélioration du suivi dosimétrique des travailleurs :

Cette amélioration commence par leur **identification**. La carte de « suivi médical » (Cf. encart p. 14) qui résulte d'un arrêté du 31.07.1991 sur la surveillance médicale des travailleurs devrait apporter une première réponse par suite de son enregistrement dans un fichier centralisé. **EDF veillera à ce que tout intervenant en zone nucléaire soit bien en possession de cette carte** garantissant l'existence de son dossier médical. **Pour donner au système toute son efficacité, ce fichier d'identification géré par le SCPRI devrait être accessible aux exploitants et aux employeurs.**

Pour mieux connaître les doses cumulées sur une période donnée (actuellement 12 mois), EDF a mis en place un système informatique national baptisé DOSINAT. Il collecte les mesures des dosimètres électroniques individuels à chaque intervention en zone contrôlée de n'importe quelle centrale. Il est ainsi possible de suivre en temps réel la situation dosimétrique des intervenants pour autant que le travail ait lieu sur des sites EDF ; les enregistrements peuvent donc comporter des interruptions pour les périodes où les travailleurs sont employés ailleurs ; aussi EDF a-t-elle

engagé des discussions avec d'autres partenaires importants du cycle nucléaire (CEA, COGEMA,...) en vue d'élargir progressivement la collecte des données dosimétriques à l'ensemble des exploitants. Des discussions ont également été engagées avec le Groupe Intersyndical de l'Industrie Nucléaire (GIIN) avec pour objectif d'associer les employeurs. Le système étendu, appelé DOSIMO, deviendrait donc commun à l'ensemble du secteur nucléaire, et sa gestion pourrait être confiée au GIIN. Mais la réalisation de ce projet ne sera de toute façon entreprise qu'avec l'accord de l'Administration -notamment le ministère du Travail et la Commission Nationale Informatique et Libertés (CNIL). Il serait alors vraisemblablement créé un Comité d'éthique pour contrôler les conditions d'accès aux données dosimétriques, avec des règles et un niveau de confidentialité propres à garantir la protection sociale des travailleurs.

DOSIMO pourrait voir le jour vers 1995, avec les réserves ci-dessus, et combler progressivement les lacunes de DOSINAT.

Rappelons que les données recueillies dans DOSINAT sont celles de la dosimétrie opérationnelle*, distincte de la dosimétrie réglementaire. EDF a obtenu l'autorisation de la CNIL de cumuler les doses sur une période de 5 ans - dans l'optique de l'évolution de la réglementation européenne puis nationale.

Le traitement des données recueillies dans DOSINAT va permettre d'optimiser l'organisation du travail, et d'attirer l'attention des responsables de radioprotection et des médecins du travail sur le cas des agents atteignant un certain niveau de dose. **Ce « niveau d'investigation » est fixé en fonction de la réglementation en vigueur. Il pourra être fixé à 15 mSv (sur 12 mois glissants) en 1995 ou 1996** avec l'émergence des nouvelles normes.

La certification « CEFRI » des entreprises (voir ci-après le paragraphe formation) contribuera également à l'amélioration du suivi dosimétrique des travailleurs, y compris dans un avenir proche ceux des entreprises de travail temporaire.

Pour exploiter utilement la complémentarité des dosimétries réglementaire et opérationnelle, dont les résultats cumulés risquent de présenter des écarts significatifs avec l'allongement ultérieur à 5 ans du temps de cumul, **la collaboration avec les Pouvoirs Publics est nécessaire**, comme mentionné au chapitre CI. La solution que souhaite EDF reste, à terme, celle du fichier national

unique commun aux autorités, aux médecins du travail, aux exploitants et aux employeurs. Ceci en attendant le stade communautaire qu'on ne peut guère espérer avant le début du siècle prochain. Il ne faut néanmoins pas se cacher les difficultés techniques et politiques d'une telle réalisation.

2 — Amélioration du suivi médical

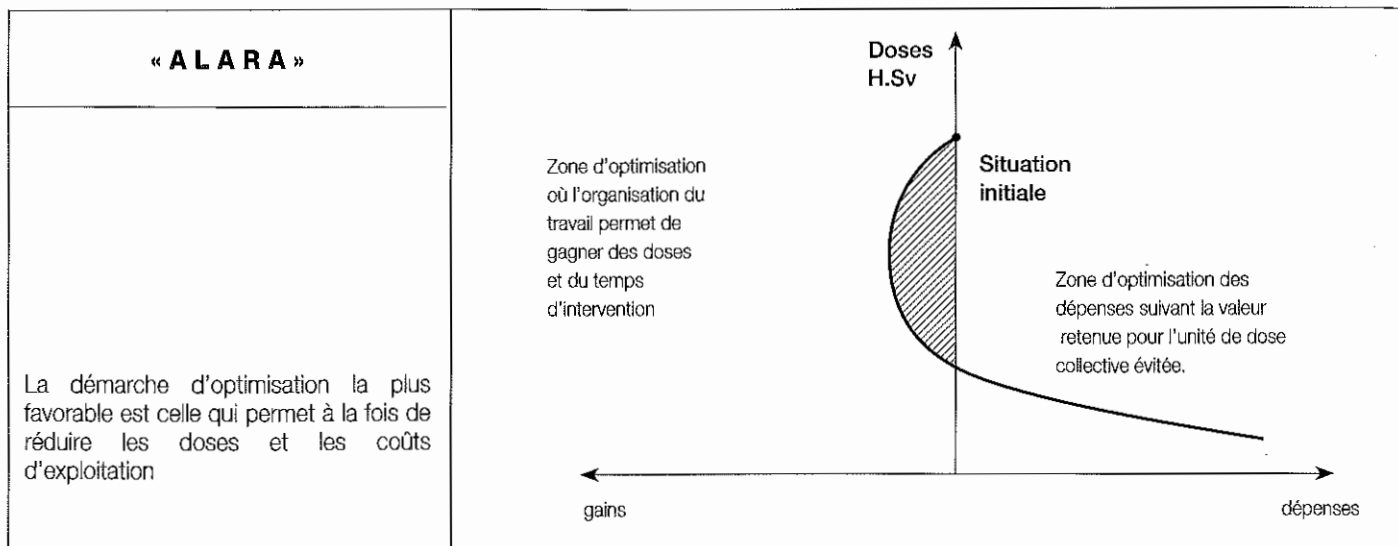
La prise en compte du décret 91-730 du 23.07.1991 sur la « médecine du travail des salariés temporaires », et du décret 92-158 du 20.02.1992 « relatif aux prescriptions particulières d'hygiène et de sécurité applicables aux travaux effectués dans un établissement par une entreprise extérieure » conduisent à **revoir l'organisation des services médicaux, et leurs relations avec les médecins des entreprises extérieures**. Ces textes renforcent en effet le rôle du médecin du travail de l'exploitant dans le suivi médical des salariés d'entreprises extérieures. **Cette réorganisation sera faite en particulier avec un développement des moyens informatiques, en examinant les moyens de faciliter les échanges d'informations avec les services médicaux des entreprises extérieures.**

La médecine du travail d'EDF souhaite collaborer avec le ministère du Travail pour mettre les textes en application ; elle propose la création de services médicaux interentreprises régionaux, spécifiques aux INB, agréés par les Directions régionales du travail et situés à proximité immédiate des sites. Ces services pourraient être jumelés avec les services de médecine du travail EDF de ces sites pour faciliter les liaisons prévues dans les textes.

Les pratiques des médecins du travail doivent en outre être harmonisées. **EDF soutient la proposition, faite par ses Services médicaux, de création d'une association nationale des médecins du travail concernés par le suivi des salariés d'entreprises intervenant dans les centrales nucléaires.**

3 — Amélioration des postes de travail

EDF prendra les dispositions nécessaires, dans le cadre des actions entreprises pour réduire les doses (voir chap. C IV) **pour s'attacher à la réduction prioritaire des niveaux d'exposition des groupes de salariés les plus exposés, en visant dès à présent les limites qui découleront des Normes de Base EURATOM en cours de révision.**



VALEUR DE L'UNITÉ DE DOSE COLLECTIVE ÉVITÉE

L'optimisation des dépenses de radioprotection implique la nécessité de disposer de coûts de référence.

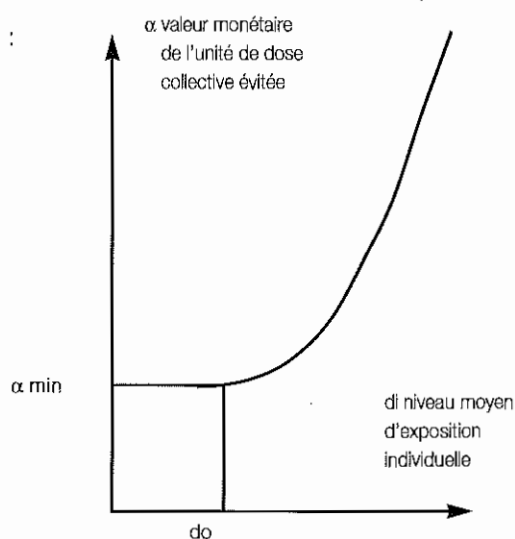
La démarche retenue par EDF fait appel à « l'aversion au risque » : on accepte de payer davantage pour éviter une unité de dose lorsque les doses individuelles augmentent

La formule retenue pour exprimer la dépense acceptée par unité de dose collective évitée est de la forme

$$\alpha = \alpha_{\min} \left(\frac{di}{do} \right)^a \quad (\text{Cf. graphique})$$

où $do = 1$ mSv/an (limite « public »)

et $\alpha_{\min} = 100$ kF/Sv par cohérence avec les estimations économiques



EDF a choisi d'appliquer en 1993 cette méthode avec la valeur $a = 1,35$, en faisant systématiquement « l'étude de sensibilité » avec les coefficients 1,2 et 1,5. Il est important de souligner qu'il s'agit d'une **méthode d'aide à la décision** et non d'un critère mathématique. D'autres facteurs sont à prendre en compte pour la décision finale du choix d'un investissement.

Pour l'application pratique, les courbes continues ont été remplacées par des plages discontinues de valeurs indiquées dans le tableau ci-après (MF/Sv) :

Plages de doses annuelles	G1 0-1 mSv	G2 1-5 mSv	G3 5-15 mSv	G4 15-30 mSv	G5 30-50 mSv
$a = 1,20$	0,1	0,4	1,6	4,2	8,4
$a = 1,35$	0,1	0,5	2,3	6,7	15
$a = 1,50$	0,1	0,6	3,3	10,8	25,5

4 — Développement des relations contractuelles avec les entreprises

Pour assurer les garanties nécessaires des travailleurs, **les relations contractuelles avec les entreprises prestataires vont être modifiées**, avec des clauses supplémentaires liées à la radioprotection. Actuellement déjà, toute entreprise fournissant du personnel exerçant une activité relevant de l'**assurance de la qualité**, notamment en zone contrôlée, doit avoir été acceptée par EDF au terme d'un audit. **Le maintien de cet agrément sera subordonné au respect des engagements en matière de Droit du Travail**. Tout licenciement lié à un dépassement de dose entraînera le retrait de l'agrément.

5 — Formation des intervenants (Cf. chap. F)

La protection des travailleurs extérieurs passe aussi par une bonne formation en radioprotection. Cette formation est exigée de toute personne appelée à travailler en milieu nucléaire.

Dans le cadre de l'amélioration de l'assurance de la qualité et du renforcement de la sûreté dans les activités de maintenance, EDF a créé en 1992 un **carnet d'accès** qui prend en compte l'aspect « prévention des risques » pour

contribuer à la protection des intervenants. La distribution de ces carnets est assurée par le GILN suivant un système de gestion qui en garantit l'unicité. Les entreprises peuvent y accéder par Minitel (accès codé).

Le carnet sera exigé de tout travailleur affecté à des travaux sous rayonnement **dès la mi-93** (et à terme pour tout intervenant sur matériel à qualité surveillée). Il remplacera le « carnet individuel DATR » actuellement utilisé.

Le premier volet du carnet doit apporter l'attestation de la formation requise (dispensée par des Organismes agréés); le troisième volet fournira les résultats de dosimétrie (provenant du système DOSINAT pour les interventions sur les sites EDF) et les résultats des contrôles anthropogammamétriques*. La carte de suivi médical sera en outre incluse dans le carnet.

La qualité de la formation en matière de prévention des risques est essentielle. C'est pour cela qu'à été créé, en 1990, le comité français de Certification des Entreprises pour la Formation et le suivi du personnel travaillant sous Rayonnements Ionisants (CEFRI) en plein accord avec les exploitants (EDF, groupe CEA,...), le SCPRI, la Caisse

Nationale d'Assurance Maladie, et avec le soutien des ministères du Travail et de l'Industrie. Le CEFRI délivre des agréments, après audit :

— aux organismes de formation spécialisés ; l'agrément est alors spécifique de la formation,

— aux entreprises intervenantes ; il porte alors sur la qualité de la formation (qu'elle soit dispensée par un organisme extérieur à l'entreprise ou par l'entreprise elle-même), et sur l'organisation mise en place pour assurer le suivi dosimétrique et la surveillance médicale de leur personnel.

A terme, seules les entreprises agréées CEFRI seront acceptées sur les sites nucléaires.

6 — Formation des médecins

En ce qui concerne la formation des médecins du travail des entreprises, **EDF souhaite qu'ils aient la même formation que celle demandée maintenant à ses propres médecins du travail** (Université René Descartes — Cf. chap F). EDF soutiendra dans ce sens l'action proposée par ses services de médecine du travail (Cf. C II.2).

C IV — RÉDUCTION DES DOSES

Le parc des centrales EDF a été construit en prenant des dispositions pour limiter les sources de rayonnement dès la conception, et les résultats observés pendant une dizaine d'années (dose collective par tranche inférieure à 2 H.Sv) étaient considérés comme très bons. Mais ces résultats ont commencé à se dégrader en 1988 (on note 2,44 H.Sv en 1991). Parallèlement on constate des progrès notables chez d'autres producteurs d'électricité, notamment sur les tranches les plus récentes de la série KONVOI mises en service en Allemagne dont les résultats sont meilleurs que ceux de nos dernières unités. En outre, les normes de radioprotection sont en cours de révision et les limites de doses individuelles seront prochainement abaissées. Il est donc nécessaire de mettre en œuvre une **politique de réduction des doses** : réduction des doses collectives (qui sont un bon indicateur de la qualité de la radioprotection) et réduction de la dispersion des doses individuelles (« principe d'équité » de la CIPR 60).

On est ainsi conduit à s'interroger sur les méthodes propres à réduire les

doses aux différentes étapes de la vie des installations, de leur conception à leur démantèlement.

On est amené également à se fixer des objectifs de doses, et des critères de décision (valeurs de l'unité de dose collective évitée) : il ne s'agit pas en effet de réduire les doses à n'importe quel prix, mais de procéder à une analyse coût/bénéfice des solutions envisageables.

A cet effet, EDF a adopté l'approche d'optimisation de la radioprotection connue sous l'appellation anglo-saxonne « ALARA » (as low as reasonably achievable/aussi bas que raisonnablement possible — en tenant compte des facteurs économiques et sociaux). « ALARA » est une méthode de gestion comportant le cycle classique : définition d'objectifs, contrôle des résultats et analyse des écarts, correction des actions puis des objectifs. Bien souvent les seules améliorations d'organisation qui en résultent doivent permettre de réduire les doses, de supprimer des opérations inutiles, et aussi de réduire les temps d'intervention. Dans d'autres cas, la réduction des doses ne peut être

obtenue qu'au moyen d'investissements qu'il convient de gérer au mieux, c'est-à-dire en affectant les ressources là où elles sont le plus efficaces ; c'est là qu'interviennent les critères de décision mentionnés plus haut : les critères retenus, qui seront éventuellement ajustés à la fin de 1993, font l'objet de l'encart ci-contre.

Certaines activités sont plus exposées que d'autres ; les travailleurs qui y sont affectés reçoivent des doses individuelles moyennes plus élevées que d'autres. C'est sur ces activités que doit porter l'effort principal.

