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The NEA Contribution to the Evolution of the International System of Radiological Protection

NUCLEAR ENERGY AGENCY

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THE NEA CONTRIBUTION TO THE EVOLUTION OF THE INTERNATIONAL SYSTEM OF RADIOLOGICAL PROTECTION

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FOREWORD

With the finalisation of the new International Commission on Radiological Protection (ICRP) recommendations, approved by the ICRP Main Commission in March 2007 and published in December 2007, eight years of significant work by the NEA Committee on Radiation Protection and Public Health (CRPPH) on the evolution of the system of radiological protection came to an end. In order to validate this work, the CRPPH agreed during its May 2007 meeting that an assessment of the impact of the NEA's extensive efforts on this subject should be undertaken. Four consultants were engaged to accomplish this. Given the large volume of CRPPH reports and documents to be considered, the work was divided into four groups, one group per consultant. In addition, four key topics were selected which all consultants were asked to address.

The work of the CRPPH was thus reviewed largely chronologically, comparing the Committee's work to the ICRP draft recommendation material available at the time. This approach allowed the assessment to illustrate the evolution of views in both the CRPPH and in the draft texts of the ICRP.

To facilitate the assessment of such a large volume of work produced by the CRPPH on this subject and during the time period of interest (1999 to 2007), the assessment work by the consultants was divided into the following four groups, one being assigned to each consultant:

- CRPPH expert group reports;
- assessments of draft ICRP materials by the CRPPH Expert Group on the Implications of ICRP Recommendations;
- CRPPH Asian regional conferences;
- other CRPPH conferences.

By retrospectively analysing the concerns of the CRPPH, four key topics were also selected for inclusion in the consultants' impact assessment:

- justification;
- dose constraints and reference levels;

- exposure situations (planned, emergency, existing);
- exclusion/exemption/clearance.

The consultants (see biographies in Appendix) interacted electronically, sending the results of their work to the lead consultant for consolidation. The lead consultant reported the status of this work to the CRPPH in May 2008, and finalised the report as a result of CRPPH discussions. The final draft was sent to the CRPPH for review, comment and approval by correspondence and was subsequently published.

The CRPPH and the NEA Secretariat would like to heartily thank the lead consultant, Dr. Richard Osborne, and the three other consultants, Ms. Wendy Bines, Professor Henri Métivier and Mr. Tetsuya Oishi, for their meticulous work and for the high quality of the final report.

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EXECUTIVE SUMMARY

Background

The development of the new recommendations of the International Commission on Radiological Protection (ICRP) has been a very public and energetic process that has involved many individuals and organisations from around the world. One of these organisations is the Committee on Radiation Protection and Public Health (CRPPH) of the Nuclear Energy Agency. The CRPPH has been very engaged in this process, through its own commentaries and reviews, through those of one of its sub-committees, the Expert Group on Implications of the ICRP Recommendations (EGIR), and through conferences that it organised in Europe, the United States and Japan that facilitated direct interaction between the participants and members of the Main Commission of the ICRP. This report is a look at that process, with the intention of assessing how influential the involvement of the CRPPH has been on the finished product and whether it has helped to improve the understanding of the new system of protection.

For our review we have:

- reviewed the reports and discussions of the CRPPH and the EGIR that have commented on the issues that needed resolving in radiological protection and that have critiqued the successive drafts of the ICRP recommendations;
- reviewed the discussions in the conferences in Japan, Europe and the United States, organised by the CRPPH, that have focused on the development of the new recommendations;
- reviewed the successive drafts of the ICRP recommendations, the related draft ICRP reports that were available whilst the recommendations were being developed, and the final published recommendations; and
- tracked the discussions in these reports and conferences on nine topics and the changes made by the ICRP in those topics through the successive drafts of the recommendations.

The topics we have chosen to follow are: justification; optimisation; exposure situations; application of the linear non-threshold model; dose

constraints and reference levels; exclusion, exemption, clearance and authorisation; collective dose; environmental protection; and stakeholder involvement. An aspect of the early development of dose constraints has been the adoption of the particular values of 0.1 mSv/a and 0.3 mSv/a. Comments on this development are included in an appendix.

Justification

An initial suggestion from the ICRP that justification was not needed as a principle in the system of protection met with strong opposition. (At least, not needed outside the medical area – the ICRP was expanding the role of justification in medicine at the time that suggestion was made). Justification's role as a principle has, in fact, been retained with much more explanation of its role than in the previous recommendations, specifically with planned and existing exposures and exposures in emergencies. Such explanations had been called for in the various reviews.

Successive drafts of the recommendations picked up many specific points made in the reviews and discussions. The evolution of the basic idea of justification was, if anything, from its initial diminished role back towards that of ICRP Publication 60. Changes that followed suggestions made include that justification involves taking a balanced view of all benefits and detriments; that it is not limited to the introduction of new practices; that there may be a broad responsibility for justifying, depending on the circumstances; and that there may need to be a re-examination of a justified situation if the technology changes or there is new information. The possible role of stakeholders in decisions regarding justification, as suggested in reviews and conferences, is now also highlighted.

There was some initial questioning of why justification in the medical field was substantially different from that in other areas but that it was different appears to have been accepted in later conferences and reviews. The ICRP, in fact, provided a substantially expanded description of justification in medicine.

Some issues that were raised in the reviews and conferences appear not have been addressed directly. There is little or no discussion of the nature of the radiological input to the decision making process. There is no description of the elements of justification decisions. The text still implicitly includes smoke detectors as an unjustified practice and justification could still be read as one of determining the best of available alternatives. Further, there is still no highlighting of the notion of benefits from exposure-causing activities.

Optimisation

The initial indication was that the role of optimisation would be reduced, with the emphasis in the new system being on the doses to individuals. This prompted strong feedback from the radiological protection community, and the CRPPH in particular. Reflecting this input, the new recommendations maintain optimisation as a key principle; indeed, the ICRP itself comments in the new recommendations that optimisation is strengthened in importance and its implementation is extended to all types of exposures.

Concern was expressed by the EGIR and others that the familiar idea of ALARA was being lost. However, the new definition of optimisation now retains the idea of *as low as reasonably achievable*. Another change made by the ICRP was in its initial suggestion that the application of *best available technology not entailing excessive costs* was the approach to be used for optimising the control of effluents. In later drafts, the ICRP indicated that it considered that approach to be complementary to the application of ALARA, which reflected comments from the EGIR. The EGIR had also expressed concern over the suggestion in an early draft of the recommendations that the basic role of optimisation was to foster a safety culture. In the new recommendations safety culture is mentioned only in the context of delegation of authority.

The need for practical guidance on optimising protection was frequently expressed. Guidance has been provided, or is promised in future reports, for a variety of situations, including in medicine. There is, however, no detailed guidance yet on some issues, which were identified in the reviews and conferences. Examples are the issues that arise in risk transfer, such as between worker, public and the environment, and those that arise in taking the potential for exposures into account during optimising.

Exposure situations

An early input from the CRPPH to the debate on changes needed in the ICRP recommendations was that difficulties had arisen in trying to distinguish between *practices* and *interventions*. The ICRP has acknowledged that the distinction was artificial and has introduced a different set of categories for what it termed *exposure situations*: namely *planned*, *emergency* and *existing*. There has been agreement that these designations would be clearer and more useful than the previous ones.

The definition and guidance on the application of the three categories of exposure were refined through the successive drafts, reflecting input from the

CRPPH, EGIR and other reviewers. Much of the input was on detailed wording. For example, potential exposure is included after being omitted from the earliest draft; potential exposures are more clearly explained; accidents are more clearly differentiated from far future potential exposures; the discussion of emergencies and existing situations has been consolidated; and a description of planned exposures as being *deliberate* has been removed.

There remains some concern about the impact of the suggested changes on national regulations and standards for intervention levels. There is also the possibility for confusion over the split of planned exposures into *normal* and *potential*, given that natural radiation exposures could be seen as being normal. (However, if the full definition of planned exposure is taken into account – a situation involving the deliberate introduction and operation of sources – there need be no confusion.)

Application of the linear non-threshold model

The first concern expressed by the CRPPH was the need to emphasise in the recommendations that the LNT model was only a regulatory tool for dose and risk management. Further, there needed to be a clear rationale for its use. In the recommendations such qualifications have been added to the rationale for using the LNT model. It is said to be a prudent basis for the *practical* purposes of radiological protection, i.e. the *management of risks* from low dose radiation exposure.

The ICRP has provided a detailed discussion of the issues surrounding the LNT model. The ICRP makes it clear that, in its view there is no weight of evidence to support the idea that a model of cancer risk with a supra-linear dose response or one with a low dose threshold should be preferred for the purposes of radiological protection. During the discussions there were strong opinions presented for the existence of a threshold for cancer induction by radiation, and, in particular, for a practical threshold for the effects from alpha emitters. The ICRP has acknowledged that the level of risk associated with very-low-dose exposure is not actually known and that the LNT model has not been universally accepted as biological truth. Nevertheless, the ICRP has retained the LNT model as a prudent basis for the practical purposes of radiological protection at low doses and low dose rates.

In describing the rationale for the use of the LNT model, the ICRP emphasises that the LNT model is a regulatory tool, although it is noted that a proportionate increased incidence of cancer or heritable effects with radiation dose is a scientifically plausible assumption. The ICRP rationale for the prohibition on the use of the LNT model for risk assessment is that, because of

the uncertainty on effects at low doses, it was not appropriate for the purposes of public health planning to calculate the hypothetical number of cases of cancer or heritable disease that might be associated with very small radiation doses received by large numbers of people over very long periods of time. The EGIR still appears to have concerns with this. Uncertainty does not preclude estimation; it means that any estimate has a commensurate confidence interval. The EGIR considered that the relevant point was not whether the predicted number of cancers was accurate but rather how far their spatial and temporal distribution made them a priority. Further, there remains a lack of quantification of small doses and very long periods. Resolving this issue with its apparent contradictions may well be a Sisyphean task.

Dose constraints and reference levels

The topic of dose constraints and reference levels was the most controversial topic in the reviews and elicited most discussion and comment. Initially dose constraints were suggested by the ICRP as becoming the fundamental indicators of protection, but there were strong objections to the implied demise of the dose limit as the criterion for the third principle of protection. This designation as the fundamental indicator has been reduced in the new recommendations. The application of the dose limit remains the fundamental third principle.

The concept of the dose constraint has evolved and expanded from that of ICRP Publication 60, however, and dose constraints and the companion reference levels are a major part of the new recommendations. Their final form reflects, to some extent, the lengthy discussions and reviews by the CRPPH, EGIR and the various NEA conference participants, though there are still outstanding concerns. Examples of both resolved and outstanding issues are given below.

There is now a reasonably clear explanation of the application of dose constraints in the three types of exposure situation, and also of the relationship between constraints and intervention levels. Most of the text on dose constraints and reference levels has been consolidated as requested.

The framework for setting the numerical values of the various constraints and levels was originally a scale of concern that was benchmarked to natural background radiation. The reaction to this approach was mixed. Some were comfortable with the link; others preferred a risk-based approach to setting values. There was the view that a basis of natural background would not help understanding. The outcome in the final recommendations was a framework with less stress on natural background; the highest band of values being related

to where health effects could be observed; the lowest band to what were considered small increments to natural background. The ICRP acknowledges in the new recommendations that there may be exceptional circumstances that might warrant allowing exposure above the maximum value for a reference level. That has been another EGIR point.

Numerical values for the specific constraints and levels were suggested by the ICRP in one of its drafts. Following advice from the discussions, specific numerical values (except for the values 0.3 mSv in a year and 0.1 mSv in a year) were not provided in the final document; only a dose-based framework to aid their selection.

A concern with early drafts was that constraints could be seen as prescriptive limits. The final recommendations are clear that constraints should not be understood or used that way. There was also a concern that there would be no flexibility in setting the numerical values and in applying them. This is addressed to some extent by the suggestion that the choice should reflect national or regional attributes and preferences. Also acknowledged in the recommendations is the point from the conferences and the EGIR that operators in large industries may fix occupational exposure constraints.

Outstanding issues that have been raised in the reviews and do not appear to have been completely addressed include:

- inadequate explanation of the difference between the old and new concepts of dose constraints and the relationship between dose constraints and dose limits;
- concern that the flexibility allowed in the choice of constraint for public exposure is insufficient to obviate practical difficulties in cases such as mines at the site boundary or for on-site exposure of non-nuclear workers;
- insufficient guidance on the scientific issues and aspects to take into account to when arriving at numerical values;
- the impression that dose constraints are still *restrictions* rather than *controls*;
- no specific role for stakeholder involvement is written in; and
- no clear discussion of the practical aspects of identifying sources and choosing appropriate constraints.

An appendix to the main report provides the history behind the choice of the values of 0.3 mSv in a year and 0.1 mSv in a year for radioactive waste

management and for radioactive waste repositories in some circumstances. The choice of these values was quite clearly based largely on qualitative considerations. These considerations may not be closely applicable in any particular situation, which lends support to the advice from the ICRP in its new recommendations that application of the dose constraints must depend on local circumstances.

Exclusion, exemption, clearance and authorisation

Initial concerns were that the concepts of exemption and exclusion were not well understood; triviality as a criterion gave rise to problems; and clearance was ignored by the ICRP.

The recommendations now have a lengthy description of the concepts and their application, backed up by the more detailed publication on the scope of the recommendations.

During the evolution of the recommendations, commentators pointed out perceived inconsistencies in ICRP's interpretation of its suggested criteria for exclusion and exemption. In the final document, the ICRP acknowledges that the distinction between exclusion (*cannot* be regulated), and exemption (*need not* be regulated) is not absolute and the different authorities might make different decisions whether to exempt or exclude. In effect the new recommendations allow the flexible, case-by-case, approach recommended during the reviews by the EGIR. Discussion of the concept of clearance, initially ignored by the ICRP, has been included in the supporting publication on the scope of the recommendations.

The process of regulatory authorisation advocated by the CRPPH was not adopted as such by the ICRP but the process as proposed by the ICRP is broadly consistent with the CRPPH's model. The process flows are essentially the same. Regulators could follow either scheme and keep within the spirit for the recommendations.

The ICRP was strongly advised not to recommend specific numerical values for exemption and clearance. The ICRP has followed this advice noting that, though such values would promote international coherence, it neither endorses nor disapproves their use.

Collective dose

The initial move by the ICRP to eliminate collective dose as a useful quantity in radiological protection met with resistance. The final document acknowledges that it should remain a key parameter in occupational protection.

The long-held contention by the ICRP that it was inappropriate to use collective dose as a tool in risk assessment and the CRPPH position that it was not a useful tool for estimating absolute detriment were in accord. But the latter position was not unanimous, as shown by the EGIR discussions. There was also disagreement about whether truncation of the collective dose in dose and time was a valid approach in risk assessment – a debate with a long history. The text that the ICRP has added to the statement in its final report to the effect that collective dose is not intended as a tool for epidemiologic risk assessment and it is therefore inappropriate to use it in risk projections based on epidemiological studies can be seen as a response to EGIR concerns.

A statement from the ICRP (in the 2005 draft recommendations) on the use of collective dose in optimising protection defined the issue with the use of collective dose. The ICRP stated that, for making decisions, a large dose to a small number of people is not equivalent to a small dose to many people, even if the two cases corresponded to numerically equal collective doses. Though not stated explicitly in subsequent drafts the sense remains and, in fact, there appears to have been a consensus, early in the discussions, that disaggregation of collective dose made sense. The development by the ICRP of the idea of a multi-element dose matrix was consistent with this but continued discussions on the topic, both in the EGIR reviews and in conferences, have pointed to uncertainty about how the matrix might be used in practice and, in particular, what criteria might guide the weighting of the various elements. The ICRP has stated it has no intention of giving detailed guidance, other than suggesting giving less weight to very low doses and to doses received in the distant future. This appears to leave the question open, although the detailed text that the ICRP now has can be seen to be responding to many points raised in the discussions and reviews.

Two identified issues remain. One is that with the recommended dose matrix scheme, in which individual dose may dominate, there seems to be no restraint on dilution appearing to be the optimum control method for radioactive contamination of the environment. The other issue is that it is still not clear how inequities should be handled within the matrix. Other than these caveats, the concerns expressed by the CRPPH and the EGIR appear to have been addressed.

Environmental protection

The reaction within the radiological protection community to the proposal by the ICRP that it should develop an environmental protection strategy was one of caution. A strongly held view was that additional recommendations on the environment were not needed from the ICRP. Many issues that would arise with such a development were voiced; the need for a definition of the environment and protection principles; the need to fit in with current frameworks for other health and environmental risks; the need to resolve disagreements about the significance of radiation exposures on the environment. There was agreement that any developments by the ICRP should be seen as not being driven by concern over environmental radiation hazards. More importantly, the need was to be able to explain the situation to the public.

The ICRP through successive drafts reflected this advice. Its position was that it did not intend to set regulatory standards for environmental protection. The intent was to provide a framework and tools for assessment to help the decision making process; initially these would be reference flora and fauna. The ICRP agreed that it was not driven by concern over the environment and it restated its previous position that the standards of environmental control needed to protect the general public would ensure that other species were not placed at risk.

The discussions in the various EGIR reviews and the conferences indicated that, though there seemed to be broad agreement on the cautionary points noted above, there was a diversity of opinions about what the ICRP should actually do (or not do). The final position of the ICRP appears to be a cautious move to providing tools that can be used now and to gather and interpret data with a view to providing further advice in the future. This is in accord with the advice it has received from the CRPPH.

Stakeholder involvement

In 1999 the ICRP had suggested that involving stakeholders could help when decisions were being made about protection when there were prolonged exposures. The CRPPH encouraged the ICRP to broaden its endorsement of involving stakeholders – such involvement helped acceptance and fostered confidence. The CRPPH noted that significant stakeholder involvement, beyond that of the regulatory authority and the licensee, would not be needed in many cases.

The ICRP's initial suggestion, reflecting this advice, was that stakeholders could be involved in determining or negotiating the best level of protection.

This prompted strong reaction on two counts. One was that there should be a clear distinction between involvement as a decision *aider* – the role of the stakeholder – and decision *maker* – the role of the regulator or other authority. The other was the cultural difference between Asian and European countries, a difference that continued to be brought up through the various conferences. In the Asian view stakeholder involvement was largely a means of gaining public acceptance. The European view was more the idea of taking part to have an input, although the public acceptance aspect was clearly also important.

Subsequent drafts from the ICRP tried to meet these caveats. The involvement was seen as means to incorporate values into decisions, to improve the quality of decisions, to resolve conflicts among competing interests, to build trust in institutions, and to educate and inform workers and the public. The ICRP referred to *appropriate social processes*.

Before the final document was completed by the ICRP the EGIR pressed for more explanation, for an emphasis on the need to set up ongoing programmes with stakeholders, and for explicit mention of stakeholders' role in optimising. In the end, the ICRP has pointed to the detailed discussion of stakeholder involvement in its report on optimising and has settled for a more general statement in its main recommendations. This notes that societal values influence final decisions on levels of protection and that the decision making process *may* often include the participation of relevant stakeholders.

Conclusions

We found that, in all the topics we reviewed, the evolution of the recommendations through the successive drafts reflected many of the views and criticisms that had been expressed by the CRPPH, the EGIR and conference participants. There were, of course, other inputs to the ICRP but those from the CRPPH groups, which represented the distillation of the views from radiological protection experts from the NEA member countries, appear to us likely to have been the most coordinated, detailed and persistent appraisals.

An indicator of the overall impact that the interactive process has had is that, as the ICRP points out, the new recommendations do not contain any fundamental changes in policy. This was not the direction that the evolution of the recommendations appeared to be taking at the start of the process.

The list below shows, for each of the topics we have reviewed, the single most important evolutionary change that reflects the suggestions and concerns of the CRPPH, the EGIR and conference participants.

- Justification is retained as a principle.
- The role of optimisation has been strengthened throughout the system of protection.
- Dose limits for individuals have been retained
- The definition of and guidance on the new categories of exposure have been refined.
- The role of the linear non-threshold model as a regulatory tool is emphasised.
- Some issues surrounding the application of dose constraints and reference levels have been resolved and more advice is promised.
- There is flexibility in the application of the concepts of exclusion and exemption, with which the CRPPH's process of authorisation is coherent.
- Collective dose remains for use in occupational settings and, in a limited way, for use with public exposures.
- The expansion into environmental protection is cautious and appropriate to ICRP's niche.
- The involvement of stakeholder is endorsed, with the emphasis that it is decision aiding.

A continuing request from the CRPPH and the EGIR in their successive reviews was for clearer explanations of the various concepts and processes in the evolving system of protection. Through successive drafts these explanations have been developed along with adjustments to the concepts and processes themselves. The focus of the EGIR discussions also evolved from review to review. Agreement with changes that had been made was noted in some cases, but, though explanations in the successive ICRP drafts did evidently become clearer, we cannot say whether the evolution of the focus of the CRPPH and EGIR comments was a result of these clearer explanations or was indicative of an increased understanding of the ICRP's concepts and recommendations by the CRPPH and EGIR.

As might be expected, not all the suggestions from the various review groups were adopted and not all identified issues were resolved. Consequently,

there are continuing concerns in some areas. One is the application of dose constraints and reference levels, where many of the concerns have not been resolved. Another reflects the misgivings about the persuasiveness of the rationale for the use of the LNT model as a regulatory tool but not its use in risk assessment, although it is accepted by the ICRP as being a scientifically plausible model. A third concern is with the criteria for weighting the elements of the dose matrix and the practical use of the matrix in optimisation.

The process that has been followed has exemplified stakeholder involvement. There has been interaction between stakeholders and the members of the Main Commission of the ICRP, and input from the stakeholders to the development of the new recommendations. The outcome has been influenced by that input. The final say has, though, been with the ICRP. The process has been one of decision aiding, rather than decision making. Further, the interactions with the ICRP have helped the understanding of the system of protection. The interactions appear to have been particularly helpful in Asia. The three conferences in Tokyo allowed for a much greater participation of the Asian radiological protection community in the decision making process than in the past, with the consequent better mutual understanding.

There are certainly changes in concepts, quantities and processes, as our review has illustrated, which could be the basis for eventual changes in national legislation and regulations. Our review has also illustrated that there remain concerns and questions about some of these changes. Given that there are no fundamental changes in the policies underlying the system of protection, there would appear to be no great urgency for national regulators to enact new legislation immediately. This means that there is time for the radiological protection community in general, and the CRPPH in particular, to take stock of the implications of moving towards the system of protection as it is now defined by the ICRP; to define the changes in regulations that might be needed and how best they might be implemented; and to assess whether the costs of such changes are likely to result in a commensurate increase in radiological safety.

1. INTRODUCTION

The development of the new recommendations of the International Commission on Radiological Protection (ICRP) has been a very public and energetic process that has involved many individuals and organisations from around the world. The Committee on Radiation Protection and Public Health (CRPPH) of the Nuclear Energy Agency (NEA) has been very engaged in this process. This report is a look at that process with the intention of assessing how influential the involvement of the CRPPH has been on the finished product and whether it has helped to improve the understanding of the new system of protection.

What might be thought of as the modern framework of radiological protection was laid down by the recommendations of ICRP Publication 26 (ICRP, 1977), a document that was developed largely within the ICRP's own committees. There was considerable refinement of the system of protection in the recommendations of Publication 60 (ICRP, 1991) and through the next decade the ICRP extended its recommendations in additional publications on specific topics. Although the members of the Main Commission of the ICRP and its committees interacted formally and informally with various international agencies and would have been well aware of issues that might have been arising amongst the practitioners in radiological protection, the production of its documents was mainly a process internal to the ICRP.