Dans le cadre général ainsi tracé EDF a décidé la mise en œuvre des politiques suivantes :

I — CONCEPTION

EDF se fixe un objectif de dose collective annuelle de 0,75 H.Sv par tranche au maximum pour les installations nucléaires de la prochaine génération dont la conception est à l'étude (« REP 2000 »).

Pour atteindre cet objectif, un effort particulier sera fait dans les 2 axes ci-après :

a) **les opérations d'exploitation et de maintenance seront mieux prises en compte dès la conception** dans l'optique ALARA : agencement des matériels, espaces de démontage, moyens de manutention, opérations de préparation des chantiers (échafaudage, calorifugeage, nettoyage, décontamination, etc.).

b) **les recherches seront poursuivies sur la qualité des matériaux** avec le double objectif de :

— réduire les doses à la source, notamment en réduisant la production de Cobalt 58 et 60,

— améliorer la fiabilité des matériels pour limiter les opérations de maintenance.

Un exemple caractéristique de ce type de décision est celui du remplacement de l'Inconel 600 par de l'Inconel 690 pour les tubes de générateurs de vapeur.

Ces améliorations de conception seront appliquées le cas échéant aux tranches en exploitation (par exemple le remplacement des stellites pour les sièges de robinets par d'autres matériaux).

Les exploitants sont associés aux concepteurs pour parfaire la prise en compte de l'expérience. EDF dispose en outre d'outils informatiques puissants pour la prévision des doses (logiciel PANTHERE) et l'analyse des résultats dosimétriques (base de données TIGRE, logiciel DOSIANA de dosimétrie analy-

LE COMITE « ALARA PARC » ET LES COMITES « ALARA SITE »

Un objectif du Plan Stratégique d'EDF Production Transport est la réduction des doses reçues à une valeur aussi basse que raisonnablement possible (ALARA) pour chacun des intervenants dans les centrales (en moyenne inférieure à 1,6 h.Sv/an/tranche d'ici 1995).

Pour ce faire, et dans le but de mobiliser les acteurs (intervenants et managers) un Comité ALARA PARC a été créé le 4 décembre 1991.

Ce Comité ALARA PARC, présidé par un membre du Comité de Direction, est chargé :

- d'amener le bilan dosimétrique global du premier parc nucléaire mondial au rang des meilleurs,
- de s'assurer que la protection dosimétrique de tous les intervenants (EDF et entreprises prestataires) est satisfaisante.

Pour assurer le relais, des Comités ALARA SITE se mettent en place progressivement (BELLEVILLE, CATTENOM, CHOOZ, GOLFECH, GRAVELINES, CRUAS, TRICASTIN en 1992).

Ils sont composés d'un Président Membre du Comité de Direction et des représentants des différentes spécialités.

Pour aider dans cette démarche ALARA PARC, le DSRE a mis en place des groupes de travail « Réduction des Doses » :

- Analyse des indicateurs et du retour d'expérience,
- Critères économiques,
- Préparation du travail, maintenance,
- Réduction des sources par l'exploitant,
- Mesures et logiciels de la radioprotection,
- Chantiers pilotes,
- Liaison Projet N4 REP 2000,
- Comité de Coordination des GT Réduction des doses.

tique — Cf. encart page suivante). **L'utilisation de ces logiciels sera développée et systématisée (DOSIANA), tant pour la conception que pour l'organisation des opérations de maintenance** (Cf. ci-après).

II — EXPLOITATION — MAINTENANCE

La dose collective annuelle moyenne par tranche est passée progressivement de 1,77 H.Sv en 1988 à 2,44 H.Sv en 1991 ; une valeur légèrement plus basse (2,36 H.Sv) est toutefois observée en 1992, et ce malgré l'incidence des interventions sur les couvercles de cuves (7 %).

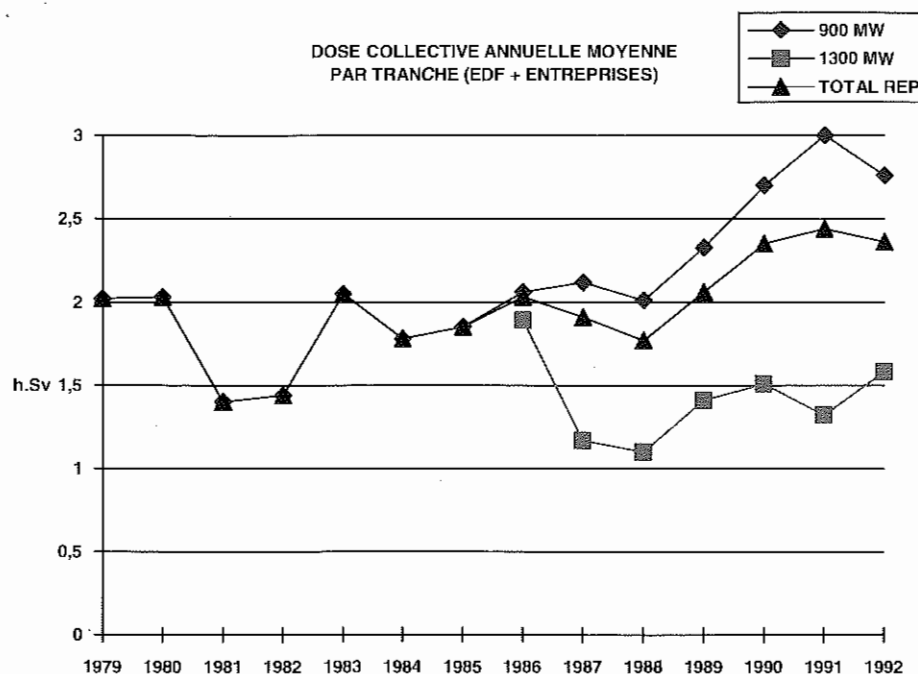
EDF se fixe pour objectif de ramener cette valeur à 1,6 H.Sv en 1995 ; le suivi des actions en vue d'atteindre cet objectif est placé sous le contrôle d'un « Comité ALARA Parc » (voir encart). A cet effet, les efforts vont porter particulièrement sur :

- l'organisation des chantiers et la formation du personnel aux méthodes d'optimisation (avec 1 comité ALARA sur chaque site),
- les techniques de réduction des doses : robotique, développement d'outillages, recherche des meilleures techniques d'exploitation.

Examinons ces 2 aspects :

1 — Organisation

La mise en œuvre des méthodes d'optimisation des doses sera généralisée à tout le parc nucléaire en



exploitation, pour toutes les opérations d'entretien programmées ou fortuites. Ces méthodes, appliquées pour la première fois sur une grande échelle lors du remplacement des générateurs de vapeur de la tranche 1 de la centrale de Dampierre-en-Burly, avaient donné d'excellents résultats grâce à une organisation bien pensée et à une motivation de toute la hiérarchie. Il convient en particulier d'éliminer toutes les opérations qui ne sont pas indispensables.

La Direction du Parc nucléaire a engagé une réflexion nationale avec la création de groupes « ALARA » traitant des différents types d'opérations concernés sous l'égide du « Comité ALARA Parc ».

■ **Un effort particulier de formation du personnel sera entrepris**, en vue d'une part de le **sensibiliser** aux objectifs visés et d'autre part de le familiariser avec les techniques correspondantes, et en particulier l'utilisation systématique du retour d'expérience (DOSIANA) pour la programmation des opérations.

■ **La démarche « ALARA »**, décidée au plan national, devant être intégrée aux opérations de maintenance, elle **sera inscrite dans les plans stratégiques des Unités** et les objectifs fixés entreront dans les contrats de gestion des chefs d'Unité. Cette disposition accélèrera **l'implication de toute la hiérarchie** dans la mise en œuvre de l'optimisation. L'organisation de la maintenance sera revue en conséquence et les actions liées à la radioprotection seront incorporées aux « plans qualité, sûreté ». Les responsables de radioprotection des

sites devront y participer activement ; leur mission à cet égard sera explicitée. Une réflexion est engagée sur ce point.

■ **Le passage des campagnes de combustible de 12 à 18 mois** sur les tranches de 1 300 MW (retour au renouvellement par 1/3 du cœur), **en réduisant la fréquence des arrêts pour maintenance, devrait également conduire à la réduction des doses.**

Les méthodes d'exploitation peuvent également être une source de gains appréciables. La limitation de l'activité des circuits (chimie du circuit primaire), le choix des procédures d'arrêt, le planning des opérations de vidange ou de remplissage des circuits jouent un rôle important. **Les modes opératoires -**

malgré le travail de réflexion déjà engagé- **ne sont actuellement pas optimisés. Ils seront revus au plan national dans cette optique.**

■ **La dosimétrie de zone sera développée** pour faciliter l'analyse dosimétrique des différentes opérations élémentaires (saisie automatique des doses individuelles sur un chantier déterminé), et ainsi permettre de mieux cibler celles sur lesquelles doivent porter les améliorations.

De façon générale, **il conviendra de s'inspirer pour la radioprotection de ce qui s'est fait dans le domaine de la sûreté, notamment dans le domaine de l'assurance de la qualité. La culture de radioprotection devra être développée.**

ARRET DEFINITIF ET DEMANTELEMENT D'UNE CENTRALE NUCLEAIRE

1-CESSATION DEFINITIVE D'EXPLOITATION

La première phase, qui commence dès l'arrêt définitif de la production (dernière chute de barres) conduit à la cessation définitive d'exploitation. Les principales opérations réalisées durant cette phase, notamment l'évacuation des combustibles neufs et irradiés (plus de 99 % de l'activité totale), des sources radioactives et des déchets, etc. sont effectuées conformément aux règles générales d'exploitation et au rapport de sûreté initial de l'installation.

Préalablement à leur mise en œuvre, ces opérations font l'objet d'un dossier de sûreté explicitant le planning, le devenir des déchets, les procédures techniques adoptées.

2-FERMETURE SOUS SURVEILLANCE

Niveau 1 de déclassement de l'AIEA

Cette deuxième phase est également appelée mise à l'arrêt définitif.

L'installation est maintenue pratiquement intacte et renferme encore des substances radioactives. Les bâtiments comportant des matériaux et matériels radioactifs et contaminés sont isolés et confinés. L'installation est placée sous surveillance et les équipements nécessaires au contrôle de radioactivité à l'intérieur et dans l'environnement sont maintenus en état de marche. Des inspections et des contrôles techniques, en particulier des tests d'étanchéité, sont effectués comme en exploitation.

L'exploitant doit préalablement - de l'ordre de 12 mois avant- présenter à la DSIN un dossier comportant en particulier : un justificatif de l'état choisi, un rapport de sûreté, les règles générales de surveillance et d'entretien - une mise à jour du Plan d'Urgence Interne (PUI).

L'autorisation d'entreprendre cette phase de démantèlement est accordée par décret ministériel.

L'état final de l'installation est alors celui d'une nouvelle installation nucléaire de base, dite d'entreposage.

3-LIBERATION PARTIELLE ET CONDITIONNELLE DE L'INSTALLATION

Niveau 2 de l'AIEA

Cette phase correspond à une réduction des zones de confinement et à un confinement plus poussé des éléments radioactifs. Les matériels contaminés qui sont aisément démontables sont évacués ou sont transférés dans des zones de l'installation qui sont scellées. Certaines parties de l'installation peuvent être converties pour répondre à de nouveaux usages ou libérées sous certaines contraintes.

Des contrôles ponctuels à l'intérieur de la centrale et dans son environnement continuent d'être assurés.

4-LIBERATION TOTALE ET INCONDITIONNELLE DE L'INSTALLATION

Niveau 3 de l'AIEA

Cette phase ultime correspond au démontage complet des installations et à l'enlèvement de tous les matériaux et équipements qui présentent encore une radioactivité significative. L'installation et le site sont libérés pour libre usage sans aucune restriction ; aucune surveillance, inspection ou vérification n'est plus désormais nécessaire.

Les niveaux 2 et 3 sont soumis à un décret d'autorisation de démantèlement après dépôt d'un dossier similaire à celui nécessaire pour entreprendre le niveau 1.

DOSIANA

Logiciel de dosimétrie analytique

DOSIANA est un logiciel de prévision des doses au cours des opérations de maintenance, faisant appel au retour d'expérience. Les enseignements des opérations passées portent sur les doses et l'efficacité des techniques employées ; leur analyse permet donc de réfléchir aux méthodes à mettre en œuvre pour réduire les doses, sur la base des doses initiales connues. Ensuite, à tout moment des travaux, on peut apporter des corrections aux prévisions. En fin d'opération, les résultats sont introduits dans la base de données ; ils permettront d'aborder une nouvelle préparation de travaux similaires avec une plus grande expérience.

2 — Techniques

Les développements techniques portent sur l'amélioration ou la mise au point d'outillages et de systèmes automatisés permettant de limiter l'exposition du personnel. **La téléopération sera développée.** L'accent est mis en priorité sur les interventions portant sur le circuit primaire et ses annexes (cuve et couvercle de cuve, générateurs de vapeur, fond de piscine, etc.) et sur la robinetterie du bâtiment réacteur, à l'origine des doses les plus élevées.

Par exemple, la mise au point d'un robot d'intervention dans les boîtes à eau de générateur de vapeur est en cours. **Progressivement, à partir de 1995, il ne devrait plus être nécessaire de pénétrer dans les boîtes à eau,** où le débit de dose est assez élevé, ce qui

permettra d'épargner des doses à une catégorie de travailleurs particulièrement exposée jusqu'à présent.

Les **améliorations des techniques de décontamination font également l'objet d'études spécifiques ainsi que l'utilisation de nouveaux matériaux et des techniques de traitement de surface.** Il faut toutefois noter que l'optimisation peut conduire à ne pas décontaminer.

III — DÉMANTÈLEMENT :

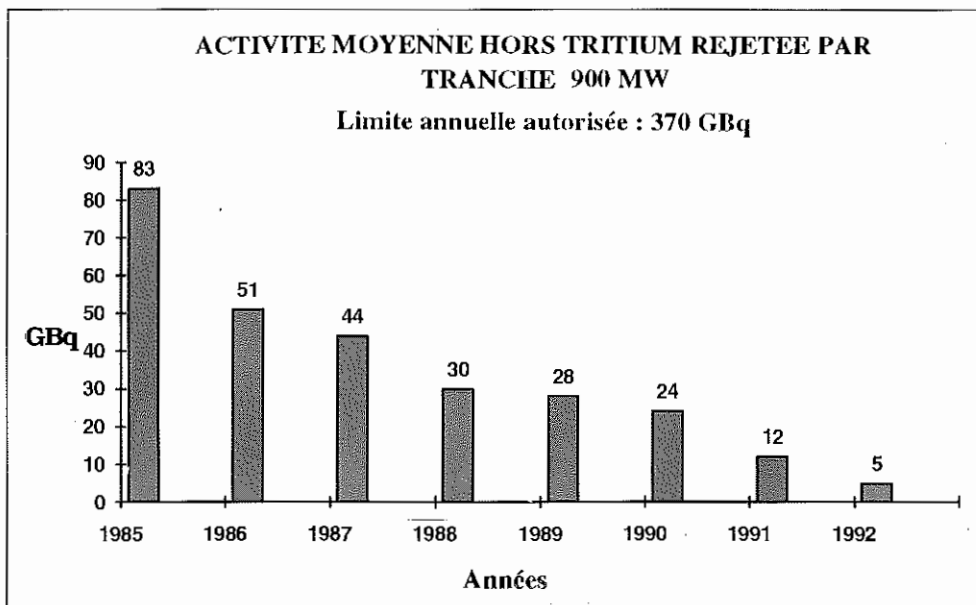
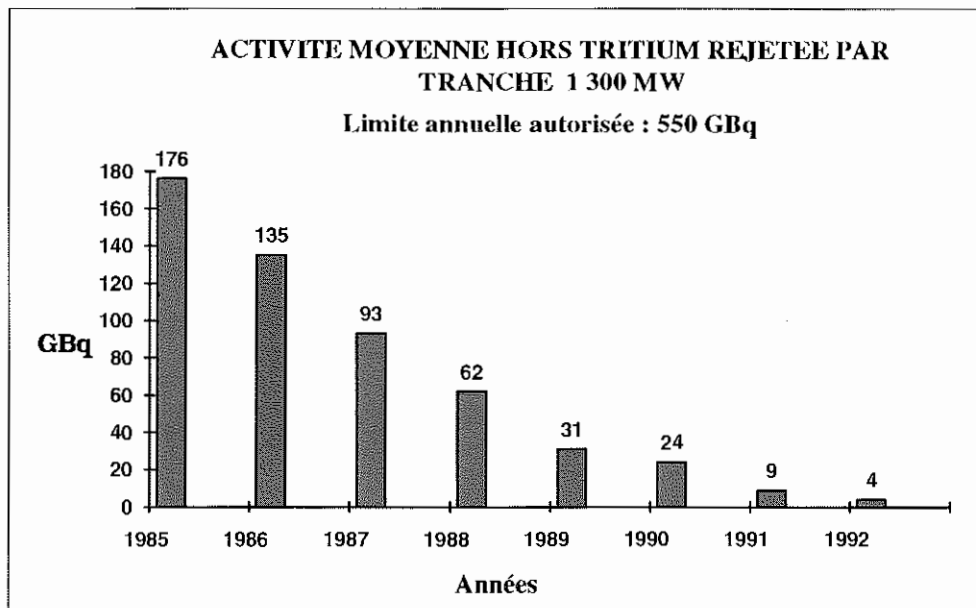
Plusieurs installations nucléaires d'EDF ont déjà été mises définitivement à l'arrêt. La dernière tranche de la filière graphite gaz (Bugey I) sera arrêtée en 1994, la première tranche française à eau pressurisée (Chooz A) a été arrêtée en 1991. Un démantèlement est une affaire de longue haleine.

EDF met en place des structures pour étudier et mettre au point les techniques de démantèlement les plus appropriées pour limiter l'exposition du personnel. Les matériels développés pour la maintenance des tranches en exploitation - objectif 1994/1995- seront utilisables pour le démantèlement.

Pour acquérir l'expérience nécessaire pour les tranches REP, EDF examine l'intérêt de procéder au démantèlement anticipé de la centrale de Chooz A.

Le réacteur de Chinon A3 sera démantelé jusqu'au niveau 2 (Cf. encart page 21). Les opérations commenceront dès 1993 (durée 4 à 5 ans).

La protection du public contre les rayonnements issus des matériaux de démantèlement est examinée au chapitre DII relatif aux déchets.



D

PROTECTION DE L'ENVIRONNEMENT ET DU PUBLIC

La protection de notre environnement est devenue un sujet de préoccupation du public. Le Congrès mondial de Rio de Janeiro en 1992 a souligné l'urgence des actions en la matière. Dans cette optique l'énergie nucléaire est et reste, malgré les craintes et les oppositions qu'elle suscite, une solution d'avenir pour la production d'énergie dont les besoins mondiaux croissent rapidement. Ceci implique bien sûr la parfaite maîtrise du cycle nucléaire ; **la radioprotection est, au même titre que la sûreté, une des**

composantes de l'acceptation des centrales nucléaires par le public.

Les dispositions draconiennes prises en matière de sûreté des réacteurs et dont l'application à tous les pays fera l'objet de contrôles de plus en plus sévères de la part de la communauté internationale (AIEA notamment), font que les risques de situation accidentelle grave pour l'environnement sont minimes pour des réacteurs bien conçus. Ce risque mis à part, le public, suivant sa sensibilité, est essentiellement préoccupé par les

3 thèmes ci-après, qui font l'objet du présent chapitre :

D I : les rejets radioactifs, en particulier les rejets liquides dans les cours d'eau ou les océans,

D II : les déchets radioactifs, qu'ils proviennent du fonctionnement des installations ou de leur démantèlement. Le devenir des déchets à vie longue provenant du retraitement du combustible est un sujet particulier d'inquiétude.

D III : la surveillance de l'environnement.

Nota : En ce qui concerne les aspects médicaux, se reporter au chapitre B.

D I — EFFLUENTS RADIOACTIFS

Les rejets d'effluents liquides et gazeux des centrales nucléaires sont régis par 7 arrêtés du 10 août 1976 qui réglementent strictement :

- les procédures d'obtention des autorisations de rejet,
- les normes et les conditions de rejet,
- le rôle et la responsabilité du chef de site nucléaire.

En outre, des arrêtés d'autorisation de rejet spécifiques à chaque installation fixent :

- les limites à ne pas dépasser (« activités »* maximales rejetées),
- les conditions particulières de rejet,
- les modalités du programme de surveillance de l'environnement (Cf. chap. D III).

I — REJETS RADIOACTIFS LIQUIDES

1 — Limites de rejet

La réglementation française fixe des limites de plusieurs natures aux rejets d'effluents radioactifs liquides :

— limite annuelle globale de rejets : actuellement fixée à 550 GBq/an hors Tritium pour une tranche de 1 300 MW ; en fait, pour les dernières tranches mises en service, la limite pratique est de 110 GBq car tout dépassement de cette valeur devrait être dûment expliqué et justifié. Cette dernière valeur est celle de la réglementation allemande,

— limite d'activité volumique dans les rejets,

— limite d'activité volumique après dilution dans le milieu récepteur.

— limites de débit minimal (étiage) et maximal (risque d'inondation au-delà) lorsque le rejet a lieu dans un cours d'eau.

A noter que ces 2 derniers critères sont uniquement appliqués en France, et qu'ils sont plus pénalisants que les limites annuelles de rejet pour les faibles niveaux de rejets obtenus.

2 — Rejets liquides des centrales

EDF depuis de nombreuses années a fait un effort considérable pour réduire les rejets liquides de ses centrales ; les

circuits de récupération des effluents ont été modifiés pour améliorer leur tri et leur traitement, et les résultats obtenus montrent les progrès réalisés : les rejets actuels hors Tritium représentent à peine plus de 1 % des limites annuelles autorisées (en moyenne, en 1992, 5 GBq pour les tranches de 900 MW, 4 GBq pour les tranches de 1 300 MW). **EDF poursuivra ses efforts** -qui portent maintenant essentiellement sur la qualité de l'exploitation- **pour réduire encore les activités rejetées en s'alignant sur les résultats des centrales françaises les plus performantes.** A cette fin, les objectifs à atteindre sont précisés dans les contrats de gestion annuels des responsables de sites nucléaires.

Mais il convient d'insister sur le fait que **la diminution des rejets au-dessous des valeurs actuelles** obtenues par les meilleures unités, au-delà de l'intérêt symbolique d'une telle performance, **ne présenterait guère d'intérêt au plan sanitaire.** En effet l'impact des rejets sur l'homme est estimé à moins de 0,01 mSv/an soit moins de 1 % des

doses dues à la radioactivité naturelle. Dans ces conditions, **EDF n'envisage pas d'engager des actions supplémentaires qui se traduiraient par des contraintes techniques et financières a priori sans objet.**

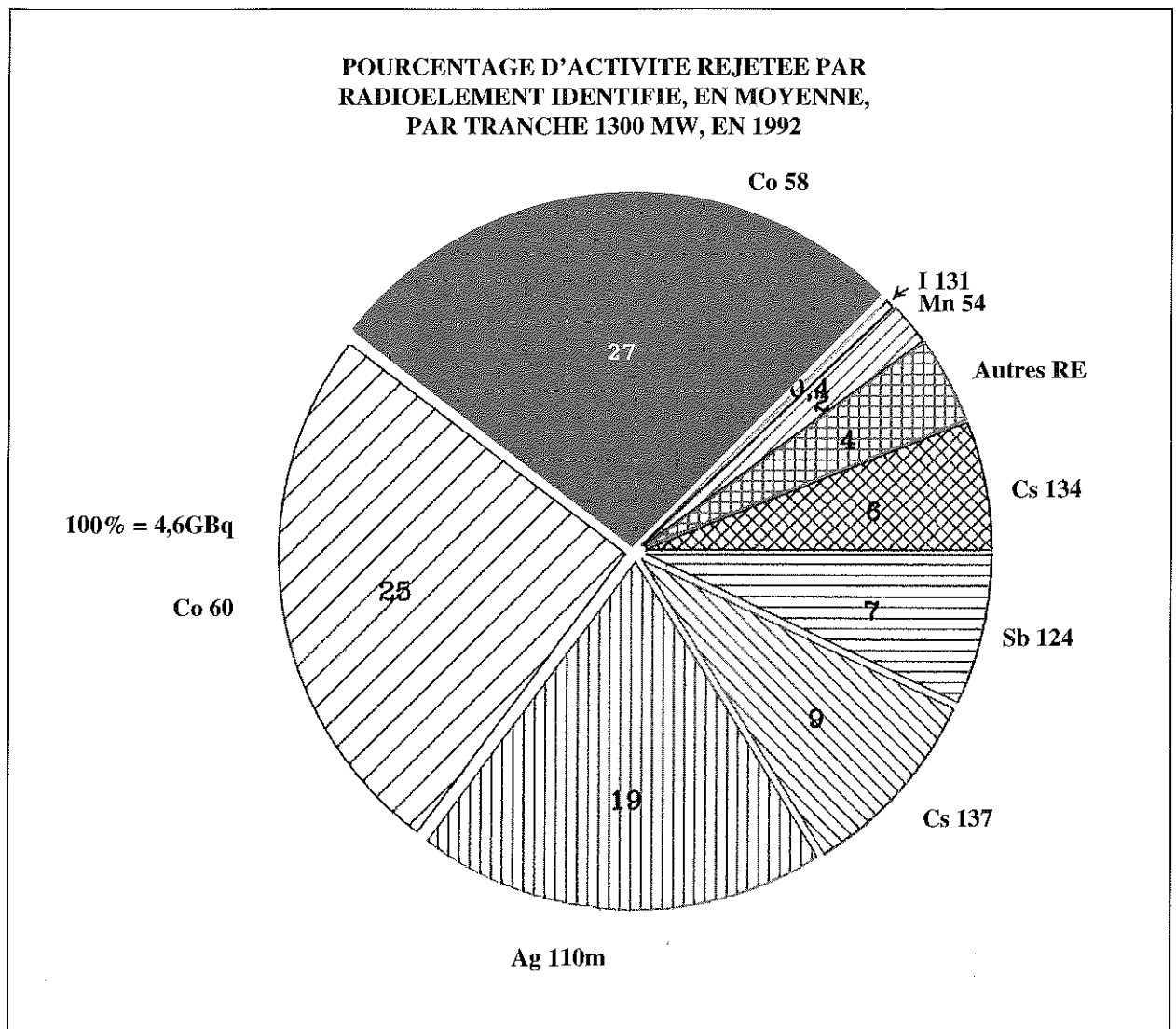
En ce qui concerne la nature des radioéléments rejetés, **EDF suscitera les études visant à compléter les connaissances sur la radiotoxicité du Tritium.** Ce radioélément est certes réputé de très faible radiotoxicité, car il est essentiellement incorporé à l'organisme sous forme d'eau tritiée facilement éliminée. Toutefois, certains mécanismes biologiques demanderaient à

être précisés. Par ailleurs, toutes les installations nucléaires dans le monde produisent inévitablement du Tritium, sans qu'il soit possible de l'éliminer de façon industrielle simple. L'attention est en outre maintenant attirée sur certains radioéléments, qui apparaissent en proportions non négligeables compte tenu de la réduction obtenue pour les autres radioéléments. C'est notamment le cas de radioéléments comme le Carbone 14 que l'on trouve surtout dans les gaz, l'Iode 129 et l'Antimoine 125 auxquels il conviendra de s'intéresser, tout en gardant à l'esprit que les quantités rejetées restent très modestes.

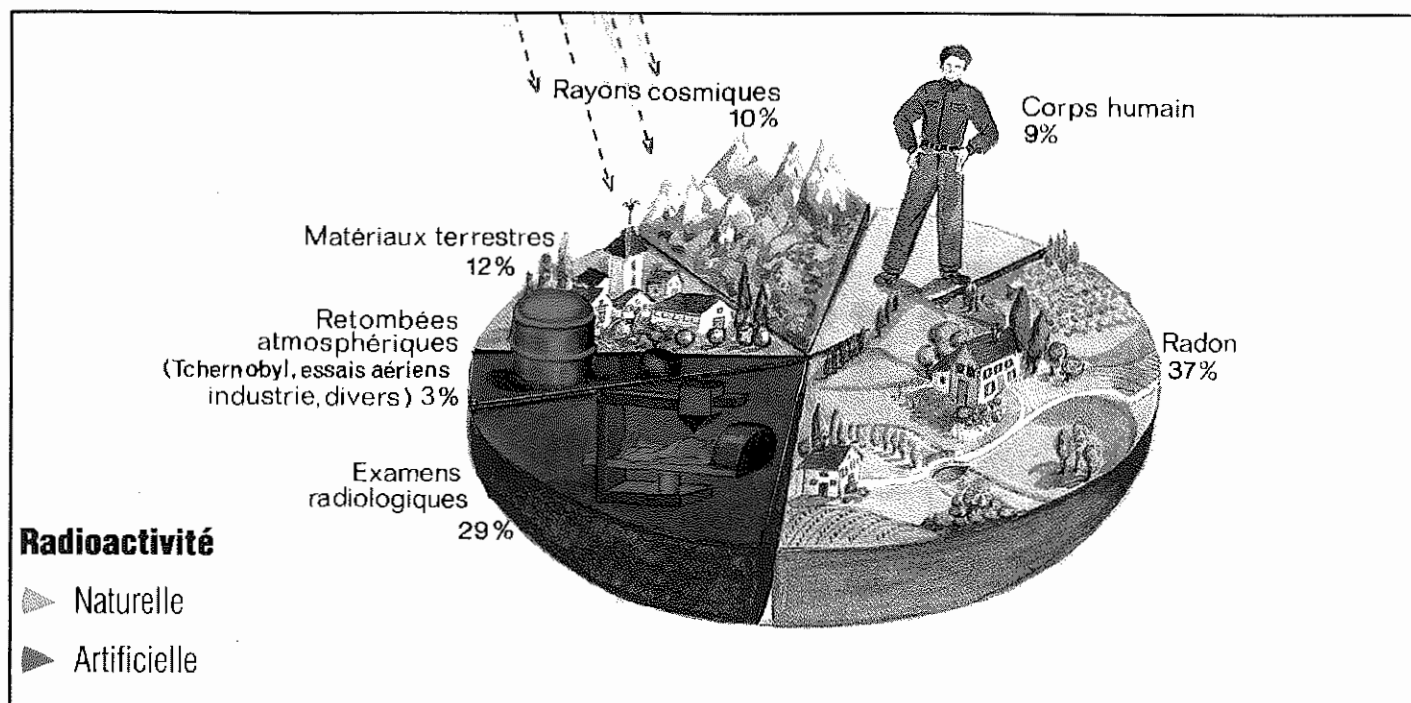
II — REJETS RADIOACTIFS GAZEUX

Les rejets radioactifs gazeux sont stables ; ils représentent de 2 à 4 % des autorisations (575 TBq et 825 TBq par an respectivement pour les tranches de 900 et 1 300 MW) en ce qui concerne les gaz rares (Argon, Xenon) et moins de 1 % des limites annuelles pour les halogènes* et aérosols - Iode et Césium- (18,75 GBq et 27,5 GBq respectivement).

Ces rejets sont sensiblement les mêmes dans le monde entier. Aucune action particulière n'est envisagée. Leur incidence sanitaire est négligeable.