Since 1991 however, it had been clear to many in the radiological protection field that the increasing complexity of the ICRP recommendations – a consequence of the broadening of their scope – had led to inconsistencies, misunderstandings, and misapplications of the principles and tools. The ICRP was very aware of many of these issues and concerns and, in the mid-90s Professor Roger Clarke, the Chairman of the ICRP at that time, initiated a reconsideration of the fundamental principles and structure of the system of protection. A series of papers and presentations by Professor Clarke (for example, Clarke, 1999) stimulated the radiological protection community to get involved with the ICRP in recasting the recommendations. The objective was to develop a coherent, less complex, system of protection without the problems that had been identified in the existing system. The initial interactions with the

radiological protection community made it clear, however, that solving any one issue could well result in issues elsewhere.

With the introduction by the ICRP of successive drafts of the new recommendations, the interactions between the protection community and the ICRP continued at the formal inter-agency level, in national and international conferences involving members of the Main Commission, through feedback on the ICRP website and feedback by way of journal publications and agency reports. The largest co-ordinated interaction has been spearheaded by the Nuclear Energy Agency (NEA) through its Committee on Radiation Protection and Public Health (CRPPH). The interaction has involved conferences in various countries at which there was direct interaction with ICRP main commission members and detailed reviews and commentaries on the successive ICRP drafts by the CRPPH and a subcommittee, the Expert Group on the Implications of the ICRP Recommendations (EGIR). The time line[1] of these interactions and documents is shown in Table 1-1, culminating with the publication of the final recommendations – Publication 103 – in 2008.

The international effort has been huge, not least that of the CRPPH. Stakeholders with interests spread throughout the field of radiological protection from many countries have had their say. How well has the process worked? Have the concerns of the CRPPH been met? These are reasonable questions, which this review addresses.

Clearly, although the CRPPH-related activities have provided or stimulated much of the feedback to the ICRP, there have been many others who have contributed, as individuals or on behalf of organisations or agencies. Separating out how any particular comment or suggestion from any particular stakeholder was treated by the ICRP is out of the question for us. The ICRP, quite reasonably, did not follow the practice of responding to all interventions with a formal disposition of comments that regulatory agencies often follow after public comments are received on draft documents. Nevertheless, we have attempted to assess the extent to which the suggestions in the contributions from the CRPPH and its related activities have been reflected in the evolution of the ICRP recommendations and we have attempted to make some judgment about how effective the consultative process has been.

1. Note that the 2005 ICRP draft appeared in 2004 and the final document, the 2007 Recommendations (Publication 103), was published in 2008.

iTable 1-1: Chronology of the development of the ICRP recommendations from 2000 to 2008, showing the timing of draft and final documents from the ICRP, of CRPPH reports, of reviews by the EGIR, and of the CRPPH-sponsored conferences that were specifically on the evolving recommendations. ICRP reports that became available in the period but which have not been explicitly discussed in the reviews and conference we are considering here are omitted from the list. Also omitted are other NEA documents that are referred to in the text but which were not specifically on the evolving recommendations.

ICRP document **NEA sponsored activity**	**Reference**
• Report: A Critical Review of the System of Radiation Protection	NEA, 2000
• Report: The Way Forward in Radiological Protection	NEA, 2002
• Conference: Taormina, Italy; 2002	NEA, 2003a,b
Protection of Non-Human Species from Ionising Radiation: Proposal for a Framework for the Assessment and Management of the Impact of Ionising Radiation in the Environment	ICRP, 2002a
• Conference: Tokyo (1), Japan; 2002	NEA, 2004a
The Evolution of the System of Protection: the Justification for the New ICRP Recommendations	ICRP, 2002b
• Report: A New Approach to Authorisation in the Field of Radiological Protection	NEA, 2003c
• Report: Possible Implications of Draft ICRP Recommendations (EGIR 1)	NEA, 2003d
• Conference: Lanzarote, Spain; 2003	NEA, 2004b,c
2005 Draft: Recommendations of the International Commission on Radiological Protection	ICRP, 2004
• Conference: Tokyo (2), Japan; 2004	NEA, 2005a
• Review: EGIR 2	NEA, 2004d
• Report: Optimisation in Operational Radiological Protection	NEA, 2005b
Draft: The Optimisation of Radiological Protection – Broadening the Process	ICRP, 2005a
• Report: The Process of Regulatory Authorisation	NEA, 2006a

2006 Draft: Recommendations of the International Commission on Radiological Protection	ICRP, 2006a
Assessing Dose of the Representative Person for the Purpose of Radiation Protection of the Public *and* The Optimisation of Radiological Protection: Broadening the Process; Publication 101	ICRP, 2006b
• Conference: Tokyo (3), Japan; 2006	NEA, 2007a
• Conference: Washington DC, United States; 2006	NEA, 2008a
• Conference: Prague, Czech Republic; 2006	NEA, 2008b
• Review: EGIR 3	NEA, 2006b
• Report: Environmental Radiological Protection in the Law: A Baseline Survey	NEA, 2007b
• Report: Summary of the Tokyo, Washington and Prague Conferences	NEA, 2008c
2007 Draft: Recommendations of the International Commission on Radiological Protection	ICRP, 2007a
• Review: EGIR 4	NEA, 2007d
2007 Draft#2: Recommendations of the International Commission on Radiological Protection	ICRP, 2007b
2007 Recommendations of the International Commission on Radiological Protection; Publication 103	ICRP, 2008a
Scope of the Radiological Protection Control Measures; Publication 104	ICRP, 2008b

2. TERMS OF REFERENCE

The objectives of the review are to show:

- What the involvement of the CRPPH was able to accomplish, both in terms of moving the ICRP position and evolution of the CRPPH understanding.
- Whether the development process followed by the CRPPH and the ICRP is a good example of stakeholder involvement that could serve as a model for the development of other international recommendations, standards and guidance.
- How the CRPPH members interpret the key aspects of the new recommendations and intend to take them forward for implementation at the national level.

3. APPROACH AND TOPICS CONSIDERED

The issues and concerns that have been expressed about the system of protection as established by ICRP Publication 60 (ICRP, 1991) and about the developing new recommendations were identified from an initial review of the NEA documents that included reports from the CRPPH, comments from the EGIR on ICRP drafts, and the proceedings of the various conferences. In order to provide a structure for the review, we selected what could be regarded as key topics for detailed appraisal of the way in which the treatment of each one evolved through the process. We recognised that our review would only be a sampling of all the ideas expressed, of the comments made throughout the interactions and of the responses from the ICRP as reflected in the successive drafts. However, we have tried to sample a sufficiently broad range of topics for us to come to some conclusions about the effectiveness of the process. The issues and concerns identified in this preliminary review are in the list below.

Principles

Justification*

Optimisation*

Dose limits

Nature of the system of protection

Exposure situations*

Components of the process of protection

Scientific base for the recommendations

Roles and responsibilities

Relationship of recommendations to those of other international organisations

Issues concerning concepts, quantities and numerical values

Application of the linear non-threshold model*

Terminology: quantities and units

Dose coefficients

Uncertainties

Risk coefficient determination

Tools in protection

Dose constraints and reference levels*

Exclusion, exemption, clearance, triviality, authorisation*

Collective dose*

Numerical criteria in general

Miscellaneous topics

Exposures to natural sources

Stakeholder involvement*

Environmental protection*

Genesis of the dose constraint values 0.1 mSv/a and 0.3 mSv/a*

Potential exposures

Medical exposures and related issues, pregnant women, caregivers

Clarity of expression in language used, reflecting need for translation

The items with the asterisk in this listing of key topics were chosen for the review, namely:

Justification

Optimisation

Exposure situations

Application of the linear non-threshold model

Dose constraints and reference levels

Exclusion, exemption, clearance and authorisation

Collective dose

Environmental protection

Stakeholder involvement

The dose constraint values of 0.1 mSv/a and 0.3 mSv/a originated before the ICRP started developing the new recommendations, although there were comments about the values during the discussion of dose constraints and reference values in general. Accordingly, we have outlined the early history of the values in an Appendix.

The initial concerns that were expressed about each of the nine key topics have been noted and the discussions and suggestions that arose in the successive CRPPH reports, EGIR reviews and CRPPH-sponsored conferences have been documented, together with relevant points from the ICRP recommendations as they evolved through the various drafts. We have focused on the aspects of each of the topics that have elicited debate and comments, rather than attempt to provide a comprehensive description of the evolution of all aspects of the topics through the successive drafts.

Our review has provided a basis for assessing the extent to which the inputs from the CRPPH activities appear to have influenced the evolution of the ICRP recommendations and for judging the extent to which the involvement of stakeholders through this process has been successful.

4. EVOLUTION OF THE RECOMMENDATIONS

4.1 Justification

The principle of justification was succinctly stated in the recommendations of ICRP Publication 26 (ICRP, 1977) as "no practice shall be adopted unless its introduction produces a positive net benefit" (§ 12). The key aspects of its application were noted in that report; namely its application in considering the introduction of sources and the reduction of exposures (§ 81) and in considering medical exposures (§ 197 et seq.). It was also noted that radiation detriment may be only one of many factors that would be considered (§ 69). The recommendations of ICRP Publication 60 (ICRP, 1991) elaborated only slightly on this guidance (see § 12, 113, 115, 116 and 179).

In discussing the directions that the ICRP might take in revising ICRP 60, Professor Clarke (Clarke, 1999) suggested that "since radiological protection essentially plays such a minor part in a government's decision to justify the introduction, or the continuation, of a given use of radiation, consideration should be given to dropping the principle of justification from the ICRP system."

However the CRPPH, in its initial review in 2000 (NEA, 2000) saw that aspects of justification were an essential part of the system of radiological protection. Though a clearer definition of justification in the context of radiological protection was needed, it was recognised that a broad based justification of, for example, nuclear power was not of particular practical use in radiological protection but there was an evident importance in justifying choices or actions, case by case. Examples were in decisions in medical diagnosis and treatments and in deciding whether a particular activity involving radioactivity should be allowed. These latter types of justification were seen by the CRPPH as being much more useful in practice, and, in the context of modern society, were seen as becoming increasingly important for choices involving stakeholders. Further, the choice of the most appropriate radiation protection option – optimisation – needed to be related to the justification. The CRPPH noted that the then current recommendations by the ICRP provided no guidance on this interaction.

Publications from the ICRP in the medical area about this time actually considerably expanded the guidance on justification in medicine and its relation to optimising (ICRP, 2000a, 2000b). The role of justification in other areas remained uncertain, though, and in 2002 the CRPPH published an elaboration of its concerns in discussing what it saw as the way forward (NEA, 2002). It reiterated its view that justification needed to remain one of the main principles of protection and that the views of stakeholders needed to be considered in the decision making. So, too, did technical and economic inputs, though the distinction between the scientific and political elements needed to be maintained. Further, the relationship between justification and optimisation needed to be explored and guidance was needed on how justification entered evaluations of old or existing practices. The CRPPH study that further explored the idea introduced in *The way forward in radiological protection*: An expert group report (NEA, 2002) for a comprehensive authorisation process reiterated the importance of having a justification step within the process (NEA, 2003c).

Another aspect of justification that needed to be considered arose in the discussions at the NEA Taormina workshop in 2002 on radiological protection of the environment (NEA 2003a, 2003b). The difficulty in harmonising the system of protection for humans with one for protecting the environment was a common theme from many participants. How the principle of justification might be applied was one of many issues; how should one factor in ideas about sustainability for example. A conclusion from the workshop was that it was not clear how justification in the ICRP sense could be approached without well-established ethical principles and a better understanding of the long-term implications of radiation-induced changes in biota.

The initial indication of the directions to be taken by the ICRP came in the document that discussed the evolution of the ICRP's system of radiological protection (ICRP, 2002b). It argued that, though the principle of justification was applied to establish an overall benefit from the introduction or continuation of a source of radiation exposure (a practice), this process was carried out by national authorities. Radiological protection was often just a minor consideration. Accordingly, the system of protection envisioned by the ICRP in its new recommendations would only apply to practices that had been declared justified and to natural sources that were controllable. The ICRP acknowledged that justification in the medical field would remain in the system but would be treated separately.

The initial reaction from the EGIR was that there was a need for more explanation of what was meant by the *new* concept of justification, and how this differed from the *old* concept of justification (NEA, 2003d). In respect of who was responsible for justifying the introduction of a new practice, the ICRP

suggestion that the responsibility lay with the appropriate regulatory authority was felt to be insufficiently precise. The EGIR suggested rather that the justification of practices should take place at the appropriate publicly accountable level, which could take a balanced view of all relevant benefits and detriments. A caveat discussing justification as it referred to medical doctors could also be included in the general description of this principle.

It also seemed too limiting to present justification as only needed for the introduction of new practices. Appropriate national authorities might wish to revisit the justification of an existing process or practice based on new science, technology or social factors. The EGIR felt strongly that the case-specific use of justification should not be limited to the medical field.

The ICRP's then current view of justification for practices and for natural sources that were controllable was seen by the EGIR as implying that there would need to be some discussion, and perhaps criteria developed, with respect to what was considered to be a controllable natural source. As this would apply to an area that had already caused some conflicts – that of naturally occurring radioactive material – the text finally developed by the ICRP would need to be clear, precise and convincing.

The implication that justification would be a very broad process, in which radiological considerations were not always the determining feature of the decision, led the EGIR to suggest that the ICRP should discuss the nature of the radiological input that could be of value to such decision processes. In the EGIR's view, it might have been helpful to reference other work also, such as that of NEA's Villigen workshops (NEA, 1998, 2001, 2004e), which could provide regulatory authorities with some insights in this area.

The description of the justification of medical exposures specified that it would be a two step process: one was a generic justification, for the broad use of X-rays in medicine, for example. The second one was for the specific use of an irradiation procedure for a specific patient. This implied that, for patients, the case-specific aspects of an irradiation were essential to the overall justification. For practices, however, the ICRP had not made this two-step distinction, implying that, for example, the siting of a new dose-causing facility would not invoke any question of justification. EGIR felt that the ICRP would need to discuss its views much more clearly on this issue. Also, the inter-relationship between justification and optimisation needed to be discussed

At the Lanzarote stakeholder conference in 2003 on the implications of the ICRP proposals (NEA, 2004b, 2004c) there was little discussion about justification as such. The need for more detailed elaboration of the application

of the principle was reiterated, as was the need for justification decisions to be broadly based; it was said that society must judge the totality of benefits from a practice against the totality of risks and that such decisions could be based on economic, strategic, medical, and defence, as well as scientific, considerations. Radiological protection input would, in general, play only a minor role. A suggestion from the conference was that the ICRP should provide guidance about the new types of public exposures for security reasons at airports and seaports. Whereas it was agreed that X-raying of luggage and materials was clearly justified, the suggestion that passengers should be irradiated for security purposes was clearly of questionable justification.

In the next (2005) draft of the ICRP recommendations (ICRP, 2004) a somewhat broader responsibility for justifying the introduction or continuation of practices was acknowledged (§ 18 "...governments or government agencies, or other relevant parties to ensure benefit in the broadest sense to society...") but the process was not elaborated any further. Methods of justifying practices were seen as being outside the system of protection. The two-step process of justifying medical procedures and exposures was expanded over the previous draft (§ 213-219). It was noted that the medical use of radiation was a practice that should be justified as was any other practice, although that justification lay more often with the profession rather than with government. In addition, the ICRP noted, a more detailed form of justification had to be applied to the procedures within the practice of medicine (§ 19). This was in the context of medicine and there was no indication that the ICRP saw this as applying to other types of practice. The particular instance of risk transfer where a second justification step could be taken had been given in the NEA study of optimisation in operational protection (NEA, 2005b). An example was in making decisions about plant modifications that incurred worker exposures in order to reduce public exposures.

In reviewing the 2005 draft ICRP recommendations the EGIR noted that, although the principle of justification was retained, it was given very little text in the draft (NEA, 2004d). The EGIR suggested that the description of the fundamental nature of justification should be augmented, and that a section specifically on justification should be added to the chapter on the principles of protection. There was a need for introductory words on what justification was, in addition to who was responsible (not only government, particularly in the case of medical exposures). It would also be very helpful if ICRP described the elements of justification decisions (while clearly not making those decisions for particular situations). Actions in existing and accident situations must also be justified. In particular, while justification and optimisation were presented as a judgemental balance of costs and benefits, the notion of benefits from exposure-

causing activities was not sufficiently highlighted and should be more visibly presented in the appropriate sections.

The EGIR emphasised that the importance of radiological protection as an input to justification should be put into perspective, not diminished. With respect to medical exposures, EGIR felt that there should be a clearer statement that professional bodies should consult national health authorities (not regulatory authorities) as relevant to the situation, rather than the vague *sometimes* of the ICRP text.

In its further discussion of the process of regulatory authorisation, the CRPPH noted that justification was regarded as a well established principle and was integral to the process (NEA, 2006a). The CRPPH, agreeing with the EGIR, acknowledged that the authority for assessing justification could be at different levels of governmental institutions, depending on the complexity of the problem, but, given their responsibilities, health or radiological protection authorities needed to be involved in the justification assessment.

The 2006 draft ICRP recommendations (ICRP, 2006a) reverted to an elaboration of a principle of justification that was close to that of ICRP Publication 60 (ICRP, 1991). Succinctly, the principle was that introducing a radiation source or reducing existing exposure should do more good than harm; i.e. the individual or societal benefit should be higher than the detriment (§ 30). There was a distinction, when considering occupational or public exposures, between generically justifying the introduction of planned sources and justifying particular actions to be taken to reduce doses when exposures already existed or in radiological emergencies (§ 188-190). ICRP noted, though, that in both cases the responsibility for judging the justification usually fell on governments or government agencies to ensure an overall benefit in the broadest sense to society and thus not to each individual.

The advice on justifying medical exposures was far more detailed than in previous drafts (§ 191, 247-253). Three levels of justification were defined: where the use of radiation was accepted as being beneficial to the patient and its justification could be taken for granted; where there was a specified procedure with a specified objective; and where a procedure was being applied to an individual patient. The responsibility for the justification of the use of a particular procedure fell on the relevant medical practitioners, and the ICRP considered that justification of medical procedures would therefore remain part of the recommendations.

The discussions at the Washington conference in 2006 (NEA 2008a) largely reiterated points that had already been made in the earlier discussions

and there was concurrence in general with the ICRP's most recent text. One point to come out strongly was that the process of justification was clearly seen as being substantially different in the medical field than in other exposure situations. There was a recommendation that the ICRP should define very clearly the rationale for the differences.

Similarly, at the Prague conference in 2006 (NEA, 2008b) the discussion on justification largely reiterated previous points. The importance of justification as a principle was emphasised and a new point was that justification might turn out to be one of the key involvements of stakeholders as they became more involved in the overall process.

In its review of the 2006 draft of the ICRP recommendations, the EGIR concluded that the responsibility for justification needed to be better described (NEA, 2006b). The ICRP had indicated that responsibility for justification usually fell on governments or government agencies (§ 190) but the thinking of the EGIR at that time was that others might need to be involved, or could even be responsible for justification. For example, the operator might justify the building of a power plant based on economic considerations, while the government might be concerned more with safety considerations. There were many aspects of justification and thus different organisations could be involved and responsible. This comment also applied to the section on the justification of medical exposures.

The 2007 draft of the recommendations (ICRP, 2007a) expanded the description of justification of the previous draft (§ 198 et seq., § 279 et seq., § 335 et seq.). Examples of unjustified practices were given (§ 204) and the importance of having public consultation during decision making was emphasised (§ 286).

The EGIR reacted strongly (NEA, 2007d) to the statement by the ICRP in its 2007 draft recommendations that implied that justification was about determining if a given practice was the best of all alternatives that were possible (§ 199). Consideration of alternative possible practices would introduce a new idea into ICRP's recommendations. Although the ICRP suggested that the radiological part of justifying should only go so far as to examine whether there was a positive net benefit, the EGIR's view was that justification in general should have the objective of only determining if there was a net benefit from the practice in question. The EGIR's conclusion was that the ICRP's broader view of justifying would go against maintaining regulatory stability; would entail considering the justification of each of the possible alternatives, which might well be complex; and would lead to a considerable workload and would stifle innovation. A better approach would be for the ICRP recommendations to note

that it would be sensible to re-examine justification should new and important evidence about the efficacy or consequences of a practice be acquired.

Previously, the EGIR had broadened the idea of justification by its suggestion that an operator might justify the building of a power plant based on economic considerations, while the government might be concerned more with safety considerations. The EGIR appeared to have realised, on reflection, that it had been inappropriate to have suggested that safety considerations would not be properly considered by an operator seeking to justify the building of a power plant based on economic considerations. Whether a power plant was justified or not was a matter for the authorities

The EGIR noted that there was a list of examples of unjustified procedures in the 2007 ICRP draft (§ 204) that involved the deliberate addition of radioactive substances to commodities or consumer products. The EGIR suggested that the list should be considered as definitive rather than exemplary, since some justifiable consumer products (e.g., smoke detectors) did have radioactivity deliberately added. Also radiological examination for legal purposes should be omitted from the list since it could be interpreted to include screening to detect criminal acts, e.g., concealed items on a person and people seeking illegal entry to a country, which might well be considered to be justified. Similarly, the reference to *mass screening* should be amended to *mass medical screening* so as not to preclude security screening.

The recommendations about justification in the final document, ICRP Publication 103 (ICRP, 2008), were essentially the same as in the previous draft, although the final suggestion from the EGIR was partially followed – *mass screening* was changed to *medical screening.*

Summary

An initial suggestion from the ICRP that justification was not needed as a principle in the system of protection met with strong opposition. (At least, not needed outside the medical area – the ICRP was expanding the role of justification in medicine at the time that suggestion was made.) Justification's role as a principle has, in fact, been retained with much more explanation of its role than in the previous recommendations, specifically with planned and existing exposures and exposures in emergencies. Such explanations had been called for in the various reviews.

Successive drafts of the recommendations picked up many specific points made in the reviews and discussions. The evolution of the basic idea of justification was, if anything, from its initial diminished role back towards that

of ICRP Publication 60. Changes that followed suggestions made include that justification involves taking a balanced view of all benefits and detriments; that it is not limited to the introduction of new practices; that there may be a broad responsibility for justifying, depending on the circumstances; and that there may need to be a re-examination of a justified situation if the technology changes or there is new information. The possible role of stakeholders in decisions regarding justification, as suggested in reviews and conferences, is now also highlighted.

There was some initial questioning of why justification in the medical field was substantially different from that in other areas but that it was different appears to have been accepted in later conferences and reviews. The ICRP, in fact, provided a substantially expanded description of justification in medicine.

Some issues that were raised in the reviews and conferences appear not have been addressed directly. There is little or no discussion of the nature of the radiological input to the decision making process. There is no description of the elements of justification decisions. The text still implicitly includes smoke detectors as an unjustified practice and justification could still be read as one of determining the best of available alternatives. Further, there is still no highlighting of the notion of benefits from exposure-causing activities.

4.2 Optimisation

The principle of optimisation has been fundamental to radiological protection for decades; indeed, it can be regarded as the most fundamental principle and, as will be seen in the review here, this position has been strengthened in the ICRP's new recommendations. Defined simply in Publication 26 (§ 12, ICRP, 1977) as "all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account" the principle has been widely applied in the control of occupational exposures. It has been less successful in other exposure situations, reflected to some extent by the more elaborate wording in Publication 60 (§ 112, ICRP, 1991). For a practice, the optimisation principle was: "In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals (dose constraints), or the risks to individuals in the case of potential exposures (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgements." For interventions the definition was: "The form, scale, and duration of the intervention should be optimised so that the net benefit of the reduction of dose,

i.e. the benefit of the reduction in radiation detriment, less the detriment associated with the intervention, should be maximised" (§ 113). The ICRP provided advice in Publication 60 and in later documents on how the principle might be applied in the various situations.

In the initial discussion of how the ICRP recommendations might evolve, Professor Clarke suggested that the concept of optimisation would have to be changed if individual dose was going to be the determining criterion in protection, which was what he was envisioning (Clarke, 1999). His suggestion to achieve this was that doses should be "as low as reasonably practicable".