Répartition des différentes expositions des populations



Expositions au rayonnement

D'après les rapports de l'UNSCEAR (Comité Scientifique des Nations Unies pour l'Etude des Rayonnements Ionisants) de 1985 et 1988, et de l'Académie des Sciences 1989
 Limite pour les personnes du public décret du 18 avril 1985 : 5 mSv/an (CIPR 60: 1 mSv/an)

Exposition en millisieverts par an	Valeurs moyennes	Valeurs courantes en France	Valeurs extrêmes dans le monde
Radioactivité naturelle			
<u>Exposition externe naturelle</u>			
Origine cosmique	0,36	0,3 à 2	55 (cosmonautes)
Origine terrestre	0,41	0,05 — 1,5	175 — (Brésil) 400 — (Iran)
<u>Exposition interne naturelle</u>			
Potassium 40	0,18		
Plomb, Bismuth + Polonium	0,12		
Radons et descendants	1,26	0,2-60	500 (Suède, France)
Total	2,33		
Radioactivité due aux activités humaines			
Origine médicale	1		Origine : SFRP
Industrie nucléaire	0,02		
Essais nucléaires atmosphériques	0,1		
Total	1,12		

D II — DÉCHETS RADIOACTIFS

Les déchets radioactifs constituent un sujet auquel le public est particulièrement sensible, celui pour lequel s'expriment peut-être le plus de craintes.

L'abondance de réflexions et de projets relatifs aux déchets montrent également l'intérêt que leur portent divers Organismes nationaux. Pas moins de trois rapports parlementaires leur ont été consacrés dans les 3 années écoulées, sans compter un rapport du Collège de Prévention des Risques Technologiques. Une loi sur les déchets à vie longue a été promulguée (décembre 1991). Le CSSIN a débattu sur ce thème (janvier 1992) après le « rapport DESGRAUPES » de juillet 1991. Cinq ministères (Santé, Travail, Environnement, Industrie et Recherche) se préoccupent également de la question, entretenant d'ailleurs une certaine confusion quant aux responsabilités dans ce domaine. A cela s'ajoutent les discussions internationales, notamment au sein des Communautés Européennes et de l'AIEA. Tout cela n'est pas fait pour faciliter la résolution de problèmes difficiles, dont les différents aspects sont examinés ci-après :

- déchets à vie longue
- déchets d'exploitation des centrales nucléaires
- déchets de très faible activité
- transport des déchets
- démantèlement

L'encadré ci-contre rappelle les quantités de déchets conditionnés (colis*) provenant de l'exploitation du parc nucléaire français, en moyenne 151 m³ par tranche et par an en 1992.

I — DÉCHETS À VIE LONGUE

EDF, en tant que propriétaire des combustibles utilisés dans ses centrales, est également propriétaire des déchets résultant du retraitement des combustibles usés, option retenue en France pour leur élimination.

Le retraitement produit, outre les isotopes de l'Uranium et ceux du Plutonium (actinides majeurs) destinés à être recyclés partiellement comme matières fissiles, des actinides mineurs (Neptunium, Américium, Curium) et certains produits de fission (Iode 129, Technétium 99, Césium 135) de périodes radioactives très longues (par exemple : 16 millions d'années pour l'Iode 129, ou 2,1 millions d'années pour le Neptunium 237). Environ 1 % des déchets retraités

entrent dans la catégorie des déchets très fortement radioactifs ou à vie longue. Qu'en faire ?

Le « rapport BATAILLE », de l'Office parlementaire d'évaluation des choix scientifiques et technologiques (décembre 1990) a conclu à la viabilité de la solution de l'enfouissement dans des couches géologiques profondes, et la loi 91-1381 du 30 décembre 1991 relative aux recherches sur la gestion des déchets radioactifs a engagé la création de laboratoires souterrains pour l'étude de ce mode de stockage.

Mais cette même loi demande un rapport annuel du Gouvernement au Parlement faisant le point sur l'avancement des recherches relatives à la gestion des déchets radioactifs à haute activité et à vie longue, et notamment celles portant sur la séparation et la transmutation* des éléments à vie longue.

Le « rapport GARDENT » (Collège de prévention des risques technologiques) signalait la situation d'EDF « en retrait », et proposait de faire participer EDF aux programmes de recherche et de développement.

En fait le problème se pose dans tous les pays disposant d'une industrie nucléaire. Si le CEA est largement impliqué au plan national dans les programmes de R et D d'une part sur la séparation des actinides, d'autre part

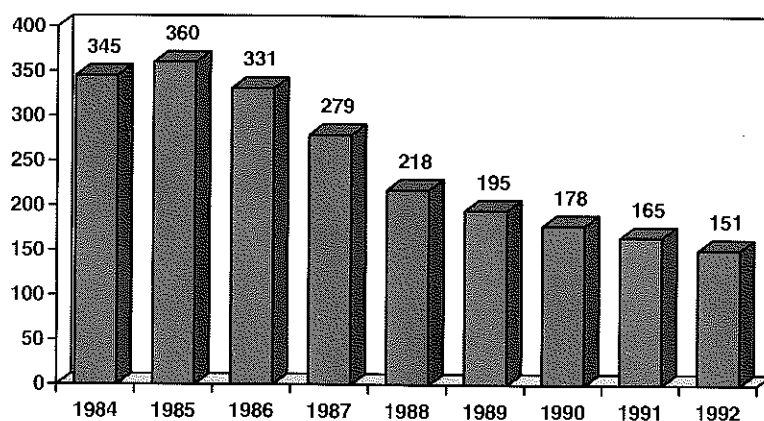
sur la transmutation -avec relance de ces programmes depuis 1991- il faut noter que plusieurs programmes importants ont été lancés récemment dans d'autres pays, notamment aux Etats-Unis et au Japon.

La CCE pour sa part a décidé de faire des études à caractère stratégique sur l'intérêt et les conséquences du retraitement poussé avant de lancer une quelconque étude technique.

Dans ce contexte, il est donc difficile de formuler des options définitives, les programmes d'étude engagés nécessitant 5 à 20 ans d'études. **EDF a créé un groupe de travail « Aval du cycle »** dont le champ d'activité couvre la séparation poussée, la transmutation des éléments à vie longue, le recyclage du Plutonium, le conditionnement et l'enfouissement des déchets. **Son objectif est d'acquérir les compétences et les connaissances nécessaires en vue de préparer les décisions stratégiques à terme.** EDF a décidé, conjointement avec le CEA et FRAMATOME, de coopérer aux programmes de recherche institués par la loi 91-1381 de décembre 1991.

Mais il faut garder à l'esprit que l'enfouissement en structures géologiques profondes est une solution acceptable pour la sûreté, et que par ailleurs il ne sera pas possible de s'er

Volume global des colis produits
(moyenne par tranche)



CENTRALES REP 900 et 1 300 MW

affranchir totalement ; il est en effet **utopique d'imaginer que la transmutation arrivera à un niveau tel qu'il ne restera plus de déchets à enfouir.**

II — DÉCHETS D'EXPLOITATION DES CENTRALES NUCLÉAIRES

Il s'agit de déchets de faible et moyenne activité, ne contenant pas de radioéléments émetteurs α ou en contenant très peu, pouvant être stockés dans les centres de stockage de surface de l'ANDRA (Centre de la Manche puis Centre de l'Aube). Ces déchets sont évacués en fûts métalliques, après compactage, pour les moins actifs, ou en fûts de béton de différents diamètres, munis de protections biologiques adaptées à la nature et l'activité des déchets.

Les efforts d'EDF dans ce domaine portent tout d'abord sur la réduction du volume de déchets à évacuer pour limiter les volumes à stocker au plan national. Cette réduction peut résulter de diverses actions :

- Réduction de la production de déchets

- par l'amélioration des techniques d'exploitation (chimie)

- par l'application des techniques d'optimisation (ALARA) pour l'organisation des chantiers (réduction du nombre de tenues, gants, vinyles, ... à enfûter) - Cf. chap. C IV.

- Recyclage de certains déchets :

EDF va explorer les différentes possibilités qui s'offrent dans la voie du recyclage.

En particulier, des essais vont être engagés sur le recyclage des vinyles.

- Mise en œuvre de moyens de réduction de volume des déchets avant stockage tels que l'incinération. La réalisation d'une installation nationale est à l'étude. Elle pourrait utiliser la technique de la torche à plasma expérimentée sur le site de Porcheville.

- Recherche de solutions spécifiques pour les déchets spéciaux entreposés sur les sites nucléaires, notamment :

- les chemises de graphite du combustible UNGG stockées sur le site de la centrale de Saint-Laurent des Eaux. **Le traitement de ces chemises sera entrepris dès que possible en vue de l'élimination totale du stockage actuel.**

- les ferrailles provenant d'opérations de maintenance. EDF étudie les moyens de recycler ces matériaux ; des expériences pilotes ont été effectuées (fusion des ferrailles). **L'objectif est de dispo-**

ser à terme d'une installation de fusion des ferrailles. Cette installation est également étudiée dans l'optique du démantèlement des installations déclassées.

Les efforts déployés par EDF ne portent pas uniquement sur la réduction du volume des déchets, mais aussi sur la qualité des colis de déchets. Les recherches se poursuivront pour améliorer encore la qualité des conteneurs en béton et les procédés de conditionnement. En ce qui concerne la gestion des colis envoyés à l'ANDRA, **l'assurance de la qualité sera accrue** par des perfectionnements apportés au logiciel de gestion, pour permettre de suivre en détail l'historique et les caractéristiques des déchets produits.

III — DÉCHETS DE TRÈS FAIBLE ACTIVITÉ

Une des difficultés majeures actuelles pour la réduction des volumes de déchets évacués vers les sites de stockage de surface de l'ANDRA réside dans l'absence de définition officielle d'un seuil au-dessous duquel un corps peut être considéré comme non radioactif. En fait il faudrait dire non radioactif, puisque dans la nature la radioactivité est présente partout. En l'absence de ce seuil, dit « de minimis », tout déchet sortant d'une centrale nucléaire est suspect d'être radioactif, même s'il ne provient pas d'une zone nucléaire. La réglementation française relative aux principes généraux de protection contre les rayonnements ionisants (découlant de la Directive Normes de Base EURATOM) ne mentionne qu'un seuil de 100 Bq/g (ou 500 Bq/g pour la radioactivité naturelle) au-dessus duquel une autorisation administrative (ou a minima une déclaration) est nécessaire. La réglementation du transport intervient de son côté au-dessus d'un seuil de 74 Bq/g. Au-dessous de cette valeur, les interprétations sont diverses ; on se trouve en présence de textes touffus et contradictoires. Les difficultés sont aggravées par la réglementation des Installations Classées pour la Protection de l'Environnement (ICPE), qui n'autorise aucun déchet « radioactif » dans les décharges industrielles.

En pratique un volume important de déchets de très faible radioactivité doit ainsi être mis en fûts et évacué sur un site ANDRA, ce qui est à la fois coûteux et sans intérêt sur le plan sanitaire ; et en outre ces opérations encombrant inutilement le centre de stockage, dont la capacité est limitée, et interdisent un recyclage possible de certains déchets.

Le problème va devenir crucial avec le démantèlement des installations nucléaires mises hors service qui vont être à l'origine de quantités très importantes de matériaux qui devraient pouvoir être réutilisés (ferrailles, béton qui après concassage permet de faire des infrastructures routières, etc.) et de déchets très peu actifs (calorifuges par exemple) voire inactifs mais refusés par principe dans les décharges.

La situation, déjà mentionnée en début de chapitre, est actuellement bloquée, dans l'attente de décisions administratives qui tardent à venir. Il serait aberrant d'envoyer massivement à l'ANDRA des déchets dont l'activité massique est inférieure à celle de nombreux produits naturels, et en tout état de cause inférieure à la limite fixée pour des denrées alimentaires dans les règlements EURATOM.

La réflexion se poursuit au niveau international (AIEA et Communauté Européenne) pour fixer des seuils « de minimis » pour les différents radionucléides. Les valeurs qui semblent émerger de ces travaux sont apparemment très basses (on parle de 0,3 Bq/g pour le ^{60}Co ou le ^{137}Cs). Ces valeurs ne permettront pas l'élimination de la plupart des déchets de très faible activité comme des déchets ordinaires. Il appartiendra donc aux autorités nationales de se déterminer, sur la base de dossiers présentés par les industriels, pour autoriser la mise en décharges spécialisées et contrôlées de déchets spécialisés de faible activité. Ceci est d'ailleurs une recommandation du « rapport BIRRAUX » (juillet 1991), reprise en janvier 1992 dans un avis du CSSIN puis par le « rapport LE DEAUT » d'avril 1992 (Office Parlementaire des Choix Scientifiques et Technologiques). **Il est donc urgent de procéder à la révision de la réglementation sur les Installations Classées pour la Protection de l'Environnement (ICPE) envisagée par le ministère de l'Environnement.**

La mise en application d'une réglementation sur les déchets de très faible activité demandera l'utilisation d'appareillages de mesure de sensibilité suffisante - qui existent sur le marché - et de méthodes d'échantillonnage. **EDF prendra les dispositions nécessaires pour assurer ces contrôles.**

IV — TRANSPORT DES DÉCHETS RADIOACTIFS

Les déchets produits par les centrales sont transportés par voie ferrée ou par voie routière, dans des emballages de

protection répondant aux normes réglementaires pour garantir la protection du public y compris en cas d'accident au cours du transport. Ces normes étant établies à partir des limites de dose au public fixées par la CIPR -qui ne peuvent être atteintes sauf en cas de scénario accidentel- leur révision est envisagée au plan international à la suite de la publication de la CIPR 60 : l'AIEA a mis en place des groupes de travail avec pour objectif de publier de nouvelles recommandations en 1998.

EDF partage, pour sa part, l'avis des utilisateurs nationaux, s'appuyant sur le retour d'expérience qui montre que les doses imputables aux transports sont très faibles, et **considère qu'il n'y a pas lieu de modifier la réglementation actuelle**. Elle souhaite toutefois participer aux discussions nationales et inter-

nationales sur ce sujet, et en particulier à la révision éventuelle des scénarios de l'AIEA.

Par contre, compte tenu des nouvelles valeurs du « facteur de pondération des neutrons »*, (doublement dans la CIPR 60), **il conviendra de réexaminer la conception ou le mode d'exploitation des châteaux de transport de combustible irradié**. Une solution devrait être retenue lors de la transcription en droit français des nouvelles normes de base EURATOM, soit vers 1996. Les études ont commencé en 1993.

V — DÉMANTÈLEMENT

Le démantèlement des installations nucléaires est une question fréquemment soulevée par le public. En fait, les

différents aspects du démantèlement liés à la radioprotection ont été évoqués à plusieurs occasions :

1 — Protection du personnel :

Les techniques de réduction des doses ont été développées au chapitre C IV. Il est vraisemblable que le démantèlement conduira à des développements robotiques spécifiques.

2 — Protection du public :

L'un des principaux problèmes est celui des déchets de très faible activité évoqué au § III ci-dessus. Les scénarios de mise en dépôt des déchets de ce type se réfèrent en général à des équivalents de dose efficace susceptibles d'être reçus par les personnes les plus exposées, fixés à des niveaux très bas, d

**OFFICE PARLEMENTAIRE D'ÉVALUATION
DES CHOIX SCIENTIFIQUES ET TECHNOLOGIQUES
EXTRAIT DES CONCLUSIONS DU RAPPORT
SUR LA GESTION DES DÉCHETS TRÈS FAIBLEMENT RADIOACTIFS**

22 avril 1992
par M. J.Y. LE DEAUT

1- Il conviendra de rendre l'actuelle réglementation plus sévère et abaisser fortement les seuils(1) au-dessous desquels les matériaux pouvant contenir des éléments radioactifs à faible dose pourront être éliminés sans procédure particulière. Même si les exploitants s'imposent pour le moment des règles strictes de rejet de déchets solides, le maintien de l'actuelle réglementation entraînerait certainement de nouvelles controverses successives entre les exploitants et les associations de défense sur les lieux des sites de stockage.

2- On ne pourra pas faire l'impasse sur le maintien de ces seuils d'exemption. **Tous les matériaux étant naturellement radioactifs, il faut bien à un moment fixer une limite en dessous de laquelle on considère la radioactivité comme négligeable**. Sans seuils d'exemption, les gestionnaires des décharges ne pourraient en effet plus recevoir -en théorie- aucun matériau provenant d'une installation nucléaire ; tout étant radioactif, l'ensemble des déchets deviendraient donc suspects a priori.

3- Les seuils définissant le niveau de radioactivité scientifiquement et socialement acceptables devront obligatoirement tenir compte des niveaux de la radioactivité naturelle.

Nous nous sommes appuyés pour cela sur une idée simple : il n'est pas possible d'imposer la mise en décharge spécialisée -et donc coûteuse- de matériaux dont la radioactivité serait inférieure à celle des minéraux courants.

4- Nous n'échapperons pas non plus, malgré toutes les difficultés que cela pourra entraîner localement, à la création de nouvelles décharges de produits radioactifs. **Nous avons en effet proposé de créer une quatrième catégorie pour les déchets, dont la radioactivité sera inférieure à celle des déchets admis dans le Centre de l'Aube de l'ANDRA mais cependant trop élevée pour qu'ils puissent être éliminés sans formalité**. Il faudra bien, dès lors, trouver un ou des sites pour les accueillir.

Il en ira de même pour les déchets radifères, autres que ceux qui sont stockés sur les sites miniers, et qu'il faudra bien -là aussi- stocker sur un site approprié.

Dans l'état actuel de l'opinion vis-à-vis de tout de ce qui concerne les déchets, radioactifs ou non, la création de ces décharges ne se fera pas sans mal, mais **il faut savoir ce que l'on veut**. Pour éviter la dissémination des déchets sur l'ensemble du territoire, il faut bien accepter de les concentrer sur des sites appropriés qui peuvent être surveillés efficacement.

5- Il faudra également si on veut restaurer la confiance, professionnaliser la gestion des déchets radioactifs.

L'ANDRA devra à terme devenir l'opérateur unique et clairement identifiable pour tout ce qui concerne le stockage définitif des déchets radioactifs.

6- Enfin, la préparation de ce rapport nous a permis de constater que l'on assistait imperceptiblement à une banalisation du nucléaire utilisé en médecine, mais aussi dans de nombreuses utilisations industrielles. Pour des doses de radioactivité ou de rayonnement -dans le cas des accélérateurs d'électrons- infiniment plus élevés que dans les sites de stockage, la réglementation n'est pas plus sévère que pour les décharges. Il faut donc de toute urgence prendre des mesures pour éviter le risque de dissémination des sources radioactives et leur utilisation par des personnels mal formés.

En tout état de cause, **le pire serait à notre sens que tout le secteur nucléaire soit gagné par le virus de l'immobilisme** et que, tétanisés par les risques de polémique et de controverse, nous nous contentions de ne rien faire et de laisser les choses en l'état.

Nous espérons que les recommandations que nous faisons aujourd'hui permettront d'apporter plus de transparence, et plus d'efficacité dans le stockage des déchets très faiblement radioactifs.

(1) Nota : il s'agit des valeurs de 100 Bq/g (et 500 Bq/g pour les substances naturelles) figurant dans le décret 66-450 corrigé par le décret 88-521 tenant compte de la Directive « Norme de Base » Euratom 80/836

l'ordre de 10 μ Sv (microSievert) par an (soit 1/250e de la dose moyenne due à la radioactivité naturelle).

La question des ferrailles et de leur recyclage après fusion répond aux mêmes critères. La Communauté Européenne a recommandé un seuil de 1 Bq/g γ pour le recyclage dans le domaine public.

En pratique, pour éviter toute contestation, **EDF prévoit de réserver la réutilisation des aciers récupérés par fusion à des usages internes à l'industrie nucléaire** : réalisations de blindages, tôles, réservoirs, etc. ou à défaut de stocker les lingots obtenus.

EDF a mis en place une première structure de réflexion sur l'ensemble des problèmes du démantèlement. Cette structure sera développée dans les prochaines années.

RADIOACTIVITE NATURELLE

Quelques valeurs repères

■ Le corps humain contient environ 5 000 Bq de potassium 40 et 3 000 Bq de carbone 14.			
L'ingestion annuelle de potassium 40 naturel, dans la nourriture courante, est de 30 à 40 000 Bq. Mêmes valeurs pour le carbone 14.			
■ sable marin	≈ 300 Bq/kg	(potassium 40)	
■ engrais phosphatés naturels	50 à 5 000 Bq/kg	(potassium 40)	
	10 à 500 Bq/kg	(radium)	
	500 à 1 000 Bq/kg	(uranium)	
■ cendres de charbon	300 à 1 000 Bq/kg	(potassium 40)	
	50 à 200 Bq/kg	(radium)	
■ Aliments : lait	50 à 80 Bq/kg		
	pommes de terre	150 Bq/kg	(potassium 40)
	poisson, viande, légumes verts	100 Bq/kg	
■ eau de mer	12 Bq/kg	(potassium 40)	

D III — SURVEILLANCE DE L'ENVIRONNEMENT

Les centrales effectuent une surveillance réglementaire de leur environnement, par des prélèvements réguliers dans le milieu ambiant (eau, air, lait, herbe, etc.) (Cf. encart au verso). Cette surveillance est régie par 4 des 7 arrêtés du 10 août 1976, et par les arrêtés d'autorisation de rejets liquides et gazeux spécifiques des installations.

Toutefois, les études radioécologiques faites avant mise en service des centrales (« point zéro radioécologique ») ne donnaient pas lieu à un suivi régulier, un contrôle étant seulement prévu périodiquement, à l'occasion des visites décennales.

Il est ainsi apparu un besoin de contrôle plus fréquent de l'impact des installations nucléaires, d'autant plus qu'EDF est périodiquement confrontée à des accusations de contamination de l'environnement (en général aquatique). Dans ce contexte :

■ **EDF a décidé de procéder, en plus du suivi permanent, à un suivi radioécologique annuel pour chacun de ses sites. Ce suivi, confié à l'Unité de Radioécologie de l'IPSN, donnera lieu à un rapport annuel pour chaque site et à un rapport global de synthèse. Ces rapports seront publiés.** Les analyses porteront sur les sédiments, les végétaux et la faune aquatique, essentiellement les poissons. Le choix des stations de prélèvement et des bioindicateurs sera déterminé pour chaque site en fonction des études antérieures et des conditions particulières locales. L'ensemble des échantillons prélevés

seront conservés pendant 10 ans, en vue de contrôles complémentaires éventuels.

En cas de nécessité, des campagnes de mesures ponctuelles pourront être décidées.

■ **Les résultats des mesures** du suivi permanent faites par l'exploitant dans le cadre de ses arrêtés d'autorisation (moyennes mensuelles) **sont publiés mensuellement**, transmis aux autorités locales et commissions d'information, et consultables sur Minitel 3614 MAGNUC, ainsi que sur 3614 TELERAY pour le rayonnement γ ambiant.

■ Afin d'assurer une bonne conservation des données de surveillance, **une base de données informatique des mesures de contrôle** (spectrométrie γ , activités totales β , tritium) **sera mise en place.**

■ Pour garantir l'objectivité des contrôles, **EDF pourra confier à des laboratoires régionaux indépendants agréés⁽¹⁾ des mesures de contrôle dans l'environnement de ses centrales nucléaires notamment en cas de contestation** la mettant en cause pour une pollution radioactive.

■ En ce qui concerne la métrologie, **il conviendra d'uniformiser les protocoles d'analyse.** Les procédures tant d'échantillonnage que de mesures devraient être normalisées⁽²⁾, suivant en cela la recommandation n° 2 du « rapport BIRRAUX-SÉRUSCLAT » de décembre 1990 (Office parlementaire d'évaluation des choix scientifiques et technologiques).

■ **EDF a décidé de se doter d'une équipe spécialisée en radioécologie**, ayant pour missions, entre autres, de

participer à la normalisation des méthodes de surveillance, à l'établissement des codes de calcul d'impact radiologique, de suivre l'évolution des recherches en matière de radioécologie, et de superviser les dossiers d'impact radioécologique des nouveaux sites. Ces spécialistes seraient également chargés d'analyser les rapports annuels et d'examiner en toute objectivité les questions soulevées à propos d'effets supposés liés aux rejets d'éléments radioactifs dans l'environnement. Ils pourraient être chargés de gérer la banque de données mentionnée ci-dessus, ainsi qu'un fonds documentaire spécialisé.

Cette action centralisée sera complétée par une formation complémentaire du personnel des laboratoires d'environnement des centrales, en vue d'étendre leurs compétences à de nouveaux types d'analyse du domaine de la radioécologie (méthodes d'échantillonnage et de mesure). En cas de besoin, si l'habilitation actuelle des laboratoires ne couvrirait pas cette extension de leurs activités, les centrales seraient amenées à demander leur agrément au titre de l'application du décret 88-715 du 9 mai 1988 relatif à l'harmonisation des mesures de la radioactivité.

(1) Il s'agit du « certificat de qualification technique » mentionné dans le décret 88-715 du 9 mai 1988 relatif à l'harmonisation des mesures de la radioactivité dans l'environnement et des denrées destinées à la consommation.

(2) Un arrêté devrait d'ailleurs être pris dans le cadre de ce même décret 88-715.

CONTROLES DANS L'ENVIRONNEMENT (arrêtés d'autorisation)				
Nature de la surveillance	Nombre de stations	Prélèvements		Echantillon type de mesure
		Nature	Fréquence	
AIR	1 (à 1 km)	aérosols pluie air	journalière mensuelle en continu	β total β total γ ambiant
	3 (à 1 km)	aérosols air	journalière en continu	β total γ ambiant
	4 (à 5 km)	air	en continu	γ ambiant
METEO	1 au sol 1 hauteur des rejets	air eau	en continu	pression, température, humidité, vitesse et direction du vent à 10 m — hauteur de précipitation
EAUX DE RIVIERE	1	eau brute	à chaque rejet d'effluent	eau filtrée β total 40K 3H filtre β total Bq/l β total Bq/g de cendres
NAPPES PHREATIQUES	4/5 piezomètres	eau brute	mensuelle	eau filtrée β total 40K 3H filtre β total Bq/l β total Bq/g de cendres
CHAINE ALIMENTAIRE LAIT VEGETAUX	2 prélèvements		mensuelle	β total 40K

E ■ INFORMATION

L'acceptation du nucléaire par l'opinion publique est nécessaire pour la persistance à long terme de l'usage de cette énergie. Cette adhésion du public appelle une information complète et exacte sur les enjeux énergétiques et sur les conditions de mise en œuvre de l'énergie nucléaire.

I — NATURE DE L'INFORMATION

Longtemps, l'information donnée par EDF l'a principalement été sous forme de réponses aux attaques des opposants du nucléaire. Depuis quelques années, EDF cherche à instaurer un dialogue avec le public afin de déceler ses attentes et de mener une politique volontariste en matière d'information.

L'information délivrée doit être claire, fondée sur la transparence, exacte et donc crédible.

1 — Une information claire :

Préparer des messages clairs est un exercice délicat car l'information doit rendre compte de la complexité des phénomènes traités qui peuvent faire appel à des notions de physique, de biologie, de technologie, d'économie, etc., qui ne font pas partie des connaissances partagées par tous les citoyens.

L'information doit donc être à la fois adaptée aux publics visés, et répondre clairement aux questions posées.

Les natures d'information sont très variées, allant de l'information à caractère scientifique à celle portant sur de simples événements.

2 — Une information fondée sur la « transparence » :

Le public ne doit pas avoir l'impression qu'on lui cache quelque chose.

Souvent dans le passé, EDF a omis de fournir au public des informations qu'elle jugeait sans importance. Cela ne procédait pas d'une intention de dissimulation mais c'était sans doute méconnaître la sensibilité du public aux dangers nucléaires et l'utilisation démagogique que pouvaient faire les opposants au nucléaire de « révélations » d'origine externe à EDF.

3 — Une information exacte :

Il ne faut pas que l'information fournie puisse être infirmée dans son contenu de faits et d'interprétations.

Dans ce domaine la moindre omission ou imprécision peut être interprétée comme une volonté de dissimulation ou de mensonge dans un climat passionnel et irrationnel.

II — LES PUBLICS VISÉS

EDF a entrepris et entend poursuivre et intensifier une politique d'information répondant à ces 3 critères et adaptée aux publics visés : le personnel d'EDF, les prestataires d'entreprises extérieures, le grand public, les relais de communication de l'Entreprise.

1 — Le personnel de l'Entreprise :

Le personnel d'EDF doit être informé en priorité. Il se pose souvent les mêmes questions que le grand public, en particulier sur les risques dus aux rayonnements. **Les efforts de coordination interne seront poursuivis pour mettre à la disposition de tous une information fiable** ; s'agissant des sujets les plus couramment évoqués, une documentation centralisée doit permettre à



Le Monde

DIRECTIVE 89/618 EURATOM
du 27 novembre 1989

CONCERNANT L'INFORMATION DE LA POPULATION
SUR LES MESURES DE PROTECTION SANITAIRE APPLICABLES
ET SUR LE COMPORTEMENT A ADOPTER
EN CAS D'URGENCE RADIOLOGIQUE

EXTRAIT

Article premier

La présente directive vise à définir, au niveau de la Communauté, des objectifs communs concernant les mesures et procédures d'information de la population ayant pour but de renforcer la protection sanitaire opérationnelle de celle-ci pour les cas d'urgence radiologique.

Article 5

Information préalable

1. Les Etats membres veillent à ce que la population susceptible d'être affectée en cas d'urgence radiologique soit informée sur les mesures de protection sanitaire qui lui seraient applicables, ainsi que sur le comportement qu'elle aurait à adopter en cas d'urgence radiologique.
2. L'information fournie porte au minimum sur les points figurant à l'annexe I.
3. Cette information est communiquée à la population mentionnée au paragraphe 1, sans qu'elle ait à en faire la demande.
4. Les Etats membres mettent à jour l'information, la communiquent régulièrement, et également lorsque des modifications significatives dans les mesures décrites interviennent. Cette information est, d'une façon permanente, accessible au public.

Article 7

Information des personnes susceptibles d'intervenir dans l'organisation des secours en cas d'urgence radiologique

1. Les Etats membres veillent à ce que les personnes ne faisant pas partie du personnel des installations et/ou ne participant pas aux activités, mais susceptibles d'intervenir dans l'organisation des secours en cas d'urgence radiologique reçoivent une information adéquate et régulièrement mise à jour sur les risques que leur intervention présenterait pour leur santé et sur les mesures de précaution à prendre en pareil cas ; cette information tient compte des différents cas d'urgence radiologique susceptibles de survenir.
2. Les informations précitées sont, dès survenance d'un cas d'urgence radiologique, complétées par des informations appropriées, eu égard aux circonstances de l'espèce.

Annexe I

Information préalable visée à l'article 5

1. Notions de base sur la radioactivité et ses effets sur l'être humain ainsi que sur l'environnement.
2. Les différents cas d'urgence radiologique pris en compte et leurs conséquences pour la population et pour l'environnement.
3. Mesures d'urgence prévues pour alerter, protéger et secourir la population en cas d'urgence radiologique.
4. Informations adéquates relatives au comportement que la population devrait adopter en cas d'urgence radiologique.

chacun d'obtenir l'information au niveau de détail souhaité. Cette documentation existe partiellement mais devra être complétée et mise à jour.

Une « culture de radioprotection » est indispensable (Cf. chap. F - Formation). Le développement des techniques d'optimisation (ALARA, Cf. chap. C IV), qui entraîne une sensibilisation du personnel à ces problèmes, contribue à cet objectif.

2 — Le personnel des entreprises extérieures

Une information générale sur les effets des rayonnements ionisants lui est fournie dans le cadre de la formation de base qui est exigée pour le travail en zone nucléaire (Cf. chap. C III).

Pour compléter cette information, *des documents simples*, rappelant les notions de base, *seront mis à la disposition des entreprises sur tous les sites*.

3 — Le grand public

EDF mène d'importantes actions de communication auprès du grand public (visites de centrales, mise à disposition de dossiers d'information sur les différents thèmes liés à la protection radiologique des personnes et de l'environnement, communication des événements importants ou incidents survenant dans la vie des centrales).