The CRPPH in its critical review (NEA, 2000) acknowledged that optimisation was one of the cornerstones of the system of protection but pointed to many issues that arose with application of the principle in many practical situations. Guidance from the ICRP was needed; case studies would be helpful to operators and regulators. The committee suggested a long list of such situations. It included releases from nuclear power plants; releases from contaminated sites; protection in nuclear medicine departments (where there was a different perception of detriments and benefits than in a nuclear power plant); handling of naturally-occurring radioactive materials (where there seemed to be a disparity in treatment compared with that of slightly contaminated material from the nuclear industry); protection after accidents (where the approach for normal situations was not appropriate); situations that involved risk transfer as when worker doses were incurred to reduce potential doses to the public; situations that also involved non-radiological risks or needed decisions whether to concentrate waste or to disperse it or involved trade-offs between probability and severity in protecting against accidents. Though the CRPPH agreed that experts in radiological protection might understand the logic to optimisation and the different approaches taken in these various situations, others – politicians, the public and decision makers – often did not.

The subsequent commentary by the CRPPH (NEA, 2002) reiterated the fundamental importance of optimisation in radiological protection and the need for guidance in applying it in the process of authorisation. The CRPPH pointed to the broad nature of optimisation. As with justification, scientific input from radiation protection specialists was necessary in the optimisation process but in many cases was not sufficient and might not be the most significant input; it was largely a social process. Also, the case-specific nature of the optimisation process could well result in different solutions from place to place.

Reflecting the suggested move by the ICRP to more of an emphasis on the individual, the CRPPH wondered how dilution of effluents would be

considered; would dilution become an effective ALARA tool? The ICRP would need to consider this.

In developing the CRPPH ideas on the process of authorisation, NEA consultants in a set of case studies, took optimising to entail considering, inter alia, the characteristics of the source and exposures in detail; any relevant dose constraints or quantitative guidelines; the feasibility and cost of protective actions; any other related impacts on health and the environment; stakeholder views; and the societal context of the exposures (NEA, 2003c). The case studies served to emphasise that optimisation of protection under constraints in the new recommendations had to involve social as well as scientific judgments, with the various factors influencing any decision clearly identified.

In its preliminary discussion of the evolutionary path the new recommendations might take (ICRP, 2002b), the ICRP recognised that difficulties had arisen in applying the optimisation principle as introduced in Publication 26 (ICRP, 1977), which had suggested using collective dose as a measure of detriment along with various decision aiding techniques, including cost-benefit analysis. The suggestion to cost unit collective dose according to the individual dose as a means of taking into account the distribution of individual doses received had not been adopted internationally (§ 4). The problem had not been solved by the refinement in Publication 60 (ICRP, 1991) of introducing constraints on the doses to individuals in order to limit the inequity that resulted from the inherent social and economic judgments[2].

With the emphasis being placed more on protecting individuals through the application of constraints, the ICRP saw a slightly different role for optimisation. Noting (§ 21) that if the individual was sufficiently protected from a source, then society was also protected from that source, the ICRP went on to describe optimisation as the process that achieved a higher level of protection of individuals and groups, when feasible and practicable, than could be attained with dose constraints (§ 21). An alternative wording was "obtaining the best level of protection from a single source, taking account of all the prevailing circumstances" (§ 31). The ICRP suggested that optimisation of protection could be a qualitative workplace process involving workers and management and it could be a more formal process that involved the regulator, the operator and representatives of those exposed (§ 34). The ICRP commented that it was to be decided how the recommendations would deal with this societal process. For medical exposures, the ICRP suggested that optimisation would concentrate on

2. Issues related to collective dose and the evolution of its application are discussed in Section 4.7.

the requirement to keep the doses to patients as low as was consistent with the medical objectives, reducing unnecessary diagnostic exposures and avoiding exposure of healthy tissues consistent with delivering required therapeutic doses (§ 50).

The EGIR, in reviewing the ICRP suggestions, was disturbed by what appeared to be the displacement of ALARA from being the goal of optimising protection (NEA, 2003d). In the EGIR's view ALARA was a widely regarded as a useful and well-understood radiological protection tool. Detailed guidance would be needed from the ICRP if such a change was to take place, for example in explaining how dose constraints would be applied in planned and existing exposures and in cleanups. The EGIR noted that if prevailing circumstances were to guide protection, as was indicated in the ICRP description of optimising, then more frequent revisiting of objectives and regulations would be needed than was the current practice. That concern led to the additional concern that there could be significant direct costs (e.g., regulation changes) and indirect costs (e.g., loss of public trust) incurred as a result of changes in the recommendations such as changing ALARA to *best available protection under the prevailing circumstances*. The ICRP itself needed to optimise with respect to the efforts and costs of changes.

The EGIR also noted (loc.cit.) that potential exposures and risk constraints had not been mentioned in the draft. Should those concepts be abandoned there would be a need for guidance on how to optimise protection in situations that involved risk transfer and that were being addressed in part through the concept of potential exposure. There was also the further potential issue that when optimising there would be the need to balance the protection of humans and of non-human species.

In the 2005 draft of the recommendations (ICRP, 2004) the requirement for the optimisation of protection was included and was described in a more comprehensive way than in the Publication 60 recommendations (at least, in the view of the ICRP). There, the need had been to ensure that, for any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these were not certain to be received, should all be kept as low as reasonably achievable, economic and social factors being taken into account. The new requirement could not be defined in such quantitative terms; it called for judgment about each situation causing exposure of individuals and was to be the concern of the operating managements and the responsible national authorities (§ S6, 139, 140). The ICRP saw optimisation not only as evaluating and, where practical to do so, incorporating measures that tended to lower radiation doses to members of the public and to workers, but also as considering the avoidance of accidents

and other potential exposures. The approaches would be qualitative and quantitative (§ S9, 188). A role would be to foster a *safety culture* (§ S10, 189, 194) and this was particularly important in optimising protection against potential exposures (§ 234). For the control of emissions to the environment, the idea of *best available technology not entailing excessive costs* could be used with due consideration to social and economic factors (§ 194). The ICRP noted that the emphasis in patient exposures was on the justification of the medical procedures and that optimising protection in patient exposures had received less attention than in other applications (§ 213). Achieving the appropriate balance between loss of diagnostic information and reducing doses to patients was difficult.

The participants in the second conference in Tokyo in 2004 on the evolution of the ICRP recommendations raised general concerns about the changes to all the principles that seemed to be taking place (NEA, 2005a). The EGIR, in its review of the 2005 draft, also had concerns and commented on specific changes in the concept of optimisation (NEA, 2004d). One change (in § 189) was that avoidance of accidents and other potential exposures was to be considered in optimising. This was new and needed explanation. The EGIR also felt that there needed to be some qualification on the use of the idea of *best available technology not entailing excessive costs* in optimising. It should be noted as only one input to optimising – it was not a substitute – and health risks and societal aspects should be part of any consideration of this idea. Further, the EGIR took issue with the idea (§ 195) that the basic role of optimising was to foster a safety culture. It would be better to position optimisation as complementary to safety culture. Finally, the EGIR noted that an adequate discussion of optimisation in medical exposures was still missing.

The next (2006) draft of the recommendations (ICRP, 2006a) drew largely on the supporting document on optimisation, which was then also in draft form (ICRP, 2005a). The ICRP emphasised that the principle of optimisation of protection should apply in all circumstances, including those where the relevant constraint was already satisfied. The manner in which the principle would be applied would, however, depend upon the specifics of the exposure situation being considered (§ 33).

The EGIR noted with approval that optimisation remained a key principle but that its application in all types of situation was not well explained (NEA, 2006b). The text focused on the use of dose constraints in optimisation, which left other aspects of optimising inadequately explained. Given its agreement that the optimisation process was judgmental and subjective, the EGIR suggested adding a sentence at the end of the optimisation section to the effect that an open dialogue must be established between the authority and the operating

management, and that the success of the optimisation process would depend strongly on the quality of this dialogue.

The subsequent and final versions of the recommendations (ICRP, 2007b, 2008) had only minor changes to the text concerning optimisation per se. The point concerning the need for an open dialogue, suggested by the EGIR was included in § 223. Details were left to the supporting document on optimisation (ICRP, 2006b). The role of *best available technology . . . etc*, which was one of the details that had been of concern to EGIR, was positioned by the ICRP as being complementary to ALARA, rather than replacing it. Also, the mention of safety culture in the new recommendations was only in the context of delegation of authority (§ 312). The ICRP commented that the recommendations reiterated and strengthened the importance of optimisation in radiological protection and extended the successful experience in the implementation of that requirement for practices (included in planned exposure situations) to other situations, i.e. emergency and existing exposure situations (§ 12). Finally, the ICRP noted that it planned to follow up Publication 103 with reports applying the process of optimisation in different situations.

Summary

The initial indication was that the role of optimisation would be reduced, with the emphasis in the new system being on the doses to individuals. This prompted strong feedback from the radiological protection community, and the CRPPH in particular. Reflecting this input, the new recommendations maintain optimisation as a key principle; indeed, the ICRP comments in the new recommendations that optimisation is strengthened in importance and its implementation is extended to all types of exposures.

Concern was expressed by the EGIR and others that the familiar idea of ALARA was being lost. However, the new definition of optimisation now retains the idea of *as low as reasonably achievable*. Another change made by the ICRP was in its initial suggestion that the application of *best available technology not entailing excessive costs* was the approach to be used for optimising the control of effluents. In later drafts, the ICRP indicated that it considered that approach to be complementary to the application of ALARA, which reflected comments from the EGIR. The EGIR had also expressed concern over the suggestion in an early draft of the recommendations that the basic role of optimisation was to foster a safety culture. In the new recommendations safety culture is mentioned only in the context of delegation of authority.

The need for practical guidance on optimising protection was frequently expressed. Guidance has been provided, or is promised in future reports, for a variety of situations, including in medicine. There is, however, no detailed guidance yet on some issues, which were identified in the reviews and conferences. Examples are the issues that arise in risk transfer, such as between worker, public and the environment, and those that arise in taking the potential for exposures into account during optimising.

4.3 Exposure situations

In ICRP Publication 60 (ICRP, 1991) two kinds of human activity that involved exposure to radiation were distinguished. In one kind, called *practices*, the exposures were characterised as occurring from the introduction of new blocks of sources, pathways and individuals, or by modifying the network of pathways from existing sources to man and thus increasing the exposure of individuals or the number of individuals exposed. The other kind, called *interventions*, referred to those human actions that could remove existing sources, modify pathways, or reduce the number of exposed individuals (§ 106). Across these two activities, three types of exposure were distinguished; occupational (the result of exposure at work); medical (the exposure from diagnoses or treatments involving radiation); and public (all other exposures) (§ 109). The appropriate control measures for all types of exposure would depend on whether the measures were being applied to a practice causing exposures or to intervention aimed at reducing exposures (§ 111). Accidents and emergencies were considered as sources of potential exposure when practices were being dealt with, but if they were to occur, they would call for intervention (§ 130).

The principles for protection from exposures associated with practices were also distinguished from those underlying interventions. For the former, the three well-established principles of justification of a practice, optimisation of protection and limitation of individual dose were reiterated (§ 112). For interventions the two principles were, first, that the proposed intervention should do more good than harm, i.e. the reduction in detriment resulting from the reduction in dose should be sufficient to justify the harm and the costs, including social costs, of the intervention. The second principle was that the form, scale, and duration of the intervention should be optimised so that the net benefit of the reduction of dose, i.e. the benefit of the reduction in radiation detriment, less the detriment associated with the intervention, should be maximised (§ 113). Two aspects of these principles are of particular interest for this review. One is that pre-determined dose limits were not to be applied in interventions (§ 131). The other is that the benefit of a particular protective action in an intervention was to be judged on the basis of the reduction in dose

achieved or expected by that specific protective action, i.e. the dose averted (§ 222).

Deciding whether a particular situation should be treated as a practice or as an intervention could be difficult, as was acknowledged by Professor Clarke in his discussion of changes that might be made to ICRP's recommendations (Clarke, 1999). The apparent incoherence between the approaches in the two kinds of activity was evident and finding a way to eliminate their ab initio distinction would be helpful. Concern about this incoherence was noted in the CRPPH's critical review (NEA, 2000). In its later document, discussing the way forward (NEA, 2002), the CRPPH detailed the issues with the attempted distinction between practices and interventions. There was an apparent contradiction in that exposures that could be justified after accidents or in extant chronic exposures would be judged unacceptable under normal situations with a practice. By example, the CRPPH pointed to the back fitting of past practices and extant exposures that had led to some perceived incoherence within the system of radiological protection. Technical logic was resulting in recommendations that were socially contentious. When de facto exposures were treated case-by-case, the distinction between practices and interventions served no purpose. The CRPPH agreed that the elimination of the distinction between practices and interventions could have the advantage of simplifying the system of radiological protection, and of eliminating what had often been seen as confusing terminology. In the follow-up study by consultants to the CRPPH on how a process of comprehensive authorisation might work (NEA, 2003c), one of the conclusions was that such a generalised process would obviate the need to decide whether one was dealing with a practice or an intervention. The key seemed to be to develop sets of characteristics for source and exposures that would help decisions on regulatory control.

The initial discussion of the possible evolution of the recommendations by the ICRP (ICRP, 2002b) made no substantial change to its designation of exposures. The normal operations of a practice, prolonged exposures, biomedical research, and single events and emergencies were mentioned only in the context of developing a set of constraints.

In looking at the possible implications of the ICRP's suggestions, the EGIR felt that the approach based largely on dose constraints and optimisation needed much more explanation, particularly of how such constraints were to be applied to planned, existing and cleanup situations (NEA, 2003d). A particular concern was that neither the concept of potential exposures nor the concept of risk constraints had been included in the new draft recommendations framework. It was not clear to the EGIR whether the omissions implied that these concepts were no longer viewed by the Commission as useful, or whether

they would be discussed when more detailed recommendations were drafted. Should the concepts of potential exposure and risk constraints be abandoned, the Commission would have to provide guidance for addressing the various risk transfer situations that had been addressed previously, in part, through the use of potential exposure. The tools for such situations would be especially necessary for optimisation.

In the 2005 ICRP draft recommendations (ICRP, 2004), the ICRP acknowledged that the system it recommended had become increasingly complex as the ICRP sought to reflect the many situations to which the system applied (§ 5). It had been found necessary, for example, to deal separately with practices that were subject to control and with existing situations for which the only feasible controls were some kind of intervention to reduce the doses. This complexity was logical, but it had not always been easy to explain. The ICRP's intention for its new recommendations was to develop an approach that applied source-related individual dose constraints in all situations. The text noted that the ICRP intended its recommendations to apply to all sources within the scope of its recommendations, not only in *normal* situations, which were everyday situations, but also in *existing* controllable exposure situations, and in *emergencies*, meaning unexpected situations requiring urgent action. An emergency may have resulted from a sudden event or from slow deterioration, leading to the point where urgent action was required. The different types of situation would require different treatment (§ 21). The approach was to be case-by-case, applying whichever value of dose constraint was appropriate, taken from one of the ICRP publications or one chosen by operating management or regulatory agencies (§ 166). Authorities were advised that they should consider the factors which characterised the source and its environment.

The EGIR considered that the three exposure situations (normal, accident and existing) identified by the ICRP in the 2005 draft recommendations were highly relevant to the application of the recommendations (NEA, 2004d). The terms were, however, little described in the text of the 2005 draft; they merited a clear explanation. Further, two points of confusion need to be cleared up. One was that *normal* seemed to be the same as *practice*. For example, § 185 described both *doses in normal situations*, and *exposures from sources related to practices*, thus somewhat confusing these terms. Two, the concepts of normal situations and existing situations could be seen to overlap in their plain English usage. For example, radon exposure was natural and thus could be viewed as the normal situation. An additional point was that potential exposures had not been clearly defined. For example, were transport exposures, which were not certain, to be classed as potential exposures? An addition to the glossary could resolve this.

The EGIR pointed out that the ICRP's choice not to distinguish practices from interventions any longer had caused a significant amount of confusion. It was not clear from the 2005 draft text what would happen to national regulations and international standards for intervention levels, or whether the new application of dose constraints to accident situations would affect the existing level of international consensus on numerical values. There needed to be a better explanation of how regulatory intervention levels could be the result of optimisation below a dose constraint.

The broad approach to regulatory control that the CRPPH was advocating was further considered by the CRPPH in 2006 (NEA, 2006a). The CRPPH report showed that a single coherent authorisation process could be used for making regulatory decisions in all radiological protection situations; one that was consistent with the concepts presented by the ICRP in its 2005 draft (ICRP, 2004). Specifically, the CRPPH concluded that such an approach avoided the need to define and use terms such as *practices* and *interventions*.

In the 2006 draft of its recommendations the ICRP treated the distinction between what it called types of exposure situations in more detail (ICRP, 2006a). The ICRP acknowledged that the distinction between practices and interventions had been seen as artificial. The new characterisation would therefore be as *planned*, *emergency* and *existing* exposure situations. The three exposure situations as described were seen as covering all conceivable circumstances and replaced the previous two categories *practices* and *interventions* (§ 163). Planned situations would be everyday occurrences involving the planned operation of sources including decommissioning, disposal of radioactive waste and rehabilitation of the previously occupied land. Practices in operation would be planned exposure situations. Emergency situations would be unexpected occurrences that take place during the operation of a practice, requiring urgent action. Emergency situations could arise from practices. Existing exposure situations would be those that already existed when a decision on control had to be taken. They would include natural background radiation and residues from past practices that were operated outside the ICRP's recommendations (§ 162). It followed that practices could be the origin of planned, emergency, and existing situations. In these exposure situations there were three categories of exposure; occupational exposure, medical exposure of patients, and public exposure (§ 164). Additionally, potential exposures that could be foreseen from planned situations and from existing situations were noted and discussed (§ 306 et seq.)

The ICRP noted that there were some small differences in application of the system of protection between the three exposure situations (§ 163) but that there was now only one set of principles for the three situations (§ 37). The

justification principle referred to altering radiation exposures (introducing a new radiation source or reducing existing exposure). The optimisation principle referred only to ensuring the selection of the best protection option under the prevailing circumstances. (There was no longer the distinction between practices where the focus was on ensuring doses were as low as reasonable achievable and interventions where the focus was on the averted dose.) Inequities in dose distributions would be taken care of by applying dose or risk constraints. The third principle of limiting the maximum dose from all regulated sources was individual-related (as opposed to the other two, which were source-related) and applied only in planned situations (§ 185).

In the Washington conference in 2006 (NEA, 2008a), the participants welcomed the introduction by the ICRP of the three exposure situations – planned, existing and emergency – to replace the practice/intervention duo. Although the topic had not been raised as an issue at the previous stakeholder conferences (NEA, 2003a, 2004b), the feeling was that the new designations were clearer and would be more helpful. At the stakeholder conference in Prague (NEA, 2008b), the designation of exposure situations was generally accepted and the discussion that involved exposure situations focussed largely on the application of dose constraints in the three situations.

The EGIR, in considering the 2006 ICRP draft recommendations, found that potential exposures were not well explained. Potential exposures from uncertain accidents were not clearly distinguished from possible exposures in the far future from waste repositories (§ 306 et seq.) and the discussion on potential exposures inappropriately included exposure prevention and mitigation; material that should have been discussed elsewhere. For example, the long-term restoration of post-accident situations should have been considered in the discussion of existing situations. The EGIR also found that material on emergency and existing situations was scattered throughout the text; it should be consolidated and made consistent.

In the 2007 draft of the recommendations (ICRP, 2007a), the descriptions of three types of exposure situation were refined slightly. Potential exposures, insofar as they complied with pertinent risk constraints, were explicitly added to the description of planned exposures. The possibility of malicious acts was added to the description of emergency exposures. Long-term exposures were added to the description of existing exposures (§ 172). The ICRP emphasised the importance of the source-related approach in all exposures situations and in particular the achieving of the appropriate level of protection by optimisation in all three exposure situations. Dose constraints were to be used in the optimisation when exposures were planned and reference levels in the optimisation of protection in emergencies or with existing exposures (§ 191).

In its review of the 2007 draft recommendations, the EGIR noted that the section on emergency exposure situations had been extensively revised but it found that there were significant difficulties with the text as written, both conceptually and with respect to consistency. The EGIR provided many suggestions to improve the presentation of recommendations in this central area and recommended that the Commission should take the time to review its recommendations in this area to assure that they were self-consistent and coherent. Two particular details were that it was not appropriate to describe planned exposure situations as being *deliberate* exposures (§ 192) and that planned urgent actions that were part of an emergency response plan should not be considered as part of planned exposure situations (§ 247).

The published recommendations of the ICRP (ICRP, 2008a) made no major conceptual changes to the sections on the types of exposure situations as presented in the earlier draft (ICRP, 2007a) but there were clarifying rewordings throughout the sections reflecting comments from the reviews. For example, planned exposures were no longer termed *deliberate* and the designation of planned urgent actions as part of planned exposure situations was qualified as being those actions *once the emergency had been brought under contro*l (§ 253).

Summary

An early input from the CRPPH to the debate on changes needed in the ICRP recommendations was that difficulties had arisen in trying to distinguish between *practices* and *interventions*. The ICRP has acknowledged that the distinction was artificial and has introduced a different set of categories for what it termed *exposure situations*: namely *planned*, *emergency* and *existing*. There has been agreement that these designations would be clearer and more useful than the previous ones.

The definition and guidance on the application of the three categories of exposure were refined through the successive drafts, reflecting input from the CRPPH, EGIR and other reviewers. Much of the input was on detailed wording. For example, potential exposure is included after being omitted from the earliest draft and such exposures are more clearly explained; accidents are more clearly differentiated from far future potential exposures; the discussion of emergencies and existing situations has been consolidated; and a description of planned exposures as being *deliberate* has been removed.

There remains some concern about the impact of the suggested changes on national regulations and standards for intervention levels. There is also the possibility for confusion over the split of planned exposures into *normal* and

potential, given that natural radiation exposures could be seen as being normal. (However, if the full definition of planned exposure is taken into account – a situation involving the deliberate introduction and operation of sources – there need be no confusion.)

4.4 Application of the linear non-threshold model

The basis for many concepts and quantities in radiological protection is a linear non-threshold model that is based on the assumption that, in the low dose range, increments in radiation doses greater than zero will increase the risk of excess cancer and heritable disease in a simple proportionate manner – the LNT model. The idea that there may not be a threshold for such effects was expressed by the ICRP more than 50 years ago in its 1955 recommendations (ICRP, 1955). The text reads: "It is obvious that any significant departure from the environmental conditions in which man has evolved may entail a risk of possible deleterious effects. Strictly speaking, therefore, it must be assumed that long continued exposure to ionising radiation at a dose rate higher than that due to natural radioactivity of the earth and cosmic rays, involves some risk."

The idea was extended to include a proportionality between dose and incidence of some diseases in ICRP Publication 1 (ICRP, 1959): "The most conservative approach would be to assume that there is no threshold and no recovery, in which case even low accumulated doses would induce leukaemia in some susceptible individuals, and the incidence might be proportional to the accumulated dose. The same situation exists with respect to the induction of bone tumours by bone seeking radioactive substances." The model had become the formal basis for the recommendations by Publication 9 (ICRP, 1966) and continued through subsequent revisions.

As reiterated in ICRP Publication 60 (ICRP, 1991), the use of the average dose as an indicator of the probability of subsequent stochastic effects depended on the linearity of the relationship between the probability of inducing an effect and the dose (§ 22). It was suggested that, for moderate increments above the background, such a linear relationship between the incremental dose and the incremental probability of a deleterious effect would be an adequate approximation, whatever might be the true shape of the relationship between equivalent dose and the probability of stochastic effects (§ 72).

The assumption of the LNT model as the basis for the protection system has been one of the most challenged aspects of the ICRP's recommendations. Professor Clarke reflected on this in his 1999 paper (Clarke, 1999). He speculated that the reason such challenges had arisen was that some people felt that too much money was having to be spent on cleaning up radioactively

contaminated land and facilities. Such contamination had arisen from accidents such as Chernobyl, and from nuclear weapons testing in the atmosphere, with historic liabilities from old plants or from excessive effluent discharges, and with decommissioning nuclear facilities. A particular issue was that, on the basis of the LNT model, infinitesimally small doses to essentially infinite populations over essentially geological timescales were being summed to assess impact. He saw that the practical implications of the LNT model were of overwhelming importance in radiological protection because the model allowed doses within an organ or tissue to be averaged over that organ or tissue; doses received at different times to be added; and doses from one source to be considered independently of the doses from other sources.