Les populations vivant près des centrales sont informées localement sur les risques de rayonnement et la conduite à tenir en cas d'accident. EDF veillera à ce que l'information nécessaire soit fournie à nouveau périodiquement (2 à 3 ans suivant la Directive EURATOM du 27.11.1989). L'initiative des centrales qui distribuent un journal d'information contribue de façon effective à cet objectif.

III — LES VECTEURS DE COMMUNICATION

EDF poursuit aussi des actions de communication ciblées vis-à-vis des populations qui constituent des vecteurs de communication vers le grand public, et tout particulièrement :

— les professions de santé (médecins généralistes et spécialistes, pharmaciens, ...)

— l'éducation nationale (professeurs, responsables de programme,...)

— les milieux politiques,

— les journalistes,

— les relais d'information régionaux (élus locaux, commissions locales d'information).

1 — Les professions de santé

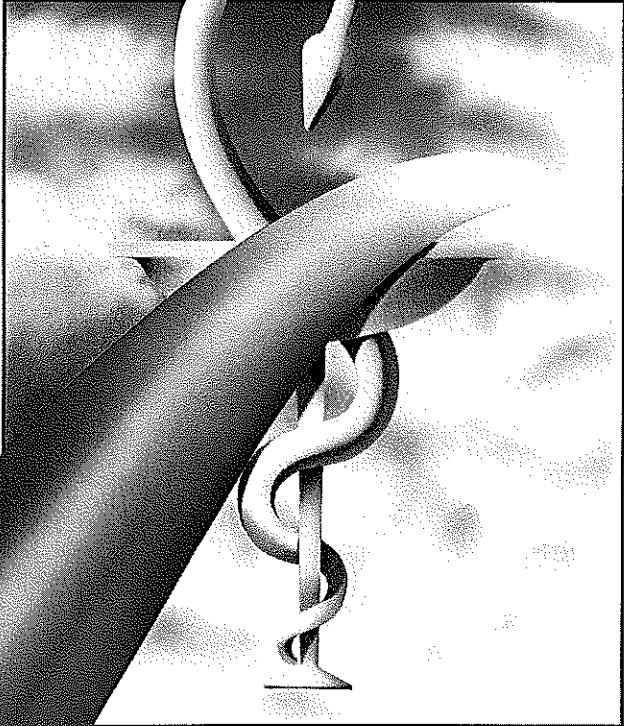
Les craintes du public portent très souvent sur les risques liés à la santé (risques de cancers, de malformations, etc.) ou à l'environnement. Tout naturel-

lement il sollicite les médecins, les pharmaciens, les vétérinaires pour avoir un avis « autorisé ». Et bien souvent ceux-ci, peu informés de ces questions nucléaires, se posent eux-mêmes des questions sur leur rôle en cas d'accident nucléaire. Un effort de formation très important a été consenti en direction des médecins.

Des réunions sont organisées fréquemment sur les sites nucléaires à l'intention des médecins généralistes, ou spécialistes particulièrement sensibilisés aux rayonnements ionisants (radiologues,

4^e EDITION
JUN 1992

MÉDECINS ET RISQUE NUCLÉAIRE



CONDUITE PRATIQUE EN CAS D'ACCIDENT

Faculté de Médecine de Grenoble
Conseil Général/Ordre des Médecins/Préfecture
Service Central de Protection contre les Rayonnements Ionisants

radiothérapeutes, médecins de « médecine nucléaire », ou aux conséquences d'un accident (endocrinologues).

Des visites sur sites nucléaires sont organisées plus particulièrement pour eux, avec participation de médecins du travail.

Des brochures spéciales sont éditées périodiquement à leur intention sur différents aspects de la protection.

On notera l'existence de la brochure « Médecins et risque nucléaire » préparée en collaboration avec l'Ordre des médecins et les Pouvoirs Publics de l'Isère par la Faculté de Médecine de Grenoble, dont la 4^{ème} édition, tirée à 90 000 exemplaires, a été distribuée à tous les médecins généralistes et aux spécialistes concernés. **EDF encourage et favorisera ce type d'action.**

2 — L'Education nationale

Il est indispensable de fournir aux professeurs comme aux élèves une information répondant à leurs besoins de connaissance. Ces informations doivent être purement factuelles. **EDF poursuivra ses discussions avec les respon-**

sables des programmes de l'Education nationale pour qu'une énergie si importante pour notre pays soit présentée objectivement dans les manuels scolaires, par exemple en évitant de l'illustrer par un champignon atomique...

L'information du public scolaire passe également par l'organisation de nombreuses visites des installations.

3 — Les milieux politiques

Les hommes politiques, plus que les autres puisqu'ils participent aux décisions du pays, doivent disposer d'éléments d'appréciation et d'informations claires. **EDF s'engage à faciliter leur tâche en ce domaine.**

4 — Les journalistes

Comme les hommes politiques, ils doivent disposer d'une information claire, abondante, quel que soit l'usage qu'ils en font ensuite. **EDF entend être « transparente » à leurs yeux et est disposée à leur transmettre toutes les informations qu'ils souhaitent relatives à la protection de la santé publique ou de l'environnement.**

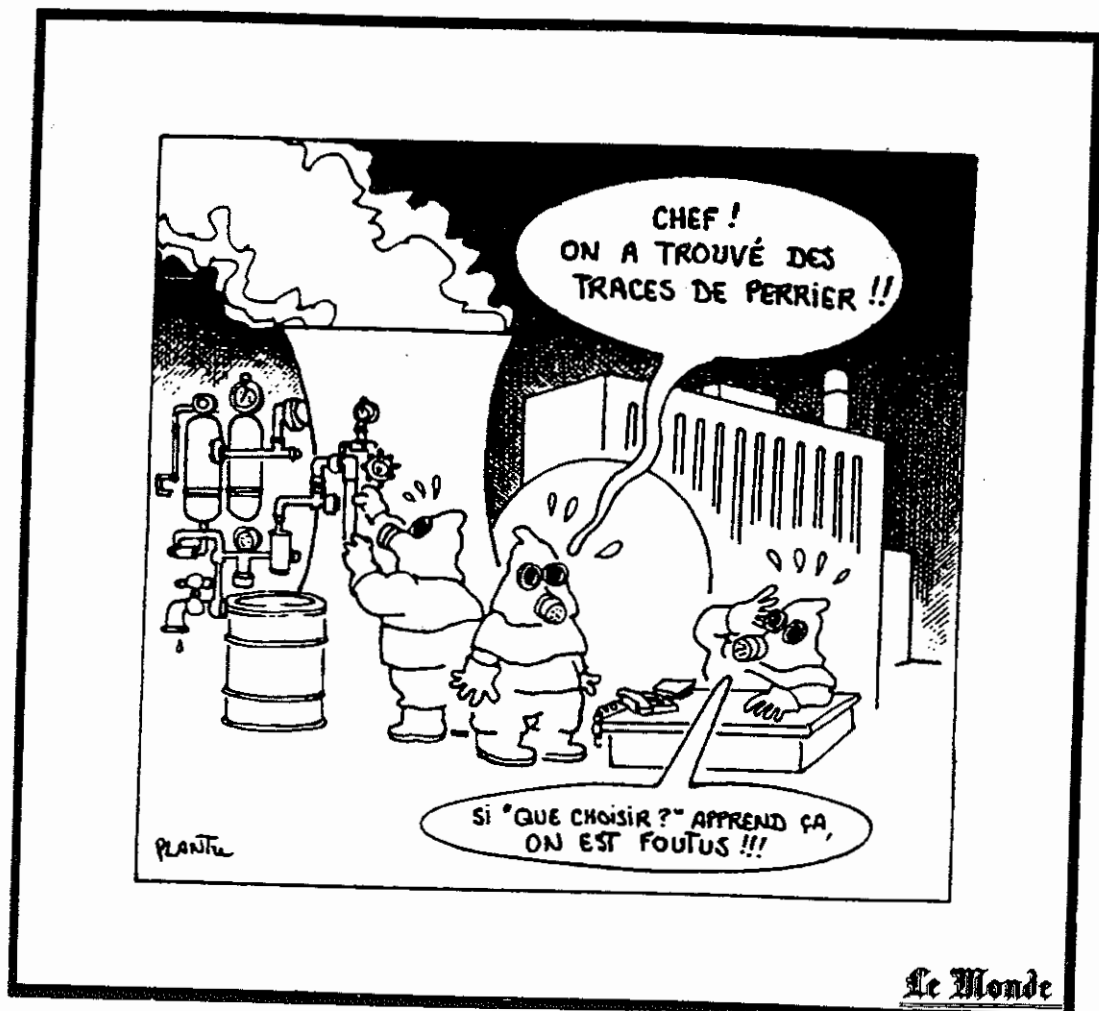
5 — Les relais d'information régionaux, en particulier les Elus locaux et les Commissions Locales d'Information.

EDF est prête à s'engager dans la voie tracée dans le rapport de l'Office d'évaluation des choix scientifiques et techniques (« rapport BIRRAUX » de décembre 1991) dans sa proposition relative à la création des Commissions Départementales d'Information et de Surveillance.

La participation de laboratoires régionaux à la surveillance de l'environnement (Cf. chap. D III) procède de la même intention de fournir une information objective aux élus et au public.

En conclusion, la multiplicité des actions entreprises, les engagements pour les années à venir témoignent de **la volonté d'EDF de fournir l'information claire et fiable** souhaitée par le public.

Notons, pour conclure, que l'Entreprise s'est dotée en 1991 d'une Direction de la Communication qui prend en compte toutes ces préoccupations au niveau de la Direction Générale.



Le Monde

F ■ FORMATION

I — LES LACUNES

La politique d'EDF en matière de prévention des risques consiste à ne pas dissocier la prévention des risques classiques de celle des risques liés aux rayonnements ionisants. La formation de base dispensée à tout agent de centrale nucléaire (stages PR1 et PR2) est conçue dans cette optique visant à l'auto-protection. Mais ceci contribue à une certaine banalisation des risques spécifiques liés aux rayonnements, contrairement à ce qui se fait pour les questions liées à la sûreté, qui donnent lieu à des formations très complètes. Dans la formation générale des ingénieurs, les aspects théoriques (physiques et biologiques) et pratiques de la radioprotection se résument à une quinzaine d'heure de cours — en plus de la formation de base générale à la prévention des risques commune à tous les agents.

Il n'est évidemment pas question de n'avoir que des spécialistes ; en centrale, il faut des règles les plus simples possible ; encore faut-il en comprendre le sens pour éviter les mauvaises interprétations pouvant conduire à des erreurs pratiques, ou simplement à des craintes injustifiées.

Et dans le cas plus particulier de ceux pour lesquels la radioprotection fait partie intégrante du métier apparaît assez nettement une insuffisance du niveau général. Cette faiblesse conduit dans certains cas les services opérationnels à être moins attentifs à la radioprotection des chantiers ; bien sûr, les règles générales sont respectées, mais il est possible de faire mieux. Les actions déjà engagées dans l'optique « ALARA » (Cf. chap. D IV) contribuent déjà à inverser la

tendance à la dégradation des résultats de dosimétrie collective mentionnée précédemment.

De façon générale, il **apparaît nécessaire de relever le niveau de culture en radioprotection.**

Au plan national, la même difficulté apparaît. On manque de spécialistes de haut niveau capables de jouer un rôle d'experts auprès des organismes nationaux et internationaux, ou même simplement vis-à-vis des centrales.

Si l'on se livre à une comparaison européenne sur l'organisation de la radioprotection sur les sites nucléaires (Cf. enquête EURELECTRIC ou enquête CEPN), on constate que la France est le seul pays où les responsabilités opérationnelles en radioprotection dans les centrales soient dans l'ensemble reléguées à un niveau hiérarchique aussi faible. Dans les autres pays, chaque site a un responsable avec au plus un niveau hiérarchique intermédiaire entre lui et le chef d'unité/ou de site ; dans la plupart des cas, ces responsabilités, de caractère légal, font l'objet d'agrèments officiels et donnent lieu à examen.

De cette analyse sommaire, il ressort tout d'abord qu'il est **nécessaire de redéfinir les fonctions et les responsabilités de radioprotection sur les sites, puis de définir une politique de formation adaptée aux objectifs.**

Un groupe de travail a été chargé de faire des propositions de réorganisation ; il a commencé à se réunir en fin 1992. Il devra **intégrer à sa réflexion la formation des experts nationaux et proposer un schéma cohérent permettant des carrières de radioprotectionnistes.** En particulier, **chaque site devra avoir un ingénieur de radioprotection** ayant suivi les spécialisations

nécessaires, **d'un niveau de responsabilités -concrétisé par un niveau hiérarchique adéquat- équivalent à celui des responsables des autres spécialités.** La Direction devra affirmer l'importance qu'elle attache à ce domaine.

II — FORMATIONS PARTICULIÈRES

1 — Cas des entreprises extérieures

Il est absolument indispensable que les agents d'entreprises extérieures pénétrant en zone contrôlée soient correctement sensibilisés aux risques radiologiques.

Pour éviter qu'il puisse y avoir des travailleurs insuffisamment avertis, **EDF s'appuie et s'appuiera de plus en plus sur les relations contractuelles avec les entreprises.** Comme indiqué au chapitre CIII, qui détaille les modalités d'utilisation du « carnet d'accès », la formation de base des travailleurs devra être attestée sur les premières pages de ce carnet et répondre aux critères définis par le CEFRI suivant un cahier des charges approuvé par EDF.

On rappelle ici que, à terme, **seules les entreprises ayant obtenu l'agrément CEFRI — au terme d'un audit — pourront accéder aux zones nucléaires.** La mise en œuvre généralisée de cette décision est tributaire des plans de charge du CEFRI, compte tenu du grand nombre d'entreprises à agréer. Elle pourrait être effective **dès 1995.** En attendant, la formation des intervenants, lorsqu'elle n'aura pas été dispensée par un organisme agréé CEFRI, donnera lieu, comme par le passé, à des vérifications systématiques sur les sites.

2 — Formation des médecins du travail

Leur qualification initiale de médecin du travail ne prévoit pas de formation à la radioprotection.

C'est pourquoi, jusqu'en 1990, une formation interne était assurée avec la participation d'intervenants aussi bien EDF que hors EDF. Depuis 1991, **les nou-**

veaux médecins de sites suivent une formation à l'université René Descartes (CHU Cochin) **pour obtenir le « diplôme de radioprotection appliquée à la médecine du travail »** (cette formation comprend 17 journées réparties sur 7 mois). Une formation interne, complémentaire, et plus spécifique, reste nécessaire ; elle sera organisée par le Service Général de Médecine du Travail.

3 — Radioprotection en situation accidentelle (Cf. chap. G)

EDF met en place sur chaque site un système d'évaluation des retombées radioactives en cas d'accident nucléaire. **Une formation spécifique** des agents susceptibles de mettre en œuvre ces moyens **sera développée** dans une optique d'aide à la mise en œuvre des Plans Particuliers d'Intervention (PPI), qui sont du ressort des Pouvoirs Publics.

Chap. G

PLAN SANITAIRE DU PUI Scenarios Enveloppes										
Numéro de scénario		Blessés-Brûlés		Intoxiqués	Contaminés		Irradiés (suivant la dose)			
		Graves	Légers		A contrôler	Réellement contaminés	- 0,3 Sv	1 Sv	+	
1	Rupture de tuyauterie vapeur	15								
2	Eclatement GTA en arrêt tranche	5	25							
3	Incendie caisse huile pompe primaire	10 5		10						
4	Chute moteur Pompe primaire au-dessus piscine BR	5			5	5		5		
		8			8	8	8 40			
5	Explosion réservoir gaz TEG	5			10	5 10	5			
6	Rupture tube GV Soupape ouverte	5			5	5				
					100 2400	100				
7	Pénétration zone rouge	1								1 5

G

SITUATIONS
D'URGENCE

Un accident de l'ampleur de celui de Tchernobyl est pratiquement impossible dans une centrale du type de celles existant dans notre pays ; si tout est mis en œuvre par les dispositions constructives et les règles très strictes d'exploitation, il faut cependant pouvoir être capable de faire face aux situations entraînant une contamination extérieure au site de la centrale. C'est l'objet des plans d'urgence.

Toutefois les situations d'urgence dans une centrale nucléaire peuvent être de natures et d'amplitudes très différentes. Le Plan d'Urgence Interne (PUI) de chaque installation comprend 3 niveaux dont seuls le deuxième et le troisième concernent des situations radiologiques :

N2 : contamination limitée au site

N3 : contamination susceptible de dépasser les limites du site

Le déclenchement d'un PUI par une centrale entraîne l'information immédiate du préfet qui décide de la mise en œuvre du Plan Particulier d'Intervention (PPI) au niveau qu'il juge adéquat.

EDF n'est responsable que de la mise en œuvre du PUI, le PPI ou le PPA (Plan Post-Accidentel) étant du ressort des autorités. Cependant EDF serait nécessairement impliquée à tous les stades d'un accident. Et l'organisation complexe des plans d'urgence peut et doit être améliorée en permanence en faisant appel au retour d'expérience tiré des exercices.

1 — PLAN D'URGENCE INTERNE — PUI

Ce plan est déclenché en cas de situation accidentelle. La distinction entre niveau 2 et niveau 3 est difficile car, en

cas d'accident grave, il n'y aurait que peu (sinon pas) de rejets immédiats, mais des **rejets potentiels**, contenus dans l'enceinte de confinement. Et c'est en fonction de ces risques potentiels que seraient prises des décisions de protection des populations. D'où **l'importance des prévisions** ; ceci implique :

■ **de connaître les rejets potentiels** : on sait calculer les quantités de produits radioactifs contenus dans le cœur du réacteur ; mais quelle quantité serait rejetée, compte tenu des différents filtres et barrières, des dépôts, du comportement physico-chimique des éléments ?

Les rejets servant de référence à l'établissement des PUI correspondent à l'hypothèse dite « S3 » par les spécialistes de la sûreté. Les doses à la population qui en résulteraient seraient en général négligeables au-delà de 10 km ; cette distance peut toutefois être dépassée dans des circonstances météorologiques défavorables, en particulier pour l'iode radioactif, d'où l'intérêt de stocks de comprimés d'iode stable mentionnés plus loin dans la mise en œuvre des PPI.

Les plans d'urgence sont bâtis sur des hypothèses défavorables à partir de l'endommagement du cœur du réacteur et beaucoup d'hypothèses pessimistes demandent à être reprises de façon plus réaliste. **Cette réévaluation du « terme-source » devra être entreprise** avec l'IPSN.

■ **de pouvoir déterminer la dispersion des radioéléments rejetés**

Les centrales disposent d'un système informatisé d'évaluation rapide des zones concernées par le panache -irradiation lors du passage et retombées -en vue d'estimer l'exposition des populations. Ce système sur micro-ordinateur

utilise les données météorologiques du site et permet des prévisions rapides à courte distance (10 km), avec pour objet d'informer le préfet sur les besoins éventuels de confinement ou d'évacuation.

Mais en cas d'accident grave, avec dispersion importante de produits radioactifs, le suivi des panaches serait très important. Il faut pouvoir passer à l'échelle régionale, puis le cas échéant internationale pour prévoir les retombées.

EDF a signé une Convention avec la Météorologie Nationale; celle-ci fournirait en cas de besoin les prévisions de conditions météorologiques et de trajectoires de panaches nécessaires à la gestion d'un accident, en liaison avec le centre de crise de l'IPSN à Fontenay-aux-Roses.

Ce dispositif sera complété pour améliorer les prévisions à l'échelle régionale, en faisant appel aux compétences de la Direction des Etudes et Recherches.

■ **d'évaluer correctement les débits de dose** et les contaminations sur le site, en particulier au voisinage d'installations spécifiques comme les filtres à sable*. **Les moyens de mesure seront réévalués dans cette optique.**

PLAN SANITAIRE DU PUI

Le plan d'urgence doit prévoir les accidents entraînant sur le site des blessés ou brûlés graves irradiés et/ou contaminés et la suspicion de contamination d'un nombre important de personnes. Les différents scénarios ont été regroupés en 7 scénarios enveloppes, les cas extrêmes étant une vingtaine de blessés contaminés ou 2 500 personnes susceptibles d'être contaminées à contrôler. Hors scénarios, le cas de victimes

fortement irradiées a également été pris en compte. Sur ces bases a été établi un **plan d'urgence sanitaire** (intégré au PUI), mettant en œuvre le personnel médical de la centrale, les SAMU, les SMUR, les services de secours et d'incendie, les hôpitaux militaires. Des conventions ont été passées avec diverses structures, ceci au plan de chaque site nucléaire. De plus des conventions ont été établies au plan national avec l'IPSN, ainsi qu'avec plusieurs hôpitaux civils et militaires (Hôpital Percy à Clamart en particulier). Mais l'organisation pratique pour faire face à des accidents à cette échelle reste à être formalisée, et testée. Un premier exercice de cette ampleur a été effectué en décembre 1992 sur le site de Paluel.

EDF se fixe comme objectif la réalisation d'exercices biennaux (suivant les scénarios enveloppes) sur tous les sites, en liaison avec les services préfectoraux : en effet des exercices de cette ampleur, demandant la participation de services de secours extérieurs ne peuvent être réalisés qu'en plein accord avec la préfecture, et avec une information adéquate des populations.

Cette mise en œuvre des plans d'urgence sanitaire sera l'occasion de revoir certains points d'organisation (en personnel et en matériel), l'expérience des sites en la matière étant très variable.

Pour compléter ce plan sanitaire pour situations accidentelles, EDF a signé une convention avec l'IPSN pour **la mise en place d'un programme quinquennal**

de recherche en radiopathologie et en dosimétrie biologique, incluant l'équipement de laboratoires qui seraient mis à contribution, en cas d'accident (Cf. chap. B), notamment pour la dosimétrie biologique. Ce programme est co-financé par l'IPSN et EDF.

2 — PLAN PARTICULIER D'INTERVENTION — PPI

Ce plan d'intervention est déclenché par le préfet et son déclenchement s'accompagne de la mise en place d'un PC opérationnel dont il prend le commandement. Le préfet prend les décisions qu'il juge utiles, en tenant compte des différentes informations et avis d'experts qu'il reçoit. EDF n'a pas à intervenir dans ce processus décisionnel, mais **les responsables des sites devront s'assurer régulièrement que les plans d'urgence qui les concernent sont à jour**, en prenant les contacts adéquats avec les services préfectoraux.

En outre, EDF peut fournir une assistance dans la mise en œuvre des PPI, en plus de l'étude prévisionnelle des rejets et de leur dispersion mentionnée ci-dessus ; en particulier, **EDF a constitué des stocks de comprimés d'iode stable** destinés à être distribués à la population en cas de risque important de rejet d'iode radioactif dans l'atmosphère. Les stocks constitués (100 000 comprimés par site + 1,5 million en réserve nationale) sont mis à la disposition du préfet -y compris pour un accident hors EDF.

A l'occasion du prochain contrôle de stock (périodicité 5 ans - prochain contrôle en 1996), **EDF reverra les conditions d'emballage de ces comprimés en vue d'en faciliter la distribution** en cas de nécessité (le stockage actuel est fait en flacons de 1 000 à 5 000 comprimés).

Information des populations

Les populations habitant à proximité des installations nucléaires doivent être informées des consignes qu'elles seraient amenées à suivre en cas d'accident. L'application de la Directive EURATOM 89/618 du 27.11.1989 conduira à revoir les conditions d'information systématique et périodique de ces populations. Cette même directive doit conduire également à compléter l'information nationale et locale de divers types de publics (Cf. chap. E) en matière de radioprotection.

3 — PLAN POST-ACCIDENTEL — PPA

C'est un document qui là encore est du ressort des Pouvoirs Publics. Etant donné la diversité des situations possibles, les problèmes qui se poseraient ont fait l'objet d'un recensement et seules les méthodes générales ont été définies. En fait, les plans post-accidentels seraient établis en fonction des situations réelles. Ils ne présentent pas le même caractère d'urgence que les PUI et PPI, et leur application s'étale sur des périodes longues.

REJETS POTENTIELS DANS L'ATMOSPHERE EN CAS D'ACCIDENT NUCLEAIRE Accident de référence pris pour le dimensionnement des plans d'urgence (S3)				
	Iode organique (non soluble)	Iode moléculaire et aérosols (solubles)	Gaz rares	Césiums (134, 137)
% cœur susceptible d'être rejeté	0,55 %	0,31 %	75 %	0,35 %
Quantité correspondante de radionucléides	8.10 ⁵ TBq	5.10 ⁴ TBq	8.10 ⁶ TBq	3.10 ³ TBq
1 TBq = 10 ¹² Bq = 27 curies Iode = après quelques heures, essentiellement ¹³³ I et ¹³¹ I ¹³¹ I : période 8 jours ¹³³ I : période 21 heures		Accident de référence : rupture du circuit primaire, perte des alimentations électriques, fusion du combustible contenu dans le cœur du réacteur		

EDF participe à l'étude de moyens d'action post-accidentels :

— programme « RESSAC » (restauration des sols après accident)

— études radioécologiques (IPSN/SERE à Cadarache)

— « système d'aide à la décision en cas d'accident nucléaire » des Communautés Européennes (DG XII). Ce système s'appuie sur des modèles mathématiques de prévision pour estimer les

doses, les effets sanitaires et les coûts des différentes contre-mesures envisageables.

EDF focalise plus particulièrement son action sur l'élimination du Césium, élément qui poserait un des principaux problèmes de contamination à long terme (Cf. Tchernobyl) (avec l'iode dans les premières semaines seulement). Dans cette optique, **EDF prend les dispositions nécessaires pour :**

— ***l'étude du piégeage du Césium « à la source »***, la meilleure façon d'éliminer le Césium étant encore de ne pas contaminer l'environnement. Cette action entre dans le cadre des programmes mixtes de recherche EDF/CEA.

— ***l'étude de la décontamination des personnes et également des animaux d'élevage.***

Dans la même optique, EDF envisagera l'étude du piégeage de l'iode « à la source » -dans le bâtiment du réacteur.

Conclusion générale

La France, au travers d'E.D.F., a développé son programme nucléaire en moins de deux décennies dans de bonnes conditions de sécurité. Dans le climat passionnel qui a suivi l'accident de Tchernobyl, tout ce qui touche au nucléaire a plus ou moins été remis en question ; le public est de plus en plus sensible à son environnement, et particulièrement aux risques liés aux rayonnements, qui lui semblent mystérieux parce qu'invisibles. On constate une certaine effervescence tant au plan national qu'international, notamment en Europe où le poids de la réglementation communautaire s'affirme chaque jour davantage.

De nouvelles exigences ont ainsi vu le jour, et ont conduit à une analyse critique de la situation actuelle. EDF souhaite se mettre à la hauteur de ces exigences, dans la mesure où elles sont raisonnables.

La vigilance, de rigueur pour tout ce qui touche à la sûreté des installations, doit être tout aussi présente dans les domaines concernés par la radioprotection ; ils ont été abordés dans les différents chapitres de ce « livre blanc » qui définit les orientations qui seront suivies d'ici la fin du siècle.

Des dates précises ne peuvent être avancées pour l'ensemble des actions, mais un point sur leur état d'avancement sera fait périodiquement.

S'il n'est pas possible de résumer ici les réflexions et les propositions de ce livre blanc en raison de leur diversité, on peut toutefois en rappeler les grandes lignes sur les thèmes principaux.

L'objectif principal est bien sûr la protection de l'homme ; les réflexions sur ce thème menées par la Commission Internationale de Protection Radiologique (CIPR), ont conduit aux nouvelles recommandations de la CIPR 60. Même si certaines de ses hypothèses sont contestables, et elles ont d'ailleurs été contestées par l'Académie des Sciences, l'objectif reste une meilleure protection des individus. C'est en fait dans cette optique prudente que la CIPR a émis ses recommandations, bien que les effets réels des très faibles doses soient mal connus. Ceci justifie la poursuite des études en radiobiologie, car les facteurs de risque réels peuvent être très largement inférieurs à ceux retenus actuellement.

Mais en fin de compte, les mesures prises - tant qu'elles restent économiquement supportables - sont acceptées par l'ensemble de la communauté internationale. Tout cela va dans le sens de l'évolution générale vers une réduction de l'exposition aux rayonnements nucléaires.

■ A cette occasion on découvre les vertus d'une meilleure organisation - démarche « ALARA » - qui conduit finalement à une réduction des doses et souvent à des gains de productivité. Le climat ainsi créé est propice à la recherche des améliorations de toutes natures. La création d'une structure de coordination interne entre les différents acteurs de l'Entreprise concernés par la radioprotection va également dans le sens d'une meilleure efficacité.

■ La protection de l'homme contre les rayonnements ionisants passe par la surveillance des doses qu'il reçoit et la surveillance médicale. Des difficultés particulières apparaissent pour tout ce qui concerne les travailleurs d'entreprises extérieures, auxquels il convient d'assurer le même niveau de protection qu'aux travailleurs d'EDF. De nombreuses dispositions ont été prises ou proposées pour arriver à ce résultat. Mais le **besoin d'une collaboration plus marquée avec les différents Services de l'Etat apparaît clairement :**

— L'amélioration de la surveillance médicale demande une réorganisation nationale des services médicaux concernés, des moyens d'identification des travailleurs, de suivi informatique des dossiers. Des solutions ont été amorcées (carte de suivi médical notamment), mais il faut absolument créer une banque de données nationale dont les conditions d'accès devront bien sûr être définies.

— Même chose pour la dosimétrie ; le système actuel ne permet pas une gestion nationale satisfaisante. La dosimétrie opérationnelle - complément indispensable de la dosimétrie réglementaire actuelle - devrait pouvoir être intégrée à cette surveillance nationale. Les problèmes de confidentialité sont à examiner de très près, mais toutes les parties concernées par la protection des travailleurs doivent avoir accès aux résultats dosimétriques. C'est d'ailleurs dans ce sens qu'évolue la réglementation européenne. La coopération paraît indispensable : il ne s'agit pas d'empiéter sur les responsabilités de l'Administration, mais de la mise en commun des méthodes adéquates et de moyens techniques dont les développements sont très coûteux ; c'est la seule possibilité raisonnable pour disposer au plan national d'un système fiable capable ensuite

de s'intégrer dans un système européen. Les autres grands opérateurs nucléaires (CEA, COGEMA,...) devraient donc tout naturellement être associés à ce projet national.

EDF a fait les premiers pas avec le système DOSINAT de suivi centralisé des doses opérationnelles reçues dans ses centrales, et avec la mise en œuvre du « carnet d'accès » ; elle suscite des recherches sur le matériel de dosimétrie individuelle et essaie également d'être présente sur la scène internationale ; avec le « grand marché » ouvert en 1993, apparaissent divers besoins d'harmonisation européenne : méthodes de mesure, comptabilisation des doses, formation des experts qualifiés, etc. EDF est prête à apporter une contribution notable dans tous ces domaines, mais là encore la collaboration avec les Pouvoirs Publics paraît nécessaire.

■ Dans l'optique de la réduction des doses, EDF s'est fixé de nouveaux objectifs pour la conception des nouvelles unités de production, en intégrant la maintenance dès ce stade ; elle poursuit ses recherches sur l'amélioration de la qualité des matériaux et développe les outils de téléopération. Les méthodes d'optimisation - ALARA - commencent à entrer dans les mœurs et sont intégrées aux plans stratégiques des Unités.

■ L'amélioration d'ensemble de la radioprotection passe par une redéfinition des « métiers de la radioprotection » ; une réflexion nationale est engagée sur ce thème pour préciser les missions spécifiques et adapter l'organisation générale aux nouveaux besoins. Toute cette évolution s'accompagnera d'efforts correspondants de formation : d'une part pour relever le niveau de formation théorique afin de disposer d'un certain nombre d'experts nationaux et internationaux, d'autre part pour généraliser une « culture de radioprotection » chez les exploitants de centrales nucléaires.