Professor Clarke considered that very substantial difficulties would be introduced if threshold relationships were to be widely relevant in radiological protection. Threshold relationships existed for deterministic effects, but the levels of dose of concern in protection were generally well below these thresholds. One example of the complexities that would be introduced by a widely applicable threshold relationship would be the interaction between occupational exposure and non-occupational exposure to natural sources, and diagnostic medical exposure of individual workers. His suggestion was for the ICRP to adopt a more individual-related approach to protection that would avoid some of the concerns with the application of the LNT model.

In its critical review the CRPPH saw that there was a need for a better definition of the role and use of the LNT model within the system of radiation protection (NEA, 2000). The CRPPH considered that the debate on LNT, while valid, had contributed significantly to a decline in trust of radiation protection by various stakeholders, as well as a general decline in understanding of radiation protection issues. Debate concerning the use of the LNT had often focused on its scientific validity. Some members of the CRPPH felt that such discussions of LNT were of little use, because LNT would never be proven or disproved through epidemiological studies. The CRPPH concluded that the LNT model was not a scientific instrument which was *correct* or *incorrect*; it was more a regulatory tool for the interpretation of quantitative and qualitative data in a conservative fashion. This, it felt, should be emphasised by the ICRP.

Such a view was reiterated in a further review by the CRPPH (NEA, 2002) but it also noted that there were divergent views. At one extreme, there was a belief in the existence of scientific proofs for a dose threshold or even radiation hormesis, while at the other extreme there was the belief that the LNT model underestimated risks. The consequences were diverging opinions concerning dose limits for the public and other more specific issues, such as the degree of effort justified in cleaning up contaminated sites, together with some loss of

confidence, by decision makers and by the public, in radiological protection. Another area of concern to the CRPPH was the questionable validity of applying the model to accidental exposures to high doses and high dose rates involving young children. The strong recommendation was that the LNT model should be presented by the ICRP as a dose and risk management tool to be used by national regulators in assessing radiological protection options.

The ICRP responded to these concerns in outlining its views on the evolution of its recommendations (ICRP, 2002b). It undertook to clarify the concept and applicable range of the LNT model.

In its 2004 draft recommendations, the ICRP simply restated its assumption that, for protection purposes, radiation-induced cancers and hereditary diseases increased with increasing radiation dose, with no threshold, and that any increment of exposure above the natural background produced a linear increment of risk (§ 38). It also noted that the averaging of absorbed dose and the summing of mean doses in different organs and tissues of the human body, as given in the definition of all the protection quantities, was only possible under the assumption of a LNT model (§ 48). The EGIR in its review that followed this draft (NEA, 2004d) took issue with the expression "above natural background" in the context of the statement above, arguing that more explanation was needed in the light of the acknowledged wide fluctuation in natural background levels.

The 2006 draft recommendations expanded the discussion of the LNT model and, whilst noting the key role of the model as the basis for the protection quantities (§ 96) and in developing guidance on values for dose constraints (§ 146), acknowledged the differing views on the possibility of a practical threshold (§ 56). Its conclusion was that the LNT model provided a prudent basis for the practical purposes of radiological protection; i.e. the management of risks from low dose radiation exposure. The qualification of *practical* and the elaboration of *management of risks* appeared to have been new. The ICRP emphasised that because of the uncertainty on effects at low doses it was not appropriate, for the formal purposes of public health, to calculate the hypothetical number of cases of cancer or heritable disease that might be associated with very small radiation doses received by large numbers of people over very long periods of time.

While not offering any comment on the implications of the draft recommendations, the EGIR did make some specific comments on the 2006 draft text (NEA, 2006b). In particular (§ 29), the EGIR thought that the ICRP should elaborate on its rationale for the use of LNT and should discuss any

restrictions that should be placed on its use, more clearly identifying the line between science and judgment.

The EGIR also queried the appropriateness of *scientifically* in § 57 of the ICRP draft, which stated: "However, the Commission emphasises that whilst the LNT hypothesis remains a scientifically plausible element in its practical system of radiological protection, biological information that would [un]ambiguously verify the hypothesis is unlikely to be forthcoming." The EGIR considered that this implied more biological certainty than was scientifically supported and that the ICRP should consider what it meant by this phrase, and should perhaps modify it to be clearer about the nature of its LNT assumption. The EGIR also took issue with the statement: "Because of [the] uncertainty on effects at low doses the Commission judges that it is not appropriate, for the formal purposes of public health resources in general, to calculate the hypothetical number of cases of cancer or heritable disease that might be associated with very small radiation doses received by large numbers of people over very long periods of time." The EGIR felt that this could be read as implying belief in a threshold, thus becoming open to claims that inconvenient answers (i.e. large numbers of fatalities) were being ignored without real explanation. Further, it was not clear what was meant by *very small radiation doses* and *very long periods of time* and some clarification should be provided.

The discussion of the LNT model and its application in the 2007 draft ICRP recommendations followed essentially that of the earlier draft (ICRP, 2007a). Use of the LNT model was considered to be the best practical approach to managing risk from radiation exposure but it was not appropriate to calculate, on its basis, the hypothetical number of cases of cancer or heritable disease that might be associated with very small radiation doses received by large numbers of people over very long periods of time (§ 37, 65). The model remained the key basis for the protection quantities and underpinned the choice of dose constraints and reference values (§ 106).

In its review of the 2007 draft, the EGIR's only expressed significant concern remained that the explanation for the use of LNT was still weak (NEA, 2007d). The EGIR argued that the document should be clear about why uncertainty was fine for individual doses etc. but unacceptable when applied to a population (= a lot of individuals). The EGIR continued to question the sentence, quoted above, that: "Because of [the] uncertainty on health effects . . . for the formal purposes of public health . . ." Did the phrase *formal purposes of public health* refer to resource allocation by Health Ministries; if so, it might be that other projections of health problems also had uncertainty attached? Also, for example (again), what were *very small radiation doses*? Low dose was less

than or equal to 100 mSv. And what was a very long period of time? Years, decades, generations? The EGIR considered that the relevant point was surely not whether the predicted number of cancers was accurate but, rather, how far their spatial and temporal distribution made them a priority.

A somewhat stronger criticism of the applicability of the LNT was made by another NEA expert group in a discussion of scientific issues (NEA, 2007c). The key point was that human and other experimental experience could be interpreted as indicating that the risk of cancer following internal contamination by alpha emitters seldom, if ever, conformed to the LNT hypothesis; for whatever reasons there were de facto dose thresholds.

The recommendations as finally published (ICRP, 2008a) added little in its main text to the discussion of LNT as given in the previous draft. The troublesome phrase *formal purposes of public health* was changed to *purposes of public health planning*. The position of the ICRP was that, although there were recognised exceptions, it was scientifically plausible to assume that the incidence of cancer or heritable effects would rise in direct proportion to an increase in the equivalent dose in the relevant organs and tissues (§ 64). Therefore, the practical system of radiological protection recommended by the ICRP would continue to be based upon the assumption that at doses below about 100 mSv a given increment in dose would produce a directly proportionate increment in the probability of incurring cancer or heritable effects attributable to radiation (§ 65). The choice of the LNT model as the best practical approach to managing risk from radiation exposure was further supported by the suggestion that it was commensurate with the precautionary principle (§ 36). The Annex A to the published recommendations provided a more detailed analysis of the issues surrounding the LNT model.

In the end, the ICRP judged that there were no good scientific reasons to include the possibilities of supra-linear dose responses or of a low dose threshold in cancer risk calculations for the purposes of radiological protection. There was the acknowledgement that the level of risk associated with very low-dose exposure was not actually known and that the LNT model was not universally accepted as biological truth (§ 65, A178, A186). Nevertheless, the ICRP retained the LNT model as a prudent basis for the practical purposes of radiological protection at low doses and low dose rates.

Summary

The first concern expressed by the CRPPH was the need to emphasise in the recommendations that the LNT model was only a regulatory tool for dose and risk management. Further, there needed to be a clear rationale for its use. In

the recommendations such qualifications have been added to the rationale for using the LNT model. It is said to be a prudent basis for the *practical* purposes of radiological protection, i.e. the *management of risks* from low dose radiation exposure.

The ICRP has provided a detailed discussion of the issues surrounding the LNT model. The ICRP makes it clear that, in its view there is no weight of evidence to support the idea that a model of cancer risk with a supra-linear dose response or one with a low dose threshold should be preferred for the purposes of radiological protection. During the discussions there were strong opinions presented for the existence of a threshold for cancer induction by radiation and, in particular, for a practical threshold for the effects from alpha emitters. The ICRP has acknowledged that the level of risk associated with very-low-dose exposure is not actually known and that the LNT model has not been universally accepted as biological truth. Nevertheless, the ICRP has retained the LNT model as a prudent basis for the practical purposes of radiological protection at low doses and low dose rates.

In describing the rationale for the use of the LNT model, the ICRP emphasises that the LNT model is a regulatory tool, although it is noted that a proportionate increased incidence of cancer or heritable effects with radiation dose is a scientifically plausible assumption. The ICRP rationale for the prohibition on the use of the LNT model for risk assessment is that, because of the uncertainty on effects at low doses, it was not appropriate for the purposes of public health planning to calculate the hypothetical number of cases of cancer or heritable disease that might be associated with very small radiation doses received by large numbers of people over very long periods of time. The EGIR still appears to have concerns with this. Uncertainty does not preclude estimation; it means that any estimate has a commensurate confidence interval. The EGIR considered that the relevant point was not whether the predicted number of cancers was accurate but rather how far their spatial and temporal distribution made them a priority. Further, there remains a lack of quantification of small doses and very long periods. Resolving this issue with its apparent contradictions may well be a Sisyphean task.

4.5 Dose constraints and reference levels

The role of a dose constraint as defined in ICRP Publication 60 (ICRP, 1991) was primarily as a bound on inequity in individual occupational doses when protection was being optimised. The value of the constraint would depend on the circumstances. When exposures of the public were involved, then a dose constraint could be applied to any particular source to allow for any appreciable contributions from other sources. The values of the constraints could be set at

the national or local level. In medical diagnostic exposures, dose constraints selected by professional bodies or regulatory agencies could be applied in common diagnostic procedures. The ICRP recommended that dose constraints needed to be applied flexibly. A possible use of dose constraints was also suggested for exposures when any benefit from the exposure was not directly accruing the individual exposed – as in experiments involving human subjects. A risk constraint was also introduced, analogous to the dose constraint, but for application with potential exposures. For non-medical applications involving members of the public, the ICRP indicated that the value of a dose constraint would be less than 1 mSv/a. For waste disposal (which included effluents from operating facilities), a value 0.3 mSv/a was suggested for the dose constraint (ICRP, 1998) and for situations of prolonged exposure, the value of 0.1 mSv/a was recommended (ICRP, 1999). An overall caveat was that dose constraints should not be confused with prescriptive regulatory limits. (The genesis of the values 0.3 mSv/a and 0.1 mSv/a is described in the Appendix.)

One of the early indications of the possible revisions that might be made to the recommendations as presented in ICRP Publication 60 was in the series of papers by Professor Clarke (e.g. Clarke, 1999) that stressed the need to focus on controlling doses on a source-by-source basis for which a source-related dose constraint was more useful than the individual dose limit. The concept presented was that all controllable doses would be best managed by such individual-related, source-specific dose constraints. Protection would still be optimised beneath these constraints.

The CRPPH, in its first critical review (NEA, 2000), noted that despite attempts to provide operational definitions of the concept of a dose constraint (e.g. NEA, 1996) there was still confusion surrounding the definition and use of dose constraints. It was evident that there needed to be a much better explanation of the concept of the dose constraint and more extensive guidance on its application.

The CRPPH developed this analysis further in its 2002 document on the way forward (NEA, 2002). There was recognition of the importance of source-related dose constraints when protection of the public from multiple sources was being considered. International support would be needed for any such numerical guidance, though it was recognised that locally applicable values for dose constraints would be useful. Guidance was needed on how to develop these. Key was the development of an overall process of authorisation of radiological exposures that included concepts such as dose constraints in a coherent manner. The CRPPH noted that dose limits, which were socially well accepted, should be maintained as part of such a system.

This analysis was further developed during 2002 in the test by consultants of the CRPPH ideas on authorisation (NEA, 2003c). Specifically, the use of dose constraints was seen as part of authorisation process. All sources and exposures that were not immediately seen to be excused from regulatory control or authorised with some defined level of control were to be considered in a process that was described as *optimisation of protection under dose constraints*. Such constraints were envisioned as internationally recommended numerical guidance that was considered in optimising, rather than as inflexible standards. The consultants noted that it would be helpful if the variety of dose constraints, exemption levels, and intervention levels that then existed could be consolidated into a set of generic reference values for a comprehensive authorisation process such as that outlined by the CRPPH and implemented by national authorities.

Later in 2002, the ICRP discussed the role of constraints in its document on the possible evolution of the system of protection (ICRP, 2002b). In the document, the ICRP acknowledged that the concept of the constraint had not been clearly explained in ICRP Publication 60 or in its subsequent publications (§ 5). It had been introduced because the dose limit was considered to be an inadequate restriction on the optimisation of protection; lower value constraints were needed (§ 6). The ICRP proposed to broaden the concept of a constraint to encompass the range of terms that then currently included constraints, clearance levels, exemption levels as well as dose limits for workers and the public (§ 17). The ICRP noted that there was certainly a plethora of numerical values for constraints that had been developed for various purposes and derived in a variety of ways – from individual annual fatal risk; the upper end of an existing range of naturally occurring values; multiples or fractions of natural background; formal cost-benefit analysis; qualitative, non-quantitative, reasons; and avoidance of deterministic effects (§ 11). In the new consolidation of constraints, the basis could be a scale of concern (or lack of concern) related to natural background radiation (§ 24 et seq.). The challenge that the ICRP foresaw was to develop a smaller but coherent set of numerical values for constraints within this scale. Driving this change was the key principle that, once a source was justified by the appropriate authorities, society was protected from the source if the individual had been sufficiently protected from a source (§ 21).

The use of constraints as defined and used by the ICRP was not discussed directly in the context of environmental protection, the focus the 2002 Taormina conference held to discuss the ICRP recommendations (NEA, 2003a, 2003b). Nevertheless, it was noted that some international agencies and some countries had already proposed or used one or more environmental dose limits as criteria for environmental protection. Such use led to the implicit indication that, in seeking to harmonise the protection of humans with that of the environment, the

ICRP would find it hard to extend its set of constraints in a consistent manner to include those for environmental protection, particularly given the shift away from optimising and more towards a best technology approach. However, the ICRP proposal that the basis for constraints could be based on a scale related to natural background caught the attention of the participants in the 2002 Tokyo conference (NEA, 2004a). There was concern that the suggestion would not help public understanding of radiation risk. There was also the view from regulatory and industrial representatives that the value of 0.3 mSv/a as a dose constraint for public doses from operating facilities was too restrictive.

In looking at the possible implications of the ICRP's proposals of 2002, the EGIR concluded that the direction in which the ICRP was intending to go with dose constraints in its new recommendations was still not clear (NEA, 2003d). There was concern that, as with justification, the difference between the old and new concepts had not been sufficiently explained (NEA, 2003d), nor had the rationale for the proposed changes. In particular, the EGIR considered that there had been no real discussion of why it was reasonable to shift from the concept of an individual dose limit to a source-related individual dose constraint as defining the fundamental level of protection. In the EGIR's view, there was a need for both an overall individual dose limit as a planning and regulatory tool, as well as source-related dose constraints. Both of these concepts were seen as very useful dose management tools for both the regulator and the practitioner. Reinforcing that point was the unequivocal support for retaining the dose limit given in the 2003 conference in Lanzarote (NEA, 2004c). Indeed, the members of the main commission of the ICRP at that meeting acknowledged that they had heard that message very clearly. At that conference, as in the earlier one in Tokyo, regulators and other stakeholders expressed serious reservations about the proposal for a 0.3 mSv/a constraint because of the excessive costs that would be incurred.

It was also seen by the EGIR as important to explain very clearly how such constraints should be applied to planned, existing and cleanup situations. Both regulators and operators would need clear guidance on how to use them. The EGIR considered that the numerical values of protection criteria should not be based solely on natural background exposures. Though some members of the EGIR were comfortable with natural background being a benchmark for numerical restrictions such as dose limits and dose constraints, others favoured retaining the traditional risk-based approach. Overall, the EGIR felt additional rationale for the numerical selections, beyond comparison to natural background, was needed. It reiterated the widely expressed concern that the proposal to use 0.3 mSv in a year for controlling exposures of the public could pose practical difficulties in certain cases, such as mines at the site boundary or for on-site exposure of non-nuclear workers. The balance that the ICRP struck

between international harmonisation of numerical criteria and allowing the flexibility necessary for local approaches was important. Also, while supporting ICRP's intention to reduce the number of recommended numerical criteria, the EGIR felt that national authorities would need guidance on how to arrive at numerical values, if they were to be expected to develop their own case-specific dose constraints.

In the first draft proper of the new recommendations as distributed by the ICRP in May 2004 – the 2005 draft (ICRP, 2004) – the ICRP recast the principles of protection such that the most fundamental level of protection would be the source-related restriction on individual dose called a dose constraint. It would be used to provide a level of protection for the most exposed individuals within a class of exposure from a single source, in all situations within the scope of the recommendations. Except for the exposure of patients, these constraints would be regarded as the basic levels of protection to be attained in all situations that were addressed by the ICRP; normal situations, accidents and emergencies, and controllable existing exposures. These constraints represented the level of dose where action to avert exposures and reduce doses was virtually certain to be justified (§ S5, § 133 et seq.). In all situations the constraints were to be complemented by the requirement to optimise the level of protection achieved (§ 6). The ICRP considered that the annual effective dose from natural radiation sources, and its variation from place to place, was relevant in deciding the levels of maximum constraints that it recommended. It was not claimed that the existence of the natural background of radiation justified additional exposures; rather it was a benchmark for judging their relative importance and the need for action (§ 157-164). (The doses from natural radon progeny were excluded from this comparison because the ICRP considered that that component was enhanced by human activities and was thus subject to control at home and at work.)

The ICRP provided a table with recommended maximum values for constraints grouped into three categories of exposure and a recommended minimum value for any constraint (ICRP, 2004, § 163). The ICRP expected that actual values chosen within each category would be lower than the respective maximum values but probably not by as much as a factor of ten. The dose limit was retained for establishing the level of protection for an individual from all sources within a class of exposure in normal situations only. The values adopted in ICRP Publication 60 (ICRP, 1991) were also retained. Indeed, the ICRP emphasised that its intention with the new recommendations was to consolidate all the advice included in Publication 60 and subsequent publications. Those 2005 draft recommendations included a detailed explanation of the rationale behind dose constraints and advice on the use of dose constraints in various situations (normal, emergency, and existing controllable exposure) as well as

advice for authorities on setting particular constraints for given sources of exposure. Dose constraints were not suggested for use in optimising the use of diagnostic medical exposures – diagnostic reference levels were more appropriate – but it was noted that exposures of informed and consenting individuals helping support and comfort patients should be considered medical exposures and any constraints on those exposures would not be restricted to the public dose limits. For potential exposures, source-related risk constraints were suggested.

The introduction of the new ideas concerning dose constraints was one of the main topics of concern in the second conference held in Tokyo in 2004 to discuss the new recommendations (NEA, 2005a). The participants felt that there would be difficulties in introducing dose constraints into a regulatory system that was based on dose limits. Additionally, the basis for the values of dose constraints was not clear and the relationships between the dose constraints and intervention levels as introduced in Publication 60 (ICRP, 1991) and the new dose constraints and reference levels, respectively, were also not clear. There was particular concern that the introduction of the new concept was coming very soon after national regulations had been enacted to reflect the recommendations of Publication 60.

Also reacting to the 2005 ICRP draft, the EGIR reiterated the need to explain clearly the difference in definition of dose constraints from that of ICRP 60, particularly how dose constraints for practices would be used in conjunction with dose limits (NEA, 2004d). As the new definition of dose constraints was that these applied to single sources only, and the definition of a single source could be difficult in practice, some clear discussion of the practical aspects of identifying sources and choosing appropriate constraints was needed.

Dose constraints had been presented by the ICRP as an upper bound for optimisation. However, it was not clear to the EGIR from the text how dose constraints could be practically used. This was particularly true in accident and existing situations where the relationship between dose constraints and what used to be called intervention levels was not at all clear. The EGIR emphasised that the application of dose constraints in the three types of exposure situations would be key to the implementation of the new recommendations and should thus be much more clearly explained.

The EGIR noted that the ICRP had decided not to retain intervention as a class of situation, in order to clarify its recommendations, The EGIR considered that there was insufficient explanation of how dose constraints could be applied in what were (then) called emergency and existing situations. More specifically, intervention levels were levels below which no action was generally needed,

while dose constraints required optimisation below them. The articulation of the new relative to the old needed to be much clearer. For example, how did the concept of averted dose, found to be very valuable for making decision, fit into the present concept? These caveats notwithstanding, in further developing the idea of a comprehensive and coherent process of regulatory authorisation, the CRPPH continued to see dose constraints in the role of bounds in the optimisation of protection (NEA, 2006).

In the 2006 draft recommendations (ICRP, 2006a), the ICRP returned to defining the three principles of protection as justification, optimisation and dose limitation (§ 11). The individual dose limits would be maintained as the maximum doses that should be accepted in planned situations by regulatory authorities. For controlling exposures from specific sources, dose constraints would be applicable. These were seen as quantifying the most fundamental levels of protection for workers and the public from single sources in all situations. Constraints would apply in all situations being used prospectively as the starting point in the optimisation process. The optimisation process should result in exposures that were below the relevant constraint (§ 198). In emergency or existing controllable exposure situations, the constraint represented the level of dose or risk where action to reduce that dose or risk was almost always warranted in that particular situation (§ 201).

In considering the factors that influenced the choice of the numerical values for dose constraints, the ICRP placed less stress on the comparison with levels of natural background. The component of public exposure due to natural sources was noted as being by far the largest of the total exposure, but that fact provided no justification for reducing the attention paid to smaller, but more readily controllable, exposures to man-made sources (§ 167). In describing the maximum values assigned to the three categories of constraint values (100 mSv, 20 mSv and 1 mSv) the ICRP noted that epidemiological studies had shown a statistically significant excess of cancer deaths in populations exposed to doses greater than about 100 mSv (§ 202) and that this value might be considered the maximum for any type of constraint. Doses constrained in the lowest category would represent only a marginal increase above the natural background (§ 204), which was the only reference to natural background in this context. The specific value for the constraint could then be established by a process of generic optimisation that took account of national or regional attributes and preferences together, where appropriate, with a consideration of international guidance and good practice elsewhere.

The ICRP considerably expanded the guidance on the selection and use of dose constraints generally, and in optimising protection particularly, when exposures were planned, when they arose in emergencies, and when they were a

result of existing sources (§ 210-274). National authorities were seen as often having a major role in selection of dose constraints (§ 210). Considerations in this selection would be the character and nature of the exposures, the benefits to individuals and society from the situation or practice causing the exposures, and the practicability of reducing or preventing the exposures. The overall direction was to use the same conceptual approach in source-related protection, irrespective of the type of source, the constraint being intended to prevent the selection of any protection scheme that resulted in individual doses being above the value of the constraint. In the particular case of waste management, the previous recommendation by the ICRP had been that the constraint should be no more than 0.3 mSv in a year and no more than 0.1 mSv in a year if the quantity was not verifiable (§ 217). An exception to the general role of a constraint continued to be in medical diagnosis where diagnostic reference levels needed to be taken as indicative of optimised levels (§ 252).

The overall message from the conferences during 2006 in Tokyo, Washington DC, and Prague (NEA, 2007a, 2006c, 2006d) on the 2006 draft recommendations was that the dose constraint was their most controversial concept; the litanies of concerns were much the same in the three conferences. The points raised at the conferences are outlined together below.

The distinction between dose limit and dose constraint still seemed to the participants to be unclear and difficult to implement. The ICRP did offer some clarification at the last conference, stressing that dose constraints were not limits, but the confusion appeared to continue amongst the participants. Indeed, the majority of participants were not convinced that constraints needed to be introduced in all exposure situations; having many constraints could make the system more complicated and confusing. Additionally, many participants thought that ICRP's definition of a dose constraint as providing a fundamental level of protection that was not to be exceeded and indicative of when action was almost always warranted confused the relationship between constraints and dose limits. It was also inconsistent with the way these concepts were being used. With constraints related to a single source as the fundamental level of protection, how would one ensure that total dose received from all possible sources would be adequately controlled? A parenthetic point here was the need for a definition of what constituted a single source. It appeared that the ICRP wished to have a unified approach to all exposure situations, but the many concerns expressed by the participants, touching on fundamental points of protection, indicated that there needed to be a much clearer explanation of the value to be gained by the use of constraints throughout the system of protection. Otherwise, regulatory bodies would not adopt the recommended approach.

The participants commented that constraints already existed in workplaces and the experience gained from such experience could be used to establish dose constraints for new workplaces. Constraints were not regarded as being set ex cathedra, at least for occupational exposures; they had been set and used for some time by operators. The participants, particularly those at the Tokyo conference, felt strongly that they should not be fixed by regulators. Furthermore, the use of dose constraints might appear redundant in many occupational settings, anyway, since protection based on the ALARA approach had already reduced doses below any reasonable value of dose constraint. It was acknowledged, though, that this might not pertain to all situations – which was a point that had been made by the ICRP.

There was concern that non-compliance with a relevant constraint, as shown by an assessment, could be regarded as a failure of protection. The conference participants suggested that the ICRP needed to state clearly that dose constraints should apply only for prospective purposes in all three types of exposure situations. The dose constraints should not be regarded as a rigid boundary and exceeding the constraint should not be a regulatory infringement.

The participants also suggested that there needed to be a better explanation of the rationale behind the bands of values for constraints and the recommended values for particular dose constraints. The variation of natural background radiation was seen as providing a helpful perspective in explaining the values. (Clearly, not all might have agreed with this, given the concerns expressed in the first Tokyo conference.) Many of the participants argued that relating the constraints to risk was not helpful.

A further concern expressed was that there needed to be more flexibility in the suggested application of constraints in medical exposure than had been indicated in the draft; for example, the exposures of the parents of a sick child treated with radionuclides. Also, participants coming from the medical field did not understand the recommendation for maximum numerical dose constraints of 0.1 and 0.3 mSv per year for public exposures resulting from medical devices in hospitals. They felt that these recommendations would unduly increase healthcare costs. Significantly increased shielding would be required with no proven benefit. Concern was particularly expressed for developing countries, where there was often great difficulty in finding funds to purchase modern X ray equipment let alone extra shielding.

Some participants felt that, as well as there being some ambiguity in the recommendation on the dose constraint for emergencies, the constraint as such might be difficult to implement. There needed to be some relaxation of the control, more in keeping with the complete statement in the draft (ICRP, 2006,

§ 213) that "every effort should be made to avoid serious tissue injury by keeping doses below about 1000 mSv and, ideally to avoid other tissue injuries by keeping doses below 100 mSv, the Commission's maximum value for a constraint." Clarification was needed.

Participants at the Tokyo conference (NEA, 2007a) additionally remained concerned about the introduction the new concept of constraint so soon after national regulations had been enacted to implement the recommendations of Publication 60 (ICRP, 1991). It was acknowledged, though, that the relative roles of the dose limit, dose constraints and reference levels were then clearer. Many participants thought its introduction was not needed since the present protection system functioned sufficiently well. Finally, the many participants at the Washington conference (NEA, 2008a) saw *constraint* as an unfortunate choice of words; *goal* or *objective* would enhance clarity. This was particularly true for the non-English speaking countries.

The EGIR, in reviewing the 2006 draft ICRP recommendations saw constraints and optimisation as the key elements (NEA, 2006b). The EGIR understood a dose constraint to correspond to a level of exposure that one planned not to exceed, and below which optimisation of protection was to be performed. Dose constraints should not be described as the fundamental level of protection but they could be useful tools. First, though, they should be clearly and consistently explained, particularly their rationale, given their important role in the draft recommendations and it would help if the text on dose constraints were to be consolidated into one section. A stated role was to reduce inequity but there needed to be some explanation of what this meant. The current text on dose constraints, particularly for existing and emergency situations, was confusing and inconsistent. The statement that all previously recommended values could now be regarded as constraints was problematic (or in fact incorrect) given the emerging understanding of constraints (i.e. intervention levels were not constraints, action levels were not constraints). However, in § 201 the text seemed to tie dose constraints to the old definition of intervention level in that constraints were compared to projected or residual dose, not to averted dose as suggested elsewhere in the text. The text also did not clarify the definition of constraints for emergency or existing situations. The EGIR considered that occupational exposure constraints could be fixed by operators of well managed operations or by regulatory authorities, depending upon the circumstances, and that the recommendations should acknowledge this.

The EGIR considered that, if constraints were only prospective tools, the ICRP should recommend what to use for a benchmark in retrospective assessments of the quality of protection that had been implemented in existing

and emergency situations. The relationship between dose constraints and dose limits needed to be clearly articulated and the place of constraints in the system explained. The relationship between constraints and the well-established use of collective dose for the optimisation of protection of workers in the nuclear industry also needed to be explained.

One peculiarity noticed by the EGIR was that the recommended constraint for radon-222 in dwellings was above the level of exposure at which statistically significant increase in risk was discernable in recent epidemiological studies. This was a unique situation, in that other dose limitation criteria had been selected to be well below where statistically significant effects could be seen. The EGIR felt that the ICRP should comment on this. An additional point was that constraints for air crew exposures had not been mentioned; advice was needed on this important issue.

In the 2007 draft of the recommendations the ICRP stated that the three fundamental principles were justification, optimisation and *the application of dose limits* (a wording change from the previous *dose limitation*); that individual dose limits would be maintained for doses from all regulated planned sources; and that optimisation should be applicable in the same way in all situations and with restrictions on individual doses (ICRP, 2007a). Such restrictions, previously all termed dose constraints, would be distinguished as *dose constraints* in planned exposures and *reference levels* for exposures in emergencies and from existing sources (Executive Summary). The reason for this distinction was that the ICRP recognised that the term *constraint* had been interpreted in many languages as a rigorous limit, which had not been the ICRP's intention (§ 42). Although for continuity with past practice the term would be used in the context of planned exposures (except for medical exposures of patients), the term *reference level* would be used when optimising protection from all other types of exposure (§ 43). The ICRP noted that there was no fundamental difference in the application of constraints and reference levels in the system of protection that was being proposed. A difference in detail was that, whereas a dose constraint could be complied with from the beginning of an optimisation of protection from a planned source, the optimisation might start at doses above a reference level in other types of exposure (§ 219). An alternative description of this idea was that it was always possible to define a level of dose constraint above which it was unlikely that protection was optimised for a given source of exposure and for which, therefore, action must almost always be taken (§ 224). In all cases, the chosen value for a constraint or a reference level would depend upon the prevailing circumstances of the exposure being considered (§ 221).

The discussion of the factors influencing the choice of the values of dose constraints and reference levels in essence followed that of the previous draft. There were extensive sections in this draft on the use of dose constraints in the context of planned exposures and of reference levels in emergencies and when there were existing controllable exposures, including applications in medicine and with indoor radon (§ 223-357). The important roles of the dose and risk constraints in mitigating individual inequities that might arise in an optimisation were emphasised (§ 225).

Specifically, on reference levels as now defined, the ICRP noted that once protective actions had been implemented through optimisation subject to reference levels, doses to workers and members of the public could then be measured or assessed. The reference level would then be used as a benchmark against which the protection options could be judged retrospectively. The distribution of doses that resulted from the implementation of a planned protective strategy might or might not then include exposures above the reference level. Effort should then be made to reduce any exposures that were above the reference level to levels that were below. The ICRP warned, however, that it should not be forgotten that optimised protection should be applied to all individuals, irrespective of their doses relative to the reference level (§ 228).

Detailed comments were made by the EGIR on the 2007 draft recommendations (NEA, 2007d). The ICRP was reminded that licensees often chose constraints in planned situations and that these were not necessarily authorised by regulators. Stakeholder involvement with workers for occupational exposure or the public for public dose was essential for successful optimisation. The EGIR also suggested that it was not technically reasonable to apply a dose constraint of 0.1 mSv in a year for waste repositories because of the great uncertainty involved. It suggested deleting this recommendation.

It appeared to the EGIR much too regulatory to write, as had the ICRP, that constraints were *complied with* (§ 172, 219). A consistent editorial comment was that constraints were better described as *controls* rather than *restrictions*. An imbalance in the descriptions of dose constraints and reference levels in § 223-229 was noted. The description of dose constraints there should concentrate on the use of constraints in planning. It would then better match the description of reference levels. The use of dose constraints retrospectively or operationally should be in a separate section. The EGIR also suggested several drafting changes to clarify the use of prospective planning and the retrospective use of reference levels. For example, it should not be implied that reference levels must never be exceeded, rather that continual iterative efforts might be needed to make progress in continuing to reduce exposures to a level below the reference level if possible. Exceptional circumstances that might warrant

allowing exposure above the maximum value for a reference level (100 mSv) needed to be addressed.

The ICRP recommendations as finally published (Publication 103, ICRP, 2008) showed minor changes from the previous draft in the sections dealing with dose constraints and reference levels. The ICRP added further emphasis to the point that dose constraints were not to be used or understood as prescriptive regulatory limits. Advice on the application of constraints and levels in various situations was reworded more succinctly but with no substantive change. For example, values of 0.3 mSv/a and 0.1 mSv/a continued to be recommended for use with radioactive waste disposals and prolonged exposures respectively. A caveat was added to the section on constraints in managing wastes to the effect that flexibility was needed with the recommended constraint of 0.1 mSv/a when considering exposures from past mining activities (§ 262). The ICRP acknowledged the argument that source-related restrictions would not provide sufficient protection where there were multiple sources. The counter argument from the ICRP was that there was the presumption that generally there would be a dominant source and the selection of the appropriate reference level or constraint would ensure an adequate level of protection. The ICRP still considered that the source-related principle of optimisation below the constraint or reference level was the most effective tool for protection, whatever the situation (§ 242).

Summary

The topic of dose constraints and reference levels was the most controversial topic in the reviews and it elicited most discussion and comment. Initially dose constraints were suggested by the ICRP as becoming the fundamental indicators of protection, but there were strong objections to the implied demise of the dose limit as the criterion for the third principle of protection. This designation as the fundamental indicator has been reduced in the new recommendations. The application of the dose limit remains the fundamental third principle.

The concept of the dose constraint has evolved and expanded from that of ICRP Publication 60, however, and dose constraints and the companion reference levels are a major part of the new recommendations. Their final form reflects, to some extent, the lengthy discussions and reviews by the CRPPH, EGIR and the various NEA conference participants, though there are still outstanding concerns. Examples of both resolved and outstanding issues are given below.

There is now a reasonably clear explanation of the application of dose constraints in the three types of exposure situation, and also of the relationship between constraints and intervention levels. Most of the text on dose constraints and reference levels has been consolidated as requested.

The framework for setting the numerical values of the various constraints and levels was originally a scale of concern that was benchmarked to natural background radiation. The reaction to this approach was mixed. Some were comfortable with the link; others preferred a risk-based approach to setting values. There was the view that a basis of natural background would not help understanding. The outcome in the final recommendations was a framework with less stress on natural background; the highest band of values being related to where health effects could be observed; the lowest band to what were considered small increments to natural background. The ICRP acknowledges in the new recommendations that there may be exceptional circumstances that might warrant allowing exposure above the maximum value for a reference level. That has been another EGIR point.

Numerical values for the specific constraints and levels were suggested by the ICRP in one of its drafts. Following advice from the discussions, specific numerical values (except for the values 0.3 mSv in a year and 0.1 mSv in a year) were not provided in the final document; only a dose-based framework to aid their selection.

A concern with early drafts was that constraints could be seen as prescriptive limits. The final recommendations are clear that constraints should not be understood or used that way. There was also a concern that there would be no flexibility in setting the numerical values and in applying them. This is addressed to some extent by the suggestion that the choice should reflect national or regional attributes and preferences. Also acknowledged in the new recommendations is the point from the conferences and the EGIR that operators in large industries may fix occupational exposure constraints.

Outstanding issues that have been raised in the reviews and do not appear to have been completely addressed include:

- inadequate explanation of the difference between the old and new concepts of dose constraints and the relationship between dose constraints and dose limits;
- concern that the flexibility allowed in the choice of constraint for public exposure is insufficient to obviate practical difficulties in cases such as mines at the site boundary or for on-site exposure of non-nuclear workers;

- insufficient guidance on the scientific issues and aspects to take into account to when arriving at numerical values;
- the impression that dose constraints are still *restrictions* rather than *controls*;
- no specific role for stakeholder involvement is written in; and
- no clear discussion of the practical aspects of identifying sources and choosing appropriate constraints.

4.6 Exclusion, exemption, clearance and a comprehensive regulatory process

In Publication 60 (ICRP, 1991), the ICRP discussed the need for there to be provision to exclude some situations involving radiation exposures from the scope of regulatory control and also to exempt some justified practices where regulatory provisions seemed unnecessary (§ 285). The criterion for deciding on exclusion was uncontrollability (§ 291) whereas the criteria for deciding on exemption were that the source of exposure in question gave rise to small (trivial) individual and collective doses in normal and accident conditions, and that no reasonable control procedures could achieve significant reductions in individual and collective doses (§ 287). A subsequent ICRP document (ICRP, 1993, § 86), quantified a small individual dose as one on the order of 10 μSv/a, and noted that if the collective dose was on the order of one man-sievert per year, protection was often assumed to be optimised.

The CRPPH in its critical review (NEA, 2000) commented on the lack of clarity in and coherence between the concepts of exclusion and exemption and, in particular, noted the practical difficulties that the idea of triviality gave rise to as a basis for those kinds of authorisations for release of radioactive materials. There continued to be disagreements in the radiological protection community over these terms and their applications; for example, the CRPPH noted that the idea of triviality was more socially divisive than it was useful.

In the subsequent document (NEA, 2002) on the way forward, the CRPPH acknowledged that not all radiation exposures needed to provoke protective actions and that the guidance in the recommended system of protection should make provision for this. Specifically, there should be the concept of and guidance on the authorisation of exclusion of some exposures from all radiological protection regulatory control and of some sources from some or all such regulatory controls, all based on an internationally agreed-upon and clearly documented rationale. The CRPPH pointed to the apparent incoherence that had resulted from the use of various numerical criteria for exemption levels. The

CRPPH's recommendation was that the system of protection should provide for regulatory consideration of all exposures and sources. Authorisation of release from some or all regulatory control would be a deliberate regulatory action based on optimisation rather than being based on pre-defined triviality levels below which no further action would be needed. Any generic numerical criteria that might be felt to be needed should be agreed internationally. The elimination, or at least de-emphasising, of various terms such as *exclusion*, *exemption*, *clearance* (a particular kind of exemption, widely used though not part of the ICRP lexicon) and *triviality* would result in a greatly simplified, more coherent and understandable system, while at the same time maintaining flexibility in application.

In its initial discussion of the possible evolution of its recommendations, the ICRP suggested that its recommendations would apply to situations when either the source or the pathways from the source to the exposed individuals could be controlled by some reasonable means (ICRP, 2002b). Sources that did not fall within that definition of controllable were to be excluded from regulatory control (§ 35). Cosmic rays at the earth's surface were an example (§ 42). Also, there were sources for which the resulting levels of annual effective dose would be very low, or for which the difficulty of applying controls would be so great and expensive, that protection could be considered already optimised and the sources would therefore be excluded (§ 35). Having defined what sources and exposures were to be excluded from the system of protection, the ICRP noted that it intended not to use the term *exemption*. It considered exemption (and clearance) as regulatory decisions that would be applied to non-excluded sources by the appropriate regulatory body. That body would have the responsibility for deciding when radioactive material could be released from its control; an authorised release that was, in effect, no different from that specified for effluent discharges after optimisation (§ 36). The ICRP noted its intention to extend the approach then used for radon-222 – the use of an optimised action level to define an exclusion level – to controllable natural sources (§ 39 et seq.). It was seen that an expansion of the concept of a constraint in such an approach would obviate the need for terms such as clearance level and exemption levels (§ 17).

The EGIR, in its appraisal of the initial ICRP document, concluded that there was insufficient explanation of what was meant by the new concept of exclusion, and how this differed from the old one (NEA, 2003d). Any new, detailed ICRP recommendation would need to address this important topic. For example:

- Why was exclusion applied differently to natural and artificial radionuclides?

- What level of international agreement should be suggested on what was or was not *controllable*?
- What types of issues or contexts should be considered when deciding whether a natural source was or was not controllable?
- Why should residual exposures from natural radionuclides be excluded?

It was broadly supported that exclusion should not be based solely on dose level. The circumstances of exposure, benefits of the practice etc., were other factors that could have important roles in the decision. The EGIR suggested that the exclusion of the residual doses resulting from an optimisation process (whether this was an assumed optimisation or an active assessment) did nothing to enhance protection or ease the burden on regulatory authorities. In fact, excluding these low doses could be detrimental in terms of the image that such exclusion gave to the public.

In the same context, it was not seen as useful for the ICRP to have declared, a priori, that doses below a particular value should be of no concern and should thus be excluded. The assessment of the regulatory aspects of exclusion should be left to the regulator. The regulator would always assess doses, even if they were low. The assessment might not be as detailed for a very low dose as for a higher dose, but the regulator would not always, *a priori*, exclude low dose situations from consideration. Considering these last two points, the EGIR suggested that the overall need for the concept of exemption could be revisited.

For natural sources, the EGIR suggested that radioactivity level constraints should be expressed as those levels below which international trade of commodities would not be inhibited for radiological protection reasons. These values should be carefully chosen to avoid problems with ongoing activities and to take into account various cultural aspects. With regard to exclusion, it suggested that there should be a clear explanation of why particular levels had been selected. The use of radioactivity level, as opposed to dose level, was supported. A specific comment about doses incurred while flying was that there seemed to be some national approaches that considered this occupational, and others that considered it excluded. The ICRP should take this into account and allow sufficient flexibility for national views.

The EGIR drew attention to two paragraphs (§ 35 and § 39) in the ICRP draft (ICRP, 2002b). The former stated that "There are sources for which the resulting levels of annual effective dose are very low, or for which the combination of dose and difficulty of applying controls are such that protection

may be assumed to be optimised and the sources are therefore excluded." The latter stated, for radon-222 and now also for all other natural sources, "Exposures below the designated action level are then excluded from the system of protection." The EGIR interpreted these to indicate that the ICRP would, a priori, indicate which natural exposures should be taken into account by regulatory authorities and which should not, simply based on a pre-determined dose level. This could be taken to imply that low doses would never be of sufficient concern to be taken into account by regulatory authorities. Although low doses from natural radionuclides might, in many cases, not provoke any regulatory reaction, it was difficult to judge that this would be the case in all situations. In addition, the EGIR pointed out that taken together, these statements could be viewed as implying that any doses below a designated action level (i.e. optimised doses) should be excluded from the system of protection and that therefore truncated exposures would be used when considering group doses. This would also imply that residual, optimised doses should not be considered in further decision making about the source in question, or about other sources that might affect the same exposed population. In the EGIR's view, such a position by ICRP would not necessarily aid regulatory authorities or practitioners.

The EGIR also noted that the statement from § 35 referred to an assumed optimisation. Optimisation was normally associated with something already within the system, thus the removal of such exposures or sources from the system would be more exemption than exclusion. Although this was a somewhat technical point, given the view expressed in § 10, that the new recommendation was intended "to give a single unified set that can be simply and coherently expressed", the mixing of concepts in this fashion would again not necessarily aid regulatory authorities or practitioners.

In the study carried out for the NEA on its suggested new approach to authorisation (NEA, 2003c), the authors showed how the approach could lead to the same end results as the application of exclusion, exemption and clearance criteria but in a more logical, transparent and coherent way. An initial screening of a source or exposure that had come under consideration by a regulator might lead to a decision that the source or exposure could be excused from protective actions. If not excused the next steps would involve examining whether such exposures were justified and carrying out a broad-based optimisation under any relevant constraints. These could lead to the authority deciding either to excuse the source and exposures from some or all regulatory conditions, or to authorise the source and exposures subject to some conditions. The process as described thus far, in effect, covered the mechanisms of exclusion, exemption and regulatory control in the then current ICRP system. Reconsideration, by the same process, of a source or an exposure that was currently under regulatory

control could lead to a change in the level of control and, in particular, might prompt the regulator to decide that that particular source and exposure no longer warranted control; they could be excused. The latter decision was equivalent to implementing the process for clearance in the ICRP system. Practical examples were worked through.

The discussions at the 2002 Lanzarote conference illustrated the confusion surrounding exemption and exclusion, particularly in the context of natural sources of exposure (NEA 2004b, 2004c). It was understood that exclusion meant that a source or an exposure was considered to be *outside the system*. The choice to exclude was to be based on the ability to affect exposures through inclusion in the system; that is, they were amenable to control. Exemption was used to judge whether a source or exposure that was already under control, within the system of radiological protection, should no longer be controlled. This decision was to be based on the level of dose; for example 10 μSv/a. In other words, exclusion defined the scope of the ICRP system of protection, exemption was a regulatory tool. Confusion then arose because most *unaltered* natural radionuclides would not be amenable to control but the ICRP proposed that an exclusion level could be based on a radioactivity concentration. That proposal appeared to mix the concepts of exclusion and exemption and did not aid understanding. Exclusion was seen by the participants as being a useful concept but the view was that it should be based primarily on amenability to control and would apply to exposures from both natural and artificial sources. Further, all sources and exposures that were not excluded should be subject to authorisation by regulatory authorities. Authorisation could replace the concepts of exemption and clearance. Clear, simple explanations of these concepts were needed.

The 2005 draft of the ICRP recommendations (ICRP, 2004) continued the earlier draft's emphasis on exclusion. Noting that, since all materials were radioactive to a greater or lesser degree, the ICRP saw the concept of exclusion as being essential for the successful application of the system of protection. In principle, it could be applied to both natural and artificial sources of radiation although in practice it would largely be of use in the control of natural sources. The ICRP considered that numerical criteria for exclusion would assist in the consistent application of the concept (§ 24). The ICRP suggested values for the concentration of activity of artificial and natural radionuclides that could be taken as the practical definition of what might be considered radioactive and therefore within the scope of the ICRP's recommendations. The values were derived from existing values in the standards from other agencies (§ 204-209). Cosmic rays at ground level were considered excluded from the scope of the recommendations (§ 210).

The ICRP reiterated its view, expressed in its 2002 document (ICRP, 2002b), that there should be provisions made for granting exemptions in cases where it was clear that further controls were unnecessary. The regulatory act of assessing the situation and granting an exemption was, in itself, a form of authorisation and the material that was exempted would remain subject to the system of protection, although without further regulatory control (§ 26). The ICRP considered that practical application of the concept required derivation of exemption levels in terms of activity concentrations. Noting the advice by the IAEA and the NEA on exemption, the ICRP suggested that international agreement on a single set of radionuclide-specific levels for exemption would facilitate a consistent regulatory approach worldwide. Sources with radioactivity concentrations above exemption levels would not necessarily be subject to the full rigor of regulations. A graded approach to regulation based on assessed hazard would focus regulatory effort onto areas where most benefit would be obtained (§ 26-28).