■ Une autre préoccupation majeure est celle de la protection de l'environnement. Les effluents et les déchets radioactifs sont des sujets sur lesquels le public s'interroge.

● En ce qui concerne les effluents radioactifs, la réduction des quantités émises se poursuit ; les rejets d'éléments radioactifs sont arrivés à un niveau très faible - à peine plus de 1 % des autorisations - et sont sans danger pour la santé publique ; la contribution des centrales nucléaires aux doses d'irradiation reçues par le public est inférieure à 1 % de celles dues à la radioactivité naturelle qui elle-même peut varier du simple au double. Toutefois, pour assurer en toute transparence l'information du public, des suivis radioécologiques annuels - s'ajoutant à tous les contrôles réglementaires - ont été décidés. Des contrôles seront en outre effectués par des laboratoires extérieurs habilités.

● Les déchets radioactifs continuent à être l'objet de nombreux débats, qu'il s'agisse de déchets fortement radioactifs à vie longue, ou de déchets très faiblement radioactifs ; les réflexions nationales et internationales sur ces thèmes ne progressent que très lentement.

Pour les premiers, EDF engage des recherches sur leur transformation en éléments à vie plus courte par transmutation. Mais le stockage en profondeur reste a priori une bonne solution qui devra nécessairement être utilisée pour les éléments non transmutés.

Le problème administratif lié aux déchets de très faible activité - toujours non résolu - va devenir crucial avec le démantèlement des installations déclassées qui va produire des quantités très importantes de déchets de cette nature. Les décharges refusent actuellement des déchets ordinaires du simple fait qu'ils proviennent d'une installation nucléaire. La question se pose de la même façon pour les matériaux théoriquement recyclables. Mais qu'est-ce qu'une substance radioactive ? Les ambiguïtés voire les incohérences de la réglementation française ne font qu'entretenir une certaine confusion. Il devient donc urgent que les Pouvoirs Publics prennent les dispositions réglementaires nécessaires pour éviter « l'embouteillage » qui risque d'apparaître sur les déchets faiblement radioactifs.

■ Enfin, pour terminer ce panorama, mention particulière doit être faite de l'information du public — des publics faudrait-il dire. EDF entend fournir au grand public comme aux différents vecteurs de l'information que sont les journalistes, les hommes politiques, les médecins, les enseignants, les organisations syndicales, etc., une information claire, fondée sur la transparence, et crédible parce que loyale.

Ce livre blanc témoigne de la prise de conscience très marquée de l'importance des enjeux et de la profonde volonté de progrès qui anime EDF.

Donnons le mot de la fin à M. LE DÉAUT, qui écrit dans le préambule de son rapport du 22 avril 1992 (à propos des déchets) : « **Le pire serait à notre sens que tout le secteur nucléaire soit gagné par le virus de l'immobilisme et que, tétanisés par les risques de polémique et de controverse, nous nous contentions de ne rien faire et de laisser les choses en l'état** ».

Sigles utilisés

AIEA	Agence Internationale de l'Energie Atomique (Vienne)
AIDN	Association Internationale de Droit Nucléaire
ALARA	« As low as reasonably achievable » — Aussi bas que raisonnablement possible (« principe ALARA »)
ANDRA	Agence Nationale pour la gestion des Déchets Radioactifs
CCE	Commission des Communautés Européennes
CEFRI	Comité Français de Certification des Entreprises pour la Formation et le suivi du personnel travaillant sous Rayonnements Ionisants
CEPN	Centre d'Etudes sur l'évaluation de la Protection dans le domaine Nucléaire
CHSCT	Comité d'Hygiène, de Sécurité, et des Conditions de Travail
CIPR	Commission Internationale de Protection Radiologique
CIUR	Commission Internationale des Unités et mesures des Rayonnements
CNIL	Commission Nationale Informatique et Libertés
CNRS	Centre National de la Recherche Scientifique
CSSIN	Conseil Supérieur de la Sûreté et de l'Information Nucléaires
DATR	Directement Affecté à des Travaux sous Rayonnements
DEPT	Direction EDF Production Transport
DSRE	Département Sûreté, Radioprotection, Environnement
EURATOM	Communauté Européenne de l'Energie Atomique
EURELECTRIC	Groupement Européen des Entreprises d'Electricité
GCR	Groupe de Coordination en Radioprotection

GIIN	Groupe Intersyndical de l'Industrie Nucléaire
ICPE	Installations Classées pour la Protection de l'Environnement
INB	Installation Nucléaire de Base
IPSN	Institut de Protection et de Sûreté Nucléaire
IRPA	International Radiation Protection Association
ISO	International Standardization Organisation
LAI	Limite Annuelle d'Incorporation
OCDE	Organisme de Coopération et de Développement Economiques
OMS	Organisation Mondiale de la Santé
PPA	Plan Post Accidentel
PPI	Plan Particulier d'Intervention
PUI	Plan d'Urgence Interne
REP	Réacteur à Eau Pressurisée (PWR en anglais)
SAMU	Service d'Aide Médicale d'Urgence
SCPRI	Service Central de Protection contre les Rayonnements Ionisants
SFEN	Société Française d'Energie Nucléaire
SFRP	Société Française de Radioprotection
SGMT	Service Général de Médecine du Travail
SMUR	Service Médical d'Urgence
UNSCEAR	Comité Scientifique des Nations Unies sur les Effets des Radiations « Atomiques ».

GRANDEURS ET UNITES UTILISEES EN RADIOPROTECTION

GRANDEUR	DEFINITION	UNITE
Activité — A	L'activité d'un radioélément est définie comme le nombre de désintégrations qu'il subit par unité de temps	le becquerel — Bq 1 Bq = 1 désintégration/s
Dose absorbée — D	C'est l'énergie qu'un rayonnement communique à la matière par unité de masse	le gray — Gy 1 Gy = 1 J/kg
Equivalent de dose — H	L'équivalent de dose tient compte des effets des rayonnements sur l'organisme, et permet de comparer l'effet d'une même dose absorbée délivrée par des rayonnements de natures différentes	le sievert — Sv
Equivalent de dose collective (ou Dose collective)	C'est la somme des équivalents de dose cumulés par tous les individus d'une population donnée	l'homme sievert — H.Sv
Equivalent de dose efficace — E (ou Dose efficace)	Les effets biologiques des rayonnements varient suivant les organes ou les tissus considérés. La dose efficace est la somme des équivalents de dose pondérés, délivrés aux différents tissus et organes du corps	le sievert — Sv
Débit de dose (Débit d'Equivalent de dose)	Il mesure en combien de temps une dose absorbée (un équivalent de dose) a été délivrée à l'organisme	le gray par heure — Gy/h (le sievert par heure — Sv/h)

ANCIENNES UNITES ET EQUIVALENCES

UNITE	ANCIENNE UNITE	EQUIVALENCE
le becquerel - Bq	le curie — Ci	1 Ci = 37 10 ⁹ Bq
le gray — Gy	le Rad	1 Gy = 100 Rad
le sievert — Sv	le Rem	1 Sv = 100 Rem
l'homme sievert — H.Sv	l'homme rem — H.Rem	1 H.Sv = 100 H.Rem
le gray par heure — Gy/h (le sievert par heure — Sv/h)	le Rad/h (le Rem/h)	

Lexique

Activité

Nombre de désintégrations par unité de temps, exprimé en Becquerels (Bq). On parle par extension « d'activité rejetée » qui donne l'image de la quantité de radioactivité relâchée. Mais il faut rappeler que l'« activité » seule ne suffit pas à définir la toxicité ; il faut prendre en compte la L.A.I. (voir définition ci-après).

« ALARA »

En anglais « as low as reasonably achievable », soit « aussi bas que raisonnablement possible », compte tenu des conditions économiques et sociales. Ce terme « ALARA » désigne toutes les méthodes d'optimisation des doses, c'est-à-dire de leur réduction intelligente, en s'appliquant à utiliser les ressources là où elles sont les plus efficaces.

Anthropogammamétrie

Mesure des quantités de radioéléments contenus dans le corps d'un individu par analyse spectrale des rayonnements gamma qu'il émet ; l'anthropogammamétrie permet de détecter des contaminations internes.

« Centrale propre »

Ce concept est fondé sur l'idée que, dans une centrale correctement exploitée et entretenue, les risques de contamination atmosphérique chronique sont très faibles. En outre la propreté va invariablement de pair avec une bonne gestion.

Coils

Terme utilisé pour désigner des déchets radioactifs mis dans un emballage de transport ou de stockage : fût métallique ou coque de béton ; les déchets peuvent être bloqués par un enrobage de résine ou de ciment.

Déterministe

Qui obéit à des lois bien définies. Lorsque les conditions sont remplies, le phénomène se produit nécessairement ; un effet déterministe est un effet reproductible. C'est le cas des effets d'une irradiation donnée au-dessus de certains seuils.

Dosimétrie biologique

Méthode de mesure de la dose reçue à partir de l'examen, par diverses méthodes, des modifications biologiques dues aux rayonnements : numération des globules blancs, anomalies des chromosomes de certains globules blancs, etc.

Dosimétrie opérationnelle

Mesure des doses reçues par les travailleurs au cours des différentes opérations. On désigne par ce nom à EDF les systèmes de mesure électronique individuels qui permettent aux travailleurs de connaître leur dose à chaque séjour en zone nucléaire. Ce système a en outre une fonction d'alerte si le débit de dose devient important.

Dosimétrie réglementaire

Mesure des doses imposée par la réglementation. Elle est faite en France au moyen de films radiosensibles. Leur développement est mensuel.

Epidémiologie

Etude des rapports existant entre les maladies et divers facteurs susceptibles d'exercer une influence sur leur fréquence, leur distribution, leur évolution.

Facteur de pondération des neutrons

Facteur multiplicateur utilisé pour convertir la dose absorbée (Gy) en équivalent de dose (Sv) qui résulterait de la même énergie reçue à partir d'un rayonnement de référence (X ou γ). Ce facteur varie entre 5 et 20 suivant les niveaux d'énergie des neutrons : ceci exprime une plus grande « nocivité » biologique des neutrons.

Filtre à sable

Installation de filtration avant rejet à la cheminée destinée à contrôler les situations accidentelles extrêmes. En cas de montée en pression de l'enceinte de confinement du réacteur, faisant suite à une dégradation du circuit primaire, il serait aussi possible de « dégonfler » cette enceinte avant sa rupture, à un moment choisi en fonction des conditions météorologiques, et en retenant le maximum de particules d'aérosols radioactifs (iode et césium).

Génotoxique

Corps pouvant avoir un effet défavorable sur le patrimoine génétique (ADN...)

Halogènes

Iode, brome, fluor, chlore. En centrale nucléaire, il s'agit essentiellement des isotopes de l'iode.

Limite annuelle d'incorporation (LAI)

C'est l'activité (« nombre de Bq ») qui, absorbée par un individu, entraîne un équivalent de dose égal à la limite annuelle réglementaire -actuellement 50 mSv.

Métrologie des rayonnements

Méthodes et moyens de mesure des énergies des différents types de rayonnements ionisants (plus particulièrement en vue de calculer les équivalents de dose reçus par les personnes exposées).

Physiopathologie

Etude des mécanismes qui entraînent les maladies, et qui permet d'en expliquer les symptômes.

Radiobiologie

Etude des effets biologiques des rayonnements

Radioécologie

Etude du comportement des radioéléments dans l'environnement terrestre et aquatique, et tout particulièrement des voies de transfert vers l'homme par les chaînes alimentaires.

Radiopathologie

Etude des maladies imputables aux rayonnements ionisants

Radiotoxicologie

Etude des effets toxiques chimiques ou radiologiques imputables aux radioéléments incorporés par inhalation ou ingestion.

Spectrométrie

Analyse de l'intensité d'un rayonnement émis par une source en fonction de son niveau d'énergie ; cette méthode permet à la fois d'identifier les radioéléments (raies γ caractéristiques) et de préciser leur « activité » (aspect quantitatif)

Stochastique

Qui obéit — en apparence du moins — aux lois du hasard ; les phénomènes stochastiques sont donc aléatoires, et s'étudient par les méthodes statistiques.

Transmutation

Transformation d'un élément radioactif en un autre de numéro atomique différent (par bombardement neutronique par exemple). Le nouveau corps obtenu -dans l'optique du stockage- doit être soit non radioactif, soit de période radioactive plus courte.

Liste des textes mentionnés

- CIPR 60 : « 1990 Recommendations of the international Commission on Radiological Protection ».
- Directives EURATOM :
 - 90/641 du 04.12.1990 concernant la protection opérationnelle des travailleurs extérieurs exposés à un risque de rayonnement
 - 89/618 du 27.11.1989 concernant l'information de la population sur les mesures de protection sanitaire applicables et sur le comportement à adopter en cas d'urgence radiologique
 - Normes de Base en radioprotection : projet final SEC (92) 1322 du 06.07.1992, destiné à remplacer la Directive 80/836 de 1980 (modifiée par la Directive 84/647)
- Réglementation française
 - Décret 91-730 du 23.07.1991 sur la médecine du travail des salariés temporaires
 - Arrêté du 31.07.1991 relatif à la surveillance médicale des travailleurs
 - Décret 92-158 du 20.02.1992 relatif aux prescriptions particulières d'hygiène et de sécurité applicables aux travaux effectués dans un établissement par une entreprise extérieure.
 - Décret 66-450 du 20.06.1966 -modifié par le Décret 88-521 du 18.04.1988- relatif aux principes généraux de protection contre les rayonnements ionisants.
 - Décret 88-715 du 09.05.1988 relatif à l'harmonisation des mesures de la radioactivité.
 - Loi 91-1381 du 30.12.1991 relative aux recherches sur la gestion des déchets radioactifs.
 - 7 arrêtés du 10.08.1976 relatifs aux autorisations de rejets radioactifs (conditions des études préliminaires -conditions de l'enquête publique- règles générales applicables aux rejets -règles propres aux centrales nucléaires, etc.)
- Rapports parlementaires (Office parlementaire des choix scientifiques et technologiques)
 - Rapport « BIRRAUX-SERUSCLAT » du 17.12.1990 sur le contrôle de la sûreté et de la sécurité des installations nucléaires (N° 1843 - Assemblée Nationale)
 - Rapport BIRRAUX du 06.12.1991 sur le même sujet (N° 2417 - Assemblée Nationale)
 - Rapport BATAILLE du 14.12.1990 sur la gestion des déchets nucléaires à haute activité (N° 1839 - Assemblée Nationale)
 - Rapport LE DEAUT du 22.04.1992 sur la gestion des déchets très faiblement radioactifs (N° 2624 - Assemblée Nationale)
- Autres rapports
 - Rapport GARDENT (Collège de Prévention des risques technologiques) -janvier 1991 (il s'agit en fait d'un avis) sur la politique de fin du cycle nucléaire.
 - Rapport DESGRAUPES (Commission d'examen des dépôts de matières radioactives) de juillet 1991 concernant les dépôts de matières radioactives.
 - Rapport N° 23 de l'Académie des Sciences « Risques des rayonnements ionisants et Normes de radioprotection » - novembre 1989
 - UNSCEAR 88 -Rapport du Comité Scientifique des Nations Unies pour l'étude des effets des rayonnements atomiques « Sources, effets et risques des Rayonnements Ionisants ».
- Documents divers
 - Recommandations du CSSIN (17.01.1991)
 - Enquête CEPN sur les caractéristiques de l'organisation de la radioprotection dans les centres de production nucléaire à l'étranger (rapport N° 186 -juin 1991)
 - Enquête EURELECTRIC sur la formation des « experts qualifiés » (novembre 1992)
 - Médecins et risque nucléaire : conduite pratique en cas d'accident (Faculté de médecine de GRENOBLE - Ordre des médecins - SCPRI - Conseil Général et Préfecture de l'Isère)

Ces documents peuvent être le cas échéant obtenus (copie ou prêt)
 au Comité de Radioprotection d'EDF
 Service Documentation
 Téléphone : (1) 40.42.37.67
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