The EGIR's reaction to the 2005 ICRP draft was that several aspects on exclusion needed to be clarified (NEA, 2004d). First, an international consensus had been built in the development of the concept of exclusion, which was reflected in the IAEA's Safety Guide (IAEA, 2004). The caveats, nuances and numerical values found there should be included in the ICRP's recommendations. An example was that it was not clear from the statement of scope in § 24 whether controllable sources, low dose or not, should be excluded. The EGIR challenged the basis for the tabulated numerical values of activity concentration for the recommended exclusion levels for natural radioactive substances (§ 209); they appeared to the EGIR members to be too high. Reduction by a factor of ten was discussed by the EGIR but even this would not necessarily be sufficient in some cases. For example, such a reduced criterion could still allow direct gamma doses rates on the order of 10 mSv/a from building materials. There were other inconsistencies; bananas would be excluded but not potassium supplements and there was an inconsistency with the exclusion value given for radon elsewhere in the document. The EGIR recommended that values should be reconsidered by the ICRP and, in particular, the ICRP should ensure that its use of the term exclusion was, indeed, in the unrestricted sense of the word.

On the process of exemption, the EGIR pointed out that decisions would be based on many aspects beyond dose considerations; for example, the nature of the radioactivity or source, and the total radioactivity being exempted. This needed to be noted in the recommendations. Also, it pointed out that that practices and sources could be exempted when there was not more value in regulating. The EGIR also reiterated its concern about what it saw as inconsistencies in the treatment of occupational exposures to radon-222. The

suggestion by the ICRP (§ 180) that the system of protection should not be applied to occupational exposure to radon-222 below the proposed maximum constraints seemed to imply that exposures below an optimised level should be excluded. The EGIR thought that, if any form of authorisation for these exposures was necessary, exemption would seem to be the more applicable concept. If so, not applying the system to these exposures was in contradiction with § 26 in the ICRP draft, which suggested that such exposures should remain within the system, although they were not regulated. This same argument would also seem to apply to public exposures below levels set through optimisation. These would not be subject to regulatory actions, but there did not seem to be a need to refer to these as not being controllable.

The EGIR noted that the process of regulatory authorisation was being elaborated by the CRPPH and that reference to the report describing it (NEA, 2006a) would help regulators apply the ICRP recommendations. Finally, the EGIR suggested that the ICRP needed to clarify that its use of the term *authorisation* was in the general sense, as was that of the CRPPH, and was not the more restrictive sense used in some national regulations.

The CRPPH, in revisiting that process of authorisation, reiterated its previous finding that though the terms exclusion, exemption and clearance were not used in its exposition of the process of authorisation, the concepts they embodied were integral to the process (NEA, 2006a). The NEA argued that concentrating only on the process aspects of radiological protection decision making emphasised the reasoning behind decision pathways rather than on specific and narrowly defined terms. Such an approach would lead to regulatory decisions that were far easier to explain and defend than the then current approaches flowing from the recommendations of ICRP Publication 60 (ICRP, 1991).

The advice on exclusion was refined in the 2006 draft of the ICRP recommendations (ICRP, 2006a). As before, numerical criteria were suggested as criteria for exclusion of natural and artificial radiation sources (§ 280-295) but there was an acknowledgement by the ICRP that decisions on what exposures were not amenable to control required a judgment by the legislator, which might be influenced by cultural perceptions. For instance, national attitudes to the regulation of exposures to natural occurring radioactive materials were extremely variable (§ 44).

In commenting on the need for regulators to have the power to exempt from regulatory obligations, the ICRP cautioned that, strictly, the term *exemption* could only apply to personal entities, either physical or legal persons, as it related to the waiving by the regulatory authority of requirements that

would otherwise have applied to a person as a legal obligation (§ 42). Further, exemption should not be linked solely to triviality of risk; it was a broader concept that reflected unwarranted control due to any reason. Consequently, it should not be surprising that different circumstances could lead to different dose levels below which regulatory control is considered unwarranted. National regulators should decide the criteria for exemption on a case-by-case basis and the dosimetric boundary of 10 μSv/a should be only one of the criteria used (§ 46). Nevertheless the ICRP pointed out that generic exemption criteria that had been developed internationally would help international consistency (§ 47).

The participants at the 2006 Washington conference noted that the concepts of exclusion and exemption were treated in a stand-alone fashion when it would be preferable to treat them systematically in the sections on the justification, optimisation and limitations principles (NEA, 2008a). The radiological aspects of a priori decisions on exclusion were not understood; there seemed to be an implication that some forms of control could be excluded without any systematic assessments based on ICRP principles.

Although the ICRP had acknowledged that exemption was not based solely on the triviality of risk, the conference participants felt that there was an implication that exemption would only be appropriate when the individual dose was very low. According to some participants an exemption may be the logical regulatory solution even when individual doses were greater than the exemption values suggested by the ICRP. Indeed, the value of 10 μSv/a was felt to be inappropriate as a boundary between significant and insignificant doses. Although some participants agreed that some international values, such as for foodstuffs and drinking water following an accident, were appropriate for generic exemption there was, in general, somewhat mixed views on the type of guidance that the ICRP should recommend. A widely held view was that it was not the role of the ICRP to make numerical recommendations in this area; the focus in the recommendations should be on the principles that should be considered when judging what to exempt.

The discussion on exclusion and exemption at the 2006 conference in Prague followed similar lines to that in Washington and made the same points (NEA, 2008b). Additional points were that the adoption of generic exemption values was seen as counterproductive by some regulators and that particular values should be restricted to a source of exposure. It was noted that in some situations it was technically feasible to reduce some radioactive discharges to zero such as from nuclear power plants on routine operation. There was the view that exemption values should be adopted on a case by case basis only and for a limited period. Also, there needed to be the flexibility to adapt to improving technologies. For example, the ICRP should not adopt as exemption

levels those guidance levels that were developed for radionuclide contamination in foodstuffs after a nuclear accident. Lastly, there needed to be an explanation of why the concept of clearance, which was widely used by the regulators, had not been adopted by the ICRP in its recommendations.

From its review of the 2006 ICRP draft, the EGIR saw the need for the ICRP to expand on the types of criteria that should be taken into account when making exclusion and exemption level decisions for artificial and natural radionuclides (NEA, 2006b). The ICRP had decided not to use the concept of clearance but it should be mentioned as a regulatory tool and the reasons for its non-adoption needed to be explained by the ICRP. The EGIR pointed out, again, that the CRPPH had shown through its elaboration of the process of authorisation, that the concepts of exclusion, exemption and clearance were not necessary for regulatory decision making.

The EGIR had come to the conclusion that the ICRP should not provide specific numerical guidance for the criteria that it recommended for making decision about exclusion and exemption. In particular, the generic exemption levels for foodstuffs, imported from the CODEX, were intended for use in a one-year post-accidental situation, and were not applicable for use as generic exemption levels, a point that reflected the discussions at the 2006 conferences. The thrust of the many comments from the EGIR on numerical guidance was that if numerical criteria were to be included (such as 10 μSv/a), then the ICRP should stress that there could be flexibility in their application.

A better approach, in the view of the EGIR, would be if the discussion of exemption focused on the concept and the rationale for selecting dose criteria for exemption, such as, for example, variation in natural background. Other sources of international agreement could be referenced – for example, IAEA texts – although again without use of the numerical values in the ICRP recommendations. Previous wordings that referred more generically to regulatory control not being warranted were better than text referring to specific doses that were insignificant.

The EGIR noted that the stated starting position of the ICRP was that the system of radiological protection applied to all radiation sources and radiation exposures from any source, regardless of its size and origin (§ 34). The EGIR took from this that even the conditions for exclusion and exemption were within the radioprotection system. (This point had been made in the CRPPH's document on the process of authorisation.) It followed from this that the legislative approach (discussed in § 42) should start by considering all possible exposures and sources and then establish a graded level of regulatory obligations that could start from no obligations at all to a level of complex

regulatory controls. Starting by considering what was inside the system of protection and what was outside the system appeared inconsistent with the ICRP's starting position. A smaller point was that *radiological protection legislation* should be replaced with *regulatory obligations* for consistency (§ 44).

In the 2007 draft recommendations (ICRP, 2007a), the ICRP summarised the main points of the previous draft but left any further elaboration to a separate supporting document, then in draft, on the scope of the ICRP's radiological protection control measures (eventually ICRP, 2008b).

The conclusion from the EGIR review of the 2007 ICRP draft was that there were still inconsistencies associated with the concepts and applications of exclusion and exemption and, in particular, what was to be excluded and what could be exempted (NEA 2007d). The EGIR felt it was particularly important for the ICRP to show how exemption and exclusion applied to radioactive sources of natural origin. On exclusion, the EGIR cited § 40, which referred to *exposures from situations* that were excluded; § 52 referred to *exclusion of certain exposure situations*; and § 174 referred to *excluded exposures*. On exemption, there was § 52 referring to *the exemption from radiological protection regulatory requirements of situations*; and § 174 referring to *exposures from exempt practices or exempt sources*. Changes for consistency and clarity were needed.

Detailed recommendations on the scope of the ICRP system of protection would be in a separate ICRP document. However, the EGIR suggested that the short section on exclusion and exemption in the main ICRP recommendations should include the point that the approach to regulation needed to be a graded one. Also the EGIR reiterated its suggestion that, given the ICRP position that all exposures and exposure situations were within the system (§ 44), then the recommendations should indicate that legislators must establish rules for leaving things out of legislation (exclusion) and regulators must establish rules for excusing some things from regulations (exemption). The EGIR reiterated a further point that the term *clearance* was commonly used and, even if ICRP was not going to use this term, it should be explained briefly.

The final recommendations, Publication 103 (ICRP, 2008a) followed in general the advice given in the previous draft, distinguishing the two concepts that delineated the extent of radiological protection control, namely (i) the exclusion of certain exposure situations from radiological protection legislation, usually on the basis that they were not amenable to control with regulatory instruments (*cannot* be regulated), and (ii) the exemption from some or all radiological protection regulatory requirements for situations where such

controls could be regarded as unwarranted, often on the basis that the effort to control was judged to be excessive compared to the associated risk (*need not* be regulated) (§ 52). The ICRP also added that the distinction between exclusion and exemption was not absolute; regulatory authorities in different countries might make different decisions about whether to exempt or exclude a specific source or situation (§ 52).

The companion document, Publication 104 (ICRP, 2008b) further elaborated the concepts of exclusion and exemption (and the special case of clearance) that had evolved through the series of draft recommendations. Depending on the relevant national regulatory systems, competent authorities, such as legislators and regulators, should consider application of the concept of exclusion to any exposure situations that were considered to be either uncontrollable or not amenable to control through regulation. For planned exposure situations, radiological protection regulations should provide for exemption from specified regulatory requirements (§ e).

Exemption from all controls was only to be granted if individual radiation risks to be incurred by those exposed would be acceptably small; protection was considered to be optimum; there was no appreciable likelihood of unintended scenarios that could lead to a failure to meet the previous conditions; and the legal persons to be exempted must be conducting activities that were considered to be justified. Materials or sites subject to regulatory requirements, but for which regulatory requirements had become unwarranted, could be exempted through the application of the concept of clearance. Regulatory control would be relinquished upon clearance. The criteria for clearance should ensure that relinquishing control would not lead to an exposure that would not meet any of the conditions for exemption (§ f). For situations involving artificial sources of radiation, the widely used individual dose criterion of about 10 μSv in a year should not be taken to be the sole criterion for granting exemption. It was the principle of optimisation rather than just the triviality of individual doses that should be considered as the basis for exemption. For situations involving radionuclides of natural origin, the national authority could establish levels for the purposes of exemption that were consistent with exemption being the optimum regulatory option (§ g). Finally, the ICRP considered that the generic exemption and clearance levels derived by international intergovernmental organisations would promote international coherence but the ICRP neither endorsed nor disapproved their use (§ h).

Summary

Initial concerns were that the concepts of exemption and exclusion were not well understood; triviality as a criterion gave rise to problems; and clearance

was ignored by the ICRP. The recommendations now have a lengthy description of the concepts and their application, backed up by the more detailed publication on the scope of the recommendations.

During the evolution of the recommendations, commentators pointed out perceived inconsistencies in ICRP's interpretation of its suggested criteria for exclusion and exemption. In the final document, the ICRP acknowledges that the distinction between exclusion (*cannot* be regulated), and exemption (*need not* be regulated) is not absolute and the different authorities might make different decisions whether to exempt or exclude. In effect the new recommendations allow the flexible, case-by-case, approach recommended during the reviews by the EGIR. Discussion of the concept of clearance, initially ignored by the ICRP, has been included in the supporting publication on the scope of the recommendations.

The process of regulatory authorisation advocated by the CRPPH was not adopted as such by the ICRP but the process as proposed by the ICRP is broadly consistent with the CRPPH's model as Figures 4.6-1 and 4.6-2 (below) show. The latter illustration, from the CRPPH document, also includes the justification decision. The process flows are essentially the same. Regulators could follow either scheme and keep within the spirit for the recommendations.

The ICRP was strongly advised not to recommend specific numerical values for exemption and clearance. The ICRP has followed this advice noting that, though such values would promote international coherence, it neither endorses nor disapproves their use.

Figure 4.6-1: The regulatory process recommended by the ICRP, illustrating exclusion, exemption and clearance. Redrawn from Figure 2 in ICRP Publication 104 (ICRP, 2008b).

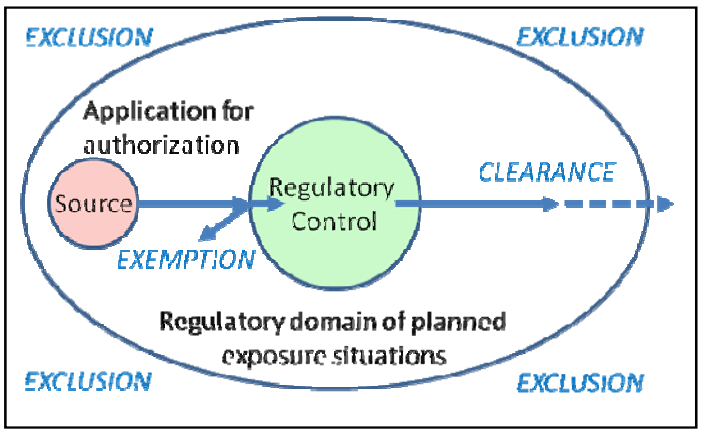
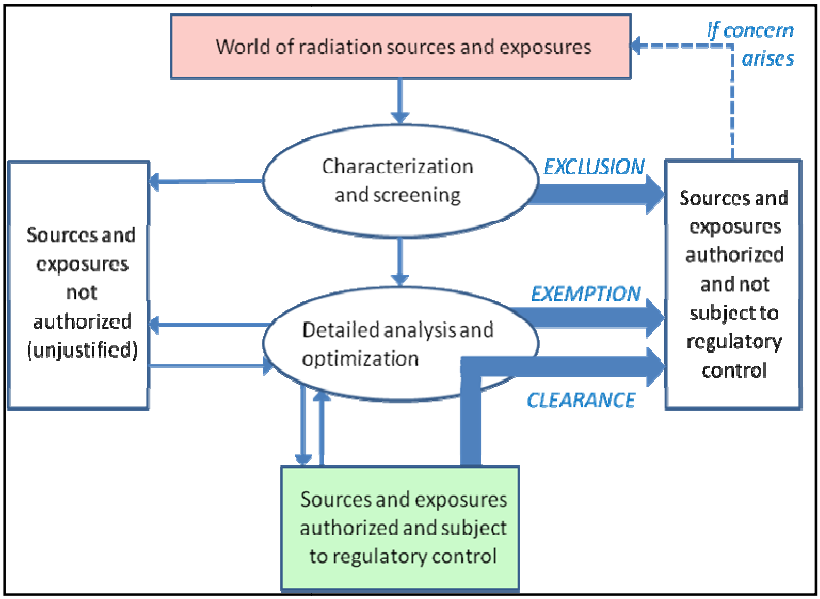


Figure 4.6-2:The process of regulatory authorisation as envisioned by the CRPPH, illustrating exclusion, exemption and clearance. Redrawn from Figures 1, 2 & 3 in Appendix 3 of NEA, 2006a.



4.7 Collective dose

The application of the quantity collective dose has a long and somewhat controversial history. As long ago as 1958, UNSCEAR noted that one could quantitatively estimate the total deleterious effects of radiation by adding the dose contributions from various sources, provided that there was a linear dose-effect relationship with no threshold. Such a *population dose* was thought valid as a measure for genetic injury and possibly for leukaemia (UNSCEAR, 1958). Even then there was concern that adding small doses might not be sensible and a quantity termed *collective dose* was often taken as the sum of individual doses in a given population, provided that these were not insignificant to the individuals who received them. There was, however, concern within the ICRP that assessments with this truncated quantity were improper. The view was that the measure of detriment in a population was the sum of all individual doses, irrespective of the size of the individual doses. Professor Lindell, reflecting on this view, commented that the common sense feeling that small doses, which were insignificant to the individuals receiving them, should not be added up had the same misleading character as the belief of Zenon and the Eleatic school that Achilles would never beat the turtle (Lindell, 1972).

In Publication 26, the ICRP noted that detriment to health could be considered proportional to collective dose equivalent (§ 24), acknowledging that this depended on the validity of the LNT model – considered a cautious assumption – but that it would be valid for increments on natural background (ICRP, 1977). The ICRP considered the quantity to be a valuable tool in protection, notably in the cost-benefit approach to optimisation (§ 72 et seq.).

By the time of Publication 60, the ICRP was suggesting that the collective dose should be disaggregated for use in optimising (ICRP, 1991). Optimisation had become "In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account" (§ 112b). It was noted that collective effective dose per unit of practice could be used in the justification of a practice and it could be one of the criteria for exemption (§ 287). The ICRP outlined but rejected the argument made by some for excluding small individual doses from the estimate of collective dose (§ 292, 293).

The thrust in the review by Professor Clarke (Clarke, 1999) was to change to an individual-based philosophy, shifting the emphasis away from societal-oriented criteria using collective dose. In his view, no use would be made of the quantity collective dose as then currently defined, since the proposed policy of protection would ensure that if the most exposed representative individual were to be sufficiently protected from a given source, then everyone else would be also sufficiently protected from that source.

In its initial critical review, the CRPPH noted with concern that the interpretation of collective dose, specifically as the integral of very small doses over extremely large populations and long time periods, had been somewhat problematic (NEA, 2000).

The view of the CRPPH (both in that review and in its later discussion of the way forward [NEA, 2002a]), was that collective dose was not a useful tool for estimating absolute detriment because of the inherent uncertainties. In such situations, collective dose would be better applied in a *disaggregated* fashion. In this context, disaggregation would mean presentation in terms of individual dose (e.g., average dose to the critical group, maximum dose to the critical group, individual dose distribution curve within the exposed population, etc.); of the number of people exposed; and of the temporal and geographic distribution of the population. This should not, in CRPPH's view, give the impression that the total detriment due to the total collective dose was without

significance. Uncertainties, however, needed to be much more explicitly expressed.

Despite that caveat on the use of collective dose, the CRPPH felt that collective dose was an important radiation protection tool. It was useful for comparisons in the optimisation process. This was particularly true in terms of selecting protection options for occupational exposures. For exposures of the public, collective dose could be useful for characterising radiological impact over limited periods. The CRPPH acknowledged that there were two schools of thought about whether summation of collective doses, even for comparative purposes, should be truncated at some predetermined lower level and/or after a limited number of years. However, truncation as such would not be an issue if collective doses were to be presented in a disaggregated fashion.

A further practical application of collective dose was that its use for worker groups inhibited the unreasonable use of dose sharing and aided tracking trends for repeated operations (e.g., steam-generator replacement) so that lessons could be learned. The overriding key would be for the ICRP to ensure that there was clear guidance on application of collective dose.

The ICRP in its look ahead (ICRP, 2002b) noted that already in Publication 77 (ICRP, 1998) it had acknowledged that collective dose, although a legitimate arithmetic quantity, was of limited utility since it aggregated information excessively (ICRP, 2002b). For making decisions, the approach advocated by the ICRP was that necessary information should be presented in the form of a matrix, wherein were specified the numbers of individuals exposed to a given level of dose and when it was received. This matrix should be seen as a decision aiding technique that would allow different weightings to be assigned to individual elements of the matrix (§ 32). The ICRP intended that this would avoid the misinterpretation of collective dose that had led to misleading predictions of deaths. The ICRP also noted the potential future role of collective dose in its expression per unit of practice were there to be a need to consider and possibly restrict the global build-up of per caput dose (§ 33).

The EGIR's main concern with the initial proposals from the ICRP was that the concept of collective dose per se was not discussed (NEA, 2003d). Most of the EGIR members agreed that the concept should be kept as part of the system of radiological protection because of its usefulness and widespread use in regulatory and guidance texts at the national and international levels. At the very least, the ICRP should explain how the concept was to be included in the new proposals. Further, the EGIR foresaw that, if the concept of collective dose was not retained, the new recommendations would need to provide guidance on how to manage the dilution of effluents or contamination.

In the 2005 draft of its recommendations, the ICRP reiterated its previous view on the need to disaggregate the components of collective dose when optimising protection (ICRP, 2004). The ICRP considered that, for making decisions, a large dose to a small number of people was not equivalent to a small dose to many people, even if the two cases corresponded to numerically equal collective doses (§ 199). Further, the weighting of the various elements or components in what it now termed the *dose matrix* would depend on the preferences and values of those involved in the decision making process, as well as on the feasibility of actions considered (§ 200). These elements could include the number of exposed individuals; the magnitude of individual doses; the dose distribution in time; the age and gender dependent risks as modifiers to dose distributions; equity considerations (achieving a balanced dose distribution); and whether the exposure was real or potential (§ 201).

The members of the EGIR, in reviewing the 2005 ICRP draft and the dose matrix idea in particular, had differing views on collective dose (NEA, 2004d). Some felt collective dose could be a representation of collective detriment, while others did not accept the use of any collective detriment based on collective dose. There was some support for the use of collective dose as an indicator, particularly in selecting optimised protection for occupational exposure. In any case, the EGIR felt that ICRP should provide its views on collective detriment more clearly. It should be made clear that the matrix could be used for defining specific boundaries on the calculation of collective dose. For example, matrix elements could be chosen to characterise exposures for one generation only, for one specific population, or over a limited geographic area. This could, in certain situations, be a useful decision tool.

A similar message came from a Working Group of the NEA Information System on Occupational Exposure (ISOE); collective dose was seen as being a useful tool in occupational exposure but should not be used to assess detriment to public health (NEA, 2005b). There would be a need, though, for practical advice on the use of the dose matrix elements.

The exposition on optimisation drafted by the ICRP in 2005, expanded the views of the ICRP on the application of collective dose and the dose matrix, already expressed in the ICRP documents noted above, but without any further substantive guidance (ICRP, 2005a). (The report was subsequently published as Publication 101 [ICRP, 2006b]). Collective dose was noted as being a commonly used indicator in occupational protection although account of the distribution of exposures even here was needed (§ 66). Total collective dose was considered not to be a useful decision aid when exposures were over large populations, large areas or long times because it aggregated information excessively (§ 68). There was the additional point that, in these circumstances

application of collective dose for a total population did not allow for "due consideration of important social and other socio-political considerations that may be particularly important for evaluating and comparing options" (§ 69).

The 2006 draft of the ICRP recommendations specifically warned against the use of collective dose in risk assessment (ICRP, 2006a). The ICRP noted: "Collective dose is not intended as a tool for epidemiologic risk assessment and it is therefore inappropriate to use it in risk projections based on epidemiological studies. Specifically, the computation of cancer deaths based on collective doses involving trivial exposures to large populations is not reasonable and should be avoided" (§ 147). This was because when individual doses were small fractions of the radiation dose received from natural sources and were spread over wide geographical areas and/or long time scales, collective dose aggregated too much information for the decision making process (§ 146). Also, in these circumstances collective dose combined several sources of uncertainty. The ICRP noted that such computations based on collective dose were never intended and were an incorrect use of that radiological protection quantity (§ 147). The view of the ICRP was that collective dose was mainly an instrument for optimisation, when comparing radiological technologies and protection procedures (§ 147). The ICRP added, however, that such calculations could be a useful tool for preliminary judgments on the feasibility of an epidemiological study or the plausibility of attributing observed health effects to a source of exposure (§ 230).

The ICRP cautioned that it did not intend to give detailed guidance on how to apply the dose matrix but did suggest that more weight could be given to moderate and high doses and to doses received in the near future, noting that in assessments the individual doses and the size of the exposed population become increasingly uncertain as time increased (§ 231). There was also the increasing uncertainty of the relevance of very low doses and doses received in the remote future.

The EGIR, reviewing the 2006 draft, was not satisfied that the ICRP had justified the statement that collective dose could not be used to estimate risk in retrospective studies – a clear, concise rationale was needed, in its view (NEA, 2006b). The EGIR saw that science and judgment were both involved here and felt that the ICRP should explain its reasoning. The *several sources of uncertainty* mentioned by the ICRP (§ 146) should be more explicitly described. The EGIR commented that that paragraph was a negative formulation of the use of collective dose. What was needed was a positive formulation on its use that would help to address the problem of dilution. There was also a need to articulate any restrictions it saw on the use of collective dose, particularly on doses in the far future and very small doses. Criteria were needed; not numerical

guidance. The matrix approach still needed more explanation. For example, inequity considerations (which could be in benefits or detriment) were to be considered in the matrix. What this meant should be clarified. The EGIR found that the advice on the use of collective dose in epidemiological studies (§ 230) was ambiguous. There was also ambiguity in a suggestion by the ICRP (in the context of emergencies and existing situations) that decision makers might be seeking to "reduce the collective dose and the detriment [where] the proposed protective action was not justified from the viewpoint of the individual" (§ 345). A better wording would be "reduce the inequity of distribution of dose and benefits" so that collective dose was not misinterpreted as being related to estimations of projected deaths.

The next draft of the ICRP recommendations (ICRP, 2007a) provided essentially the same text on collective dose as in the previous draft. The EGIR, reviewing that next draft, expanded on its previous criticisms (NEA, 2007c). It took exception to the statement: "Specifically, the computation of cancer deaths based on collective doses involving trivial exposures to large populations is not reasonable and should be avoided" (§ 157, latest draft; § 147, previous draft). According to the EGIR, the problem was not the use of small doses and large populations but rather the use of collective dose to make firm predictions on outcomes, without context and outside of its use as a prospective protection quantity within an optimisation process. Also in that same paragraph there was the weak argument: "Collective effective dose is not intended as a tool for epidemiologic risk assessment and it is therefore inappropriate to use it in risk projections for such studies. Such computations based on collective effective dose were never intended and are an incorrect use of this radiological protection quantity." The EGIR interpreted this to say "collective dose was not intended to be used for this, so don't use it for this". Rather, the ICRP should say why not, or why it was not reasonable. The EGIR suggested adding the following at the end of § 158: "When the range of individual doses spans several orders of magnitudes, one approach to characterise the dose the distribution could be by dividing it into several ranges of individual dose, each covering no more than two or three orders of magnitude, with the population size, mean individual dose, collective dose and uncertainty being considered separately for each range. When the collective dose is smaller than the reciprocal of the relevant risk detriment the risk assessment should note that the most likely number of excess health effects is zero." Reference was made to (NCRP, 1995). This addition was an attempt to rationalise the use of collective dose as a useful tool for making decisions.

The final version of the recommendations (ICRP, 2008a) confirmed that collective effective dose remained a key parameter for optimising protection for workers provided that there was careful consideration of the characteristics of

the individual exposure distribution within an exposed population (§ 220). It was reiterated that, when exposures occurred over large populations, large areas, or long times, the total collective effective dose was not useful for making decisions because it might aggregate information inappropriately and could be misleading when selecting protective actions (§ 221). Such use of collective dose would only be meaningful if there were sufficient knowledge of the risk coefficients for the detrimental radiation effects in all dose ranges which contribute to the collective dose; such knowledge was lacking (§ B236). The ICRP emphasised that the extrapolation with the LNT model provides risk factors for low incremental doses above natural background with a high degree of uncertainty (§ B237). The previous statement warning against the use of collective dose in risk projections, which had been criticised by the EGIR (see above), was further supported by the argument that the assumptions implicit in the calculation of collective dose concealed large biological and statistical uncertainties and presupposed a number of caveats that tended not to be repeated when estimates were quoted out of context (§ 161). The application of the dose matrix (as described above in earlier drafts and in ICRP, 2006b) was a way of avoiding the misuse of collective dose (§ B238). The ICRP included (in § 162) most of the text suggested by the EGIR (see above paragraph) on the NCRP (1995) suggestion concerning the use of the reciprocal of the relevant risk coefficient criterion.

Summary

The initial move by the ICRP to eliminate collective dose as a useful quantity in radiological protection met with resistance. The final document acknowledges that it should remain a key parameter in occupational protection.

The long-held contention by the ICRP that it was inappropriate to use collective dose as a tool in risk assessment and the CRPPH position that it was not a useful tool for estimating absolute detriment were in accord. But the latter position was not unanimous, as shown by the EGIR discussions. There was also disagreement about whether truncation of the collective dose in dose and time was a valid approach in risk assessment – a debate with a long history. The text that the ICRP has added to the statement in its final report to the effect that collective dose is not intended as a tool for epidemiologic risk assessment and it is therefore inappropriate to use it in risk projections based on epidemiological studies can be seen as a response to EGIR concerns.

A statement from the ICRP (in the 2005 draft recommendations) on the use of collective dose in optimising protection defined the issue with the use of collective dose. The ICRP stated that, for making decisions, a large dose to a small number of people is not equivalent to a small dose to many people, even

if the two cases corresponded to numerically equal collective doses. Though not stated this explicitly in subsequent drafts the sense remains and, in fact, there appears to have been a consensus from early in the discussions that disaggregation of collective dose made sense. The development by the ICRP of the idea of a multi-element dose matrix was consistent with this but continued discussions on the topic, both in the EGIR reviews and in conferences, have pointed to uncertainty about how the matrix might be used in practice and, in particular, what criteria might guide the weighting of the various elements. The ICRP has stated it has no intention of giving detailed guidance, other than suggesting giving less weight to very low doses and to doses received in the distant future. This appears to leave the question open, although the detailed text that the ICRP now has can be seen to be responding to many points raised in the discussions and reviews.

Two identified issues remain. One is that with the recommended dose matrix scheme, in which individual dose may dominate, there seems to be no restraint on dilution appearing to be the optimum control method for radioactive contamination of the environment. The other issue is that it is still not clear how inequities should be handled within the matrix. Other than these caveats, the concerns expressed by the CRPPH and the EGIR appear to have been addressed.

4.8 Environmental protection

Until the last decade, the prevailing ICRP view was that the level of safety required for protection of all human individuals was likely to be adequate to protect other species, although not necessarily individual members of those species (§ 14 in ICRP, 1977). In a more recent wording, the statement was that the standard of environmental control needed to protect man to the degree thought desirable would ensure that other species were not put at risk (§ 15 in ICRP, 1991). It was acknowledged that occasionally individual members of non-human species might be harmed, but not to the extent of endangering whole species or creating imbalance between species.

Through the 1990s environmental protection came to the fore and Professor Clarke, in his thoughts on the future of the ICRP recommendations (Clarke, 1999), suggested that the then current ICRP view was probably no longer sufficient. He saw the controllable dose system that he was proposing as facilitating the development of an environmental protection strategy for radiation protection that would be more compatible with those for other environmental agents.

The CRPPH in its critical review reflected on the changing societal mores with respect to protecting the environment and suggested that it should not be presupposed that additional ICRP recommendations would be necessary for protection of the environment (NEA, 2000). It suggested that the rationale for making or for not making recommendations should be more thoroughly and openly discussed by the ICRP. Any change in the recommendations should flow from these discussions. An expert group of the CRPPH expanded on this topic in a 2002 review, noting for example that the ICRP approach might not be applicable to situations where humans were not present in the radiation field or where there were no pathways to humans (NEA, 2002). Also, there was a feeling that the approach to the regulation of radiation exposure of humans and biota should be broadly in line with those adopted for non-radioactive pollutants. The conclusion was that radiological protection should try to fit within a policy framework that was consistent with the assessment and management of other environmental and health risks, such as those from chemicals.

The discussions on radiological protection of the environment in the conference in Taormina in 2002 provided a somewhat cautionary note on the development by the ICRP of a strategy for radiological protection of the environment (NEA, 2003a, 2003b). Basic impediments to developing such a strategy were seen as being the lack of a clear definition of the environment and disagreements on the significance of any changes resulting from radiation exposures, or even of the mere presence of radionuclides in the environment. The discussions there also showed clearly that there was no simple ethical principle for forging a system of environmental protection. Although science was an essential input, there needed to be an ethical base. The conference participants discussed three possible approaches. The first was the anthropocentric approach, which was being challenged. The second was the biocentric approach, which had emerged to succeed the anthropocentric approach but which many considered not to be the best solution. It prompted the question: do we protect a fish rather than a butterfly? Such a so-called biocentric approach depended on of human judgments. The last one was the ecocentric approach, based on the preservation of the ecosystems. That approach was favored by some scientists, but was difficult to implement. The ICRP appeared to have chosen the biocentric approach.

One suggestion from the Taormina conference was that a programme to validate the statements of the existing ICRP recommendations might be a more prudent strategy for the radiological protection of the environment and in any case was a necessary first step in determining if a *standard reference man* approach should subsequently be developed for biota. The ICRP was advised to take a global overall view in addressing this subject, by considering and

weighing the views of all interested parties in the debate, and not to be unduly influenced by any particular special or vocal interest group. A further cautionary point was that the ICRP should demonstrate that any recommendations they published would lead to a valid use of society's resources (i.e. funds and personnel) with a commensurate improvement in public and environmental health and safety.

The initial proposal from a Task Group of the ICRP on the framework it was considering for protecting non-human species pointed to the niche that the ICRP might be able to fill (ICRP, 2002a). The text noted that there was a diversity of legislative needs concerning environmental protection around the world that needed to be taken into account. The consequences of the presence of radionuclides in the environment might have to be managed by way of pollution control legislation although other legislative needs – such as those arising from nature conservation legislation – might predominate in some circumstances and for some countries (§ 141). Each of these might require different approaches, including those that were similar to toxicity-based or ecotoxicity-based approaches used in the management of other threats to the environment. They might require the local derivation of environmental standards – in terms of dose rates or radionuclide concentrations in particular environmental materials – to manage particular situations. Alternatively, they might simply require independent evaluations of the potential effects of radiation on the biological parameters of interest within any particular habitat or site. However, these were decisions to be made at a national level. The ICRP Task Group suggested that additional and necessary guidance would also be provided nationally via other fora. The conclusion was that it would greatly help the overall acceptability and interpretation of such decisions if they were all to be based upon some system of reference methods, models and data bases. The development by the ICRP of reference fauna and flora would enable different countries to assess and protect their environments in relation to their own national requirements, drawing on a common understanding at an international level of the effects of radiation on different types of animals and plants (§ 149).

In the 2002 draft of its new recommendations (ICRP, 2002b), the ICRP commented that a systematic approach for radiological assessment of non-human species was needed in order to provide the scientific basis to support the management of radiation effects in the environment (§ 55). The decision to develop a framework for the assessment of radiation effects in non-human species had not been driven by any particular concern over environmental radiation hazards. Rather, it had been developed to fill a conceptual gap in radiological protection and to clarify how the proposed framework could contribute to the attainment of society's goals of environmental protection by developing a protection policy based on scientific and ethical-philosophical

principles. The ICRP endorsed its Task Group's recommendation to develop a set of quantities and units, a set of reference dose models, reference dose-per-unit-intake data and an effects-analysis. Reference fauna and flora would be developed by ICRP to aid assessments, and others could then develop more area- and situation-specific approaches to assess and manage risks to non-human species (§ 58). The ICRP acknowledged that, though it had a unique position in relation to human radiological protection from which it has played a major role in influencing legal frameworks and objectives at international and national levels, this was not the case for environmental protection. Protection of other species was more complex and multi-faceted, with many international and national environmental legislative frameworks and objectives already in place. The ICRP did not intend to set regulatory standards for such protection, but rather to provide an explicit assessment framework to help the decision making process (§ 57).

Reacting to the ICRP's proposals on environmental protection, the EGIR accepted that the ICRP was the appropriate international body to develop and publish a recommendation on radiological protection of the environment (NEA, 2003d). However, during the process of developing that recommendation, broad consultation with the relevant stakeholders was seen as being essential. As part of the process of developing its new recommendation, and for rationalising the need to make such a recommendation at this time, it was felt that the ICRP should discuss the current system in terms of where improvements could be made. For example, if man was present and protected, was biota then also protected? The recommendation should address what would be needed to answer this question. Radiological protection of the environment should then be seen as an evolution of the current system of radiation protection, which already provided a certain level of protection for the environment but did not yet consider explicitly situations where humans were not a good reference.

The EGIR cautioned that, given the basis of environmental protection that already existed in national regulations and international conventions, it was important that any proposed system for radiological protection of the environment would not be in conflict with internationally agreed general principles agreements, standards and regulations for environmental protection that already existed.

On the specifics of what was being proposed, the EGIR saw the need for more detail on how radiological protection criteria would be developed on the basis of reference flora and fauna. An issue that particularly concerned the EGIR was that of risk transfer, particularly within the optimisation process. This had been one of the more difficult aspects of the current system of radiological protection. The additional emphasis being placed on the radiological protection

of the environment would complicate this even further. It would be essential for the ICRP, in its new recommendations, to discuss the aspects that it would see as useful for the balancing of protection of humans and non-human species at the policy, regulatory and operational levels.

The EGIR suggested that the system developed by the ICRP should have a scientific foundation and, as for the radiological protection of humans, rest on clearly defined principles. The newly proposed system for humans was based on justification, dose constraints, and optimisation. A parallel set of principles should be defined and clearly described for the protection of non-human species though it was recognised that the application of these principles might well be different for humans and non-humans. Optimisation of the radiological protection for non-human species, for example, might be achieved de facto through the application of other environmental protection initiatives.

The view from the participants in the 2002 Lanzarote conference on the ICRP recommendations (NEA, 2004b, 2004c) took note that the ICRP had stated that, in developing a system of radiological protection for non-human species, it was not driven by concern over the state of environmental protection but rather by the need to communicate to the non-scientific world that the radiological protection system was providing protection of the environment. The conference participants supported that rationale and goal. On the suggested development of reference flora and fauna, the view was that a limited set would not be sufficient for all types of ecosystems. Finally, the conference participants agreed that the developed system must be complementary for humans and non-humans and that it should be harmonised with the protection systems in place to address other environmental stressors such as chemicals.

The 2005 draft of the ICRP recommendations (ICRP, 2004) expanded the discussion of the intentions of the ICRP in developing a system of environmental protection, following essentially along the lines of the earlier draft. There were no specific recommendations. The position of the ICRP was caught in what was in essence a preamble to a more detailed discussion of what it might do. The ICRP noted that it still believed that the position as presented in Publication 60 (ICRP, 1991) was correct in general terms (§ 242). Thus, the ICRP continued, it was probably true that the human habitat had been afforded a fairly high level of protection through the application of the current system of protection. However there were then also other demands upon regulators, in particular the need to comply with the requirements of legislation directly aimed at the protection of wildlife and natural habitats; the need to make environmental impact assessments with respect to the environment generally; and the need to harmonise approaches to industrial regulation, bearing in mind that releases of chemicals from other industries were often based upon their

potential impact upon both humans and wildlife. All of those demands were being met in a multitude of differing ways, partly because of the lack of advice on the subject at international level and partly because there were no agreed assessment procedures, criteria, guidelines or data sets with which to approach those issues in a coherent way. Those deficiencies, in turn, had led to different national approaches being developed and it made international harmonisation difficult. That was the context in which the ICRP saw the need to explore further the nature of the risks that might apply to other species, how such risks might be quantified, and thus how it could be positively demonstrated that they were, indeed, not put at risk (§ 243). Those circumstances provided the drive for the ICRP in developing a combined approach to the protection of humans and other species, and to do so within an overall framework that recognised the different but complementary aims and objectives involved. Further, the ICRP saw the need to develop a common scientific basis and approach for relating exposure to dose, and dose to effect, for all living things (§ 244).

The EGIR in its review (NEA, 2004d) recognised that the ICRP's draft section on protection of the environment presented what the ICRP intended to pursue, rather than having any recommendations for protection. The EGIR felt it would be more helpful for the ICRP to shorten the section on environmental protection, to focus on policy issues and to provide recommendations about what should be done until there was a better scientific base of knowledge. Protection of ecosystems was the most likely goal, in the view of the EGIR, but it was too little understood. Therefore protecting individual biota, through a reference individual approach, was a reasonably precautionary approach until more was known about the link between individuals of particular species and overall ecosystem protection.

The next draft of the recommendations (ICRP, 2006a) considerably condensed the text on its intentions for recommendations for protecting the environment but kept to the same general approach. In reviewing the draft the EGIR, which had suggested such a condensation, noted that there were still no actual recommendations although the ICRP had expressed its intention to clarify its position on the previous statement that protection of man was (generally) sufficiently protective of the environment (NEA, 2006b). (The EGIR preferred *the environment* to the term used by the ICRP – *non-human species* – arguing that the former allowed more flexibility.) The EGIR could not agree how best this might be accomplished. Some members thought that the entire section on environmental protection should be deleted, though all agreed that, were the section to be kept, it should be made clear that there were no detailed policy statements. There could be more discussion, however, on how reference plants and animals could be used in the broader framework for the radiological protection of ecosystems.

At the workshops on the ICRP recommendations held during 2006 in Tokyo, Washington DC and Prague (NEA, 2007a, 2006c, 2006d) there was little discussion on protection of non-human species (NEA, 2008c). While there was no international guidance in that area, it appeared that most developed nations included environmental assessments as part of their national environmental protection legislation. It was agreed that the discussion of the impact of ionising radiation on non-human species provided in ICRP Publication 91 (ICRP, 2002a) was sufficient. However, it was recommended that a framework focusing on this aspect should be defined as soon as possible, since it would be more difficult to harmonise the worldwide environment protection policy in the future as countries proceeded to develop and adopt their own national policies.

The 2007 draft of the recommendations (ICRP, 2007a) contained essentially the same text as the previous draft with the addition of three paragraphs that considered what might be done immediately. The ICRP noted that some form of practical means was obviously required in order to make judgments, based on the current level of knowledge of the effects of radiation on different types of animals and plants. There was a paucity of information upon which dose response curves could be established at the relatively low dose rates likely to obtain in most exposure situations. The data bases on radiation effects for the majority of animals and plants were not dissimilar from those relating to chemical toxicity studies, where the levels required to produce a given effect were many orders of magnitude greater than those expected in the majority of environmental situations (§ 375). However, the ICRP noted that there was a source of reference, and that was the natural background radiation to which such animals and plants were continuously and typically exposed. Thus, additional radiation doses to animals and plants could be compared with those dose rates known or expected to have certain biological effects in those types of animals and plants, and with the dose rates normally experienced by them in their natural environments (§ 376).

The ICRP emphasised (§ 377) that it did not propose to set any form of dose limits with respect to environmental protection. More practical advice would be offered than in the past by setting out data for some reference animals and plants. The ICRP intended to use this framework to gather and interpret data in order to provide more comprehensive advice in the future

The EGIR in its final comments (NEA, 2007c) suggested that the ICRP should be more emphatic in stating that the environment had been protected through the provisions of the previous recommendations. The then current draft of the recommendations only had the statement that, in the context of planned exposure situations, the ICRP continued to believe that the standards of

environmental control needed to protect the general public would ensure that other species were not placed at risk (§ w). The EGIR felt that reference to Publication 60 (ICRP, 1991) should be made to clarify what was written there. There was further support for this view from the results of the survey carried out for the CRPPH (NEA, 2007b), which also concluded that the most appropriate way to proceed was to develop the tools and knowledge base that would allow environmental protection measures to be linked to environmental harm.

In the final text from the ICRP (2008b), the section on environmental protection was unchanged from the previous draft.

Summary

The reaction within the radiological protection community to the proposal by the ICRP that it should develop an environmental protection strategy was one of caution. A strongly held view was that additional recommendations on the environment were not needed from the ICRP. Many issues that would arise with such a development were voiced; the need for a definition of the environment and protection principles; the need to fit in with current frameworks for other health and environmental risks; the need to resolve disagreements about the significance of radiation exposures on the environment. There was agreement that any developments by the ICRP should be seen as not being driven by concern over environmental radiation hazards. More importantly, the need was to be able to explain the situation to the public.

The ICRP through successive drafts reflected this advice. Its position was that it did not intend to set regulatory standards for environmental protection. The intent was to provide a framework and tools for assessment to help the decision making process; initially these would be reference flora and fauna. The ICRP agreed that it was not driven by concern over the environment and it restated its previous position that the standards of environmental control needed to protect the general public would ensure that other species were not placed at risk.

The discussions in the various EGIR reviews and the conferences indicated that, though there seemed to be broad agreement on the cautionary points noted above, there was a diversity of opinions about what the ICRP should actually do (or not do). The final position of the ICRP appears to be a cautious move to providing tools that can be used now and to gather and interpret data with a view to providing further advice in the future. This is in accord with the advice it has received from the CRPPH.

4.9 Stakeholder involvement

The possible role of stakeholders in aiding decisions in radiological protection was first noted explicitly by the ICRP in Publication 82 (ICRP, 1999), where seeking stakeholder input was advocated when deciding what actions were needed in cases involving prolonged exposure. An important aspect of such involvement in a wider context was pointed out by the CRPPH in its critical review of the system of protection; namely that of fostering confidence in the entire system of protection (NEA, 2000). The process of justification, particularly when public exposures were involved, was an example where stakeholder involvement could be beneficial. Another example was in the concept of triviality, which was inherently judgmental. Controversy over this issue had led to the failure of the use of the concept in several circumstances where, for example, experts and regulators had judged radiation exposures to be trivial, while members of exposed populations, and often other stakeholders, felt that doses were from *quite significant* to *unacceptable*.

There were further discussions at a series of workshops organised by the CRPPH in Villigen on the policy-level aspects of how stakeholder involvement could affect decisions made in situations involving radiation exposure to the public or to workers (NEA, 1998, 2001, 2004e). In a following discussion of the way forward in radiological protection, the CRPPH further expanded its ideas on such involvement (NEA, 2002). It concluded that the discussions within the radiological protection community, which had mirrored broader discussions of the much more general subject of modern governance, had converged on the idea that a better understanding of the roles of various stakeholders in the decision making process would very much facilitate finding solutions that could be accepted. Specifically, in situations involving radiological protection decisions, when stakeholders beyond the regulators and radiological protection experts were involved, it was important that the decision maker not be perceived as being the *expert/decision aider* and the *decider* all in one. In complex societies, governments (national and perhaps local) and parliaments could be considered in many cases as the ultimate decision makers. The role of radiological protection experts was to assess and quantify risks; to define alternatives; and to advise, recommend, and explain the radiological implications of decisions. However, when experts also held the role of regulator or decision maker, there could be a mixing (or perceived mixing) of the scientific understanding of risk, and the social justification and acceptance of risk. That could lead to a lack of trust in the decision making process. If the role of *decision making* were to be kept conceptually apart from the role of *decision aiding*, the identification of a socially accepted solution could be greatly facilitated. The CRPPH pointed out that most regulatory decisions would not be

socially contentious, and that stakeholder involvement would only be necessary for some decisions.

Given the above, the CRPPH suggested (in NEA, 2002) that the ICRP could usefully provide guidance on identifying, in advance, those situations where radiological protection decisions could most be helped by involving stakeholders. A consultants' report (NEA, 2003c) provided an example of stakeholder involvement in the process of authorisation as envisioned by the CRPPH.

In its preliminary look at the evolution of its recommendations, the ICRP indicated that there was a role for stakeholders (ICRP, 2002c). It suggested that the more formal authorisations, which were traditionally decided by the regulator in conjunction with the operator, might in future best be carried out by involving all the bodies most directly concerned, including representatives of those exposed, in determining, or in negotiating, the best level of protection in the circumstances. It was to be decided how the ICRP's recommendations would deal with that degree of societal process. However, the result of the process would lead to the authorised levels applied by the regulator to the source under review.

At the 2002 Tokyo conference to discuss the evolution of the ICRP recommendations (NEA, 2004a), it was made clear by the participants that there was a big difference between European and Asian nations in the fundamental philosophy about stakeholders and the necessity for their involvement. In Europe the idea was that stakeholders would take part in the decision making process. On the contrary, in Japan (for example) the stakeholder involvement was treated more as a means of gaining public acceptance. At the 2002 European conference – in Lanzarote – he involvement of stakeholders was viewed as being more central to and early in decision making processes (NEA, 2004b, 2004c).

The EGIR, in its review of the initial ideas from the ICRP, saw that the ICRP recommendations should be formulated so as not to hinder the involvement of stakeholders in national decision making processes (NEA, 2003d). However, the feeling was that the ICRP should not recommend methods by which stakeholder involvement in the optimisation of protection could be achieved. The group reiterated the point made in the earlier CRPPH reports that in the recommendations there should be a clear distinction between those parts that were based on science and those parts that were based on social choice through appropriate stakeholder involvement. The EGIR believed that the judgment of what level of dose was *safe* or *unsafe* was a societal decision. As such, the ICRP recommendations should not make this judgment in society's

place and should clearly point out the judgmental nature of terms such as *low concern* and *high concern* if these were to be used.

In its 2005 draft recommendations, the ICRP strengthened its endorsement of the involvement of stakeholders (ICRP, 2004). The term *stakeholders* was defined as those parties who had interests in and concern about a situation (§ S11, 194). While the extent of stakeholder involvement would vary from one situation to another in the decision making process, the ICRP saw it as a proven means to incorporate values into decisions; to improve the quality of decisions; to resolve conflicts among competing interests; to build trust in institutions; and to educate and inform workers and the public. Furthermore, involving all parties affected by the decision reinforced the safety culture and introduced the necessary flexibility in the management of the radiological risk that was needed to achieve more effective and sustainable decisions. The message in the more detailed exposition of how stakeholders might be involved in the optimisation process in the ICRP draft text on optimisation (ICRP, 2005a) was essentially the same. These views coincided very closely with those developed at the 3rd Villigen conference (NEA, 2004e).

The EGIR, whilst endorsing the new emphasis that the ICRP placed on stakeholder involvement, felt that more explanation was needed (NEA, 2004d). A particular point that needed emphasis was that optimisation did not end when there was agreement amongst stakeholders. The decider made the decision, taking into account various inputs including those from stakeholders. The EGIR (again) pointed to the process of authorisation that the CRPPH was advocating, in which the role of stakeholders was key (NEA, 2006a). Most cases would not require broad public involvement; in the suggested process an initial screening by the regulatory authority would indicate the level of stakeholder involvement that might be needed to arrive at appropriate, sustainable and acceptable decisions.

The philosophical differences between the European and Asian ideas about stakeholders surfaced again in the second conference in Tokyo in 2004 (NEA, 2005a). The concerns remained but the common understanding reached by the participants was that the concept of stakeholder involvement depended on culture and country, but that, nevertheless, stakeholder involvement was important. Uncertainties remained about the definition of stakeholder and the process of involvement.

The 2006 draft of the recommendations (ICRP, 2006a) reiterated the text of the earlier draft but clarified that the role of the stakeholders was as an aid to making decisions. Thus, in § 361, it was noted that members of the public were often stakeholders when decisions concerning radiological issues were to be

taken, and had a legitimate interest in access to such decisions and information on how they were reached. Also, in § 369, the involvement of stakeholders was "an important decision aiding input to decision making on radiological protection issues, not least in the optimisation process."

At the third conference in Tokyo in 2006 (NEA, 2007a) the bone of contention with respect to stakeholder involvement remained the different cultural approaches. The EGIR's only recommendation at this stage on the ICRP's evolving position on stakeholder involvement was that the text that elaborated on the application of optimisation should explicitly state that stakeholder views should be taken into account (NEA, 2006b). This would support the view expressed earlier in the document that the optimisation process was judgmental and subjective in nature.

During the discussion in the 2006 conference on the ICRP recommendations in Prague (NEA, 2006d) the point was made that justification could, in the future, be the most important area of stakeholder involvement. Some participants even wished to see stakeholder involvement as the fourth pillar of radiation protection.

Although the involvement of stakeholders had, in fact, been implicit in the earlier ICRP drafts, in the 2007 draft the ICRP was more explicit (ICRP, 2007a). Adding to the earlier stated point that the responsibility for justifying usually fell on governments or national authorities to ensure an overall benefit in the broadest sense to society and thus not to each individual, the ICRP went on to state (in § 202): "However, input to the justification decision may include many aspects that could be informed by users or other actors outside of government. As such, justification will generally be carried out through appropriate social processes, depending upon, among other things, the size of the source concerned."

The only addition suggested by the EGIR at this stage (NEA, 2007c) was that, in the general considerations of the section on the implementation of the ICRP recommendations, there should be a paragraph that stated that active programmes to involve the public in decision making processes should be established and maintained to ensure openness and transparency.

The final version of the ICRP recommendations (ICRP, 2008a) maintained the previous wording on the involvement of stakeholders but added a paragraph (§ 224) that further clarified their role. The ICRP stated that: "Societal values usually influence the final decision on the level of radiological protection. Therefore, while this report should be seen as providing decision aiding recommendations mainly based on scientific considerations on radiological

protection, the Commission's advice will be expected to serve as an input to a final (usually wider) decision making process, which may include other societal concerns and ethical aspects, as well as considerations of transparency (ICRP, 2006b). This decision making process may often include the participation of relevant stakeholders rather than radiological protection specialists alone."

Summary

In 1999 the ICRP had suggested that involving stakeholders could help when decisions were being made about protection when there were prolonged exposures. The CRPPH encouraged the ICRP to broaden its endorsement of involving stakeholders – such involvement helped acceptance and fostered confidence. The CRPPH noted, however, that significant stakeholder involvement beyond that of the regulatory authority and the licensee would not be needed in many cases.

The ICRP's initial suggestion, reflecting this advice, was that stakeholders could be involved in determining or negotiating the best level of protection. This prompted strong reaction on two counts. One was that there should be a clear distinction between involvement as a decision *aider* – the role of the stakeholder – and decision *maker* – the role of the regulator or other authority. The other was the cultural difference between Asian and European countries, a difference that continued to be brought up through the various conferences. In the Asian view stakeholder involvement was largely a means of gaining public acceptance. The European view was more the idea of taking part to have an input, although the public acceptance aspect was clearly also important.

Subsequent drafts from the ICRP tried to meet these caveats. The involvement was seen as means to incorporate values into decisions, to improve the quality of decisions, to resolve conflicts among competing interests, to build trust in institutions, and to educate and inform workers and the public. The ICRP referred to *appropriate social processes*.

Before the final document was completed by the ICRP, the EGIR pressed for more explanation, for an emphasis on the need to set up ongoing programmes with stakeholders, and for explicit mention of stakeholders' role in optimising. In the end, the ICRP has pointed to the detailed discussion of stakeholder involvement in its report on optimising and has settled for a more general statement in its main recommendations. This notes that societal values influence final decisions on levels of protection and that the decision making process *may* often include the participation of relevant stakeholders.

5. SUMMARY AND CONCLUSIONS

We have:

- reviewed the reports and discussions of the CRPPH and the EGIR that have commented on the issues that needed resolving in radiological protection and that have critiqued the successive drafts of the ICRP recommendations;
- reviewed the discussions in the conferences in Japan Europe and the US, organised by the CRPPH, that have focused on the development of the new recommendations;
- reviewed the successive drafts of the ICRP recommendations, the related draft ICRP reports that were available whilst the recommendations were being developed, and the final published recommendations; and
- tracked the discussions in these report and conferences on nine topics and the changes made by the ICRP in those topics through the successive drafts of the recommendations.

We found that, in all the topics we reviewed, the evolution of the recommendations through the successive drafts reflected many of the views and criticisms that had been expressed by the CRPPH, the EGIR and conference participants. There were, of course, other inputs to the ICRP but those from the CRPPH groups, which represented the distillation of the views from radiological protection experts from the NEA member countries, appear to us likely to have been the most coordinated, detailed and persistent appraisals.

An indicator of the overall impact that the interactive process has had is that, as the ICRP points out, the new recommendations do not contain any fundamental changes in policy. This was not the direction that the evolution of the recommendations appeared to be taking at the start of the process.

The list below shows, for each of the topics we have reviewed, the single most important evolutionary change that reflects the suggestions and concerns of the CRPPH, the EGIR and conference participants.

- Justification is retained as a principle.
- The role of optimisation has been strengthened throughout the system of protection.
- Dose limits for individuals have been retained
- The definition of and guidance on the new categories of exposure have been refined.
- The role of the linear non-threshold model as a regulatory tool is emphasised.
- Some issues surrounding the application of dose constraints and reference levels have been resolved and more advice is promised.
- There is flexibility in the application of the concepts of exclusion and exemption, with which the CRPPH process of authorisation is coherent.
- Collective dose remains for use in occupational settings and, in a limited way, for use with public exposures.
- The expansion into environmental protection is cautious and appropriate to ICRP's niche.
- The involvement of stakeholder is endorsed, with the emphasis that it is decision aiding.

A continuing request from the CRPPH and the EGIR in their successive reviews was for clearer explanations of the various concepts and processes in the evolving system of protection. Through successive drafts these explanations have been developed along with adjustments to the concepts and processes themselves. The focus of the EGIR discussions also evolved from review to review. Agreement with changes that had been made was noted in some cases, but, though explanations in the successive ICRP drafts did evidently become clearer, we cannot say whether the evolution of the focus of the CRPPH and EGIR comments was a result of these clearer explanations or was indicative of an increased understanding of the ICRP concepts and recommendations by the CRPPH and EGIR.

As might be expected, not all the suggestions from the various review groups were adopted and not all identified issues were resolved. Consequently, there are continuing concerns in some areas. One is the application of dose constraints and reference levels, where many of the concerns have not been resolved. Another reflects the misgivings about the persuasiveness of the rationale for the use of the LNT model as a regulatory tool but not its use in risk

assessment, although it is accepted by the ICRP as being a scientifically plausible model. A third concern is with the criteria for weighting the elements of the dose matrix and the practical use of the matrix in optimisation.

The process that has been followed has exemplified stakeholder involvement. There has been interaction between stakeholders and the members of the Main Commission of the ICRP, and input from the stakeholders to the development of the new recommendations. The outcome has been influenced by that input. The final say has, though, been with the ICRP. The process has been one of decision aiding, rather than decision making. Further, the interactions with the ICRP have helped the understanding of the system of protection. The interactions appear to have been particularly helpful in Asia. The three conferences in Tokyo allowed for a much greater participation of the Asian radiological protection community in the decision making process than in the past, with the consequent better mutual understanding.

There are certainly changes in concepts, quantities and processes, as our review has illustrated, which could be the basis for eventual changes in national legislation and regulations. Our review has also illustrated that there remain concerns and questions about some of these changes. Given that there are no fundamental changes in the policies underlying the system of protection, there would appear to be no great urgency for national regulators to enact new legislation immediately. This means that there is time for the radiological protection community in general, and the CRPPH in particular, to take stock of the implications of moving towards the system of protection as it is now defined by the ICRP; to define the changes in regulations that might be needed and how best they might be implemented; and to assess whether the costs of such changes are likely to result in a commensurate increase in radiological safety.

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Appendix

GENESIS OF THE DOSE CONSTRAINT VALUES OF 0.3 MSV/A AND 0.1 MSV/A

The role of a dose constraint as defined in ICRP Publication 60 (ICRP, 1991) was primarily as a bound on inequity in individual occupational doses when protection was being optimised. The value of the constraint would depend on the circumstances. When exposures of the public were involved, then a dose constraint could be applied to any particular source to allow for any appreciable contributions from other sources. The values of the constraints could be set at the national or local level. A further role was to reflect minimum requirements for protection in what might be considered good practice.

This concept of the dose constraint was an expansion of what had previously been called an *upper bound*. For example, the IAEA in its Safety Series #77 on the principles for limiting releases of radioactive effluents into the environment (IAEA, 1986) noted that a source specific limit, often called an upper bound, should apply to the dose contribution to individuals from any specific single sources or practices. The upper bound, to be imposed by the competent authority, should be so selected that the envisaged total of sources, present and future, would not cause doses above the primary limits (§ 1.5.3). The report cited an expression for a source-specific upper bound, H_{UB}, as given by Beninson (1982):

$$H_{UB} = F.H_{limit} - H_{regional} - H_{global}$$

where F was the fraction of the primary dose limit, H_{limit}, set by the competent authority to reserve some margin for future developments of the practice (source) in question or others; and $H_{regional}$ and H_{global} were the regional and global components respectively of the critical group dose.

The Safety Series report did not attempt to derive any actual values but a later IAEA Technical Committee, which met in 1990 and 1991 and was chaired by Dr. Beninson, elaborated the Beninson formulation by including a further multiplying factor. This factor was intended to allow for a possible increase in individual exposures due to changes in critical group habits, etc., while the

source was operating (IAEA, 1992). In the nomenclature of the earlier report, and with the new multiplying factor G, the formulation for what was by then called the dose constraint (H_{DC}) became:

$$H_{DC} = \{F.H_{limit} - H_{regional} - H_{global}\}.G$$

An example for practices discharging long-lived radionuclides to the environment was worked through by the Committee. The peak future global radionuclide contribution to a critical group annual dose (H_{global}) was of the order of 0.04 mSv. This was derived from a 500 year truncated collective effective dose from ^{14}C. The regional contribution was derived from a scenario that included reactor operations, reprocessing and mine and mill operations; the assumption that all fuel was reprocessed; and the assumption that discharge levels were similar to the best then being obtained. The annual regional contribution ($H_{regional}$) after 500 years was estimated to be 0.045 mSv. The regional and global components were based on data in the 1988 UNSCEAR report (UNSCEAR, 1988). The Committee concluded that the regional and global annual contributions would be approximately 0.1 mSv and would certainly be less than 0.2 mSv, even with a significant contribution from heavy water reactors. The Committee suggested that 0.2 mSv should be reserved under the dose limit for future unknown practices (i.e., F=0.8 in the nomenclature here), though it pointed out that this was based on no knowledge; it just seemed reasonable. Further, the possible uncertainties in population habits, land use etc. were reflected in the choice of 0.5 for the value of G. Hence, the generic annual dose constraint was determined to be 0.3 mSv [(0.8 x 1000-200) x 0.5].

The Committee also considered the situation where there was no release of long-lived radionuclides to the environment. The far future global contribution could then be ignored and the population habit factor (G) could be taken as close to one. The annual dose constraint would then be 0.7 mSv.

The maximum levels of individual exposure from various practices (predominantly nuclear power activities) that had been set by regulatory authorities in eleven countries were tabulated by the Technical Committee. The range in values was from 0.1 to 0.5 mSv in a year. The Committee suggested that these values were effectively dose constraints and concluded that the value derived in its study was of the same order. The recommendation from the Committee was that national authorities would need to establish, in the licensing, prescribed limits below the constraints for particular sources.

In a response to ICRP Publication 60, the UK National Radiological Protection Board (NRPB) provided detailed advice on the application of the new recommendations and, inter alia, recommended that the dose constraint for

a single new source should not exceed 0.3 mSv per year (NRPB, 1993). The constraint was introduced by the NRPB "in order to meet the criterion . . . of an annual risk of 1 in 100 000 . . ." (There was no explanation of why the value 0.3 mSv per year was chosen on the basis of this criterion, rather than 0.2 mSv per year, which would have been more consistent with the nominal risk coefficient of 5% per sievert adopted by the NRPB.) The NRPB acknowledged that there could be cases where a facility could not realistically be expected to operate within the constraint and that in such cases, there must be a demonstration that doses were below the dose limit and were as low as reasonably achievable. There was a further rationale for the choice of the value of 0.3 mSv per year based on the value of 0.3 mSv being about 10% of the average annual exposure from all sources of radiation, principally natural radiation, which itself had a variation that was much greater than 0.3 mSv from place to place, even excluding exposures from radon. There was the further comment that it would seem unlikely to justify a lower maximum value for the constraint, given the small fraction that 0.3 mSv was of natural background radiation.

Shortly after the publication of this advice, the NRPB undertook an assessment of critical group doses at nuclear facilities in the UK (Robinson *et al*., 1994). Underlying this study was the belief by the NRPB that existing plants could be operated so that the critical group dose did not exceed 0.3 mSv/a.

The results of the study showed that there were a few instances where a secondary source made an appreciable contribution, although for most facilities the critical group dose was dominated by the local source. In only two instances was a contribution from a secondary source greater than 0.1 mSv/a (~ 0.13 mSv/a in each case) and one of these, interestingly, was a result of natural radionuclides (particularly ^{210}Po) from a phosphoric acid production plant. In the years after the NRPB study was completed, the annual contribution from these natural radionuclides released by the phosphate plant (which was demolished in 2004) has been conservatively estimated to be as high as 0.23 mSv (EA, 2007).

In its recommendations on a radiological protection policy for the disposal of radioactive waste, Publication 77, the ICRP cited this NRPB study in its discussion of accounting for multiple sources (§ 44, ICRP, 1998). It should be noted that disposal of radioactive waste in the context of this report included the discharge of effluents from operating facilities. The ICRP report also concluded from UNSCEAR data (UNSCEAR, 1993) that the contribution of widespread secondary sources of radioactivity to doses to critical groups would amount to only a few percent of the dose limit for members of the public. The report

continued: “Nevertheless, there are a few rare situations in which there are significant exposures to multiple sources within a practice. Some allowance should then be made for exposure to these multiple sources.”

The recommendation from ICRP Publication 77 for the control of waste disposal was that the maximum value of the constraint used in the optimisation of protection for a single source should be less than 1 mSv in a year to allow for exposures to multiple sources. Further, a value for the constraint of no more than about 0.3 mSv in a year would be appropriate (§ 48). This is the value cited in subsequent ICRP recommendations for application as the constraint in optimising protection for any single source.

The adoption by the ICRP of the value of 0.1 mSv in a year for some situations where exposures were prolonged occurred in ICRP Publication 82 (ICRP, 1999). The text noted that there needed to be special consideration given to situations where combinations of transitory and prolonged exposures, or a build up over time of prolonged exposures from a source, could occur (§ k). In those situations it should be verified that appropriate dose assessment methods were being used to ensure compliance with the established dose constraint. Also, the assessment should take account of any reasonably conceivable combination and build-up of exposures. Further, the text noted that, if such verification of compliance was not feasible, it would be prudent to restrict the component of the individual dose from the source with a dose constraint of the order of 0.1 mSv in any given year during the operational lifetime of the source.

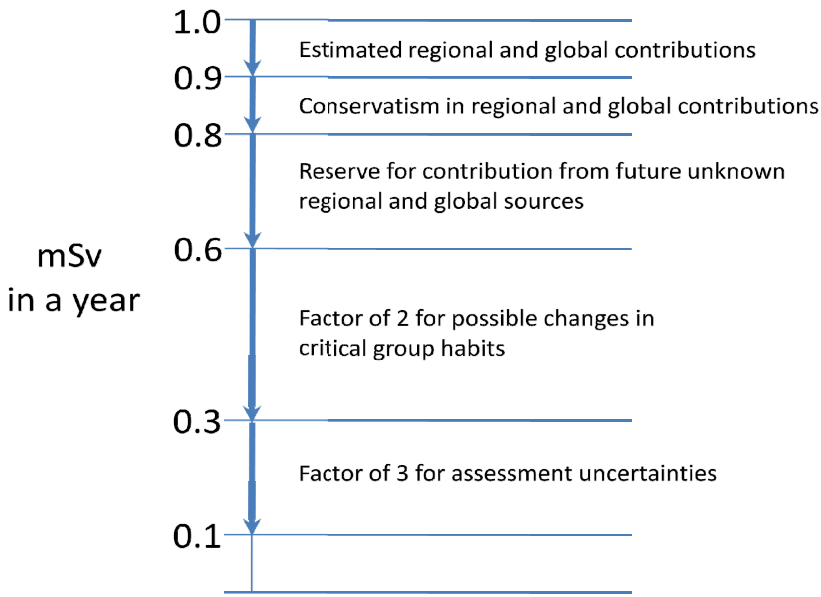
In the new recommendations, Publication 103 (ICRP, 2008), the same recommendation is made, with reference back to Publication 82, although the explanation of what was recommended in Publication 82 is worded differently. In the new text the wording is that planning assessments should consider whether build-up in the environment would result in the constraint being exceeded, taking into account of any reasonable combination and build-up of exposure (§ 261). Where such verification considerations are not possible or are too uncertain, it would be prudent to apply a dose constraint of the order of 0.1 mSv in a year to the prolonged component of the dose attributable to the long-lived artificial radionuclides. (The concept that there should be *compliance* with the constraint, and the adjective *conceivable* has been dropped.) It would appear to be implicit in both these ICRP documents that the constraint to be used as the criterion in the assessment (the *established dose constraint* in the former, *the constraint* in the latter) is no more than 0.3 mSv in a year.

Hence, the recommendation would appear to be that if it is not possible to verify that annual dose would always be less than 0.3 mSv in a year or if the

results of any assessment are too uncertain, then the dose constraint should be reduced by a factor of three to 0.1 mSv in a year.

The ICRP document on the evolution of the system of protection (ICRP, 2002) indicated that "qualitative, non quantitative reasons" were the basis for the choice of the values of 0.3 mSv in a year and 0.1 mSv in a year. Figure A1, based on the discussion above, illustrates one set of reasons. Ten percent of the dose limit (i.e., 0.1 mSv in a year) was allocated to doses that could be considered to have some quantitative basis. The remaining decrements of 0.6 mSv in a year and 0.8 mSv in a year were based entirely on qualitative arguments.

Figure A1: One derivation of values for the dose constraint of 0.3 mSv in a year and 0.1 mSv in a year for a particular source. The ordinate shows the "residual" mSv in a year left after decrements have been applied to the value of the public dose limit to take into account contributions from other noted sources and for other reasons.



Other rationales have been advanced, as noted above, for the choice of 0.3 mSv in a year as the appropriate value for the dose constraint. One was that such a value (approximately) corresponded to a particular annual risk (1 in 100 000 per year). Another was that such a value could be considered small

relative to doses from natural background radiation and, indeed, small relative to spatial variations in the natural background doses.

Also as noted above, there are three roles for a dose constraint. One role is to reflect the possibility of multiple sources contributing to the dose received by a reference individual from a single source. A second role is to help reduce inequities that might otherwise arise in an optimisation of protection that focused on collective dose. A third role is to reflect what can be achieved by good practice in similar circumstances elsewhere. The derivation described here has been primarily concerned with the first role. The other rationales or derivations were not really related to these roles.

Optimisation of protection as now defined by the ICRP is a broad process. Given this, there could be an alternative to introducing the generic values of dose constraints when setting out to optimise protection from particular planned sources. This would be to include the qualitative considerations entailed in their derivation with the relevant qualitative and quantitative factors in an assessment that could therefore be more relevant to the particular situation. Although the derivation illustrated in Figure A1 is largely generic, even there the choice of the appropriate values for most of the decrements could be considered better made in the light of local knowledge or national criteria. Similarly, rather than the simple application of a generic dose constraint, considerations specific to a particular situation may well be more effective in ensuring that inequities in any particular dose distribution do not arise as a result of undue emphasis on collective doses. As well, a generic constraint may not be the most appropriate way of ensuring that protection practices and performances reflect "good practice" elsewhere.

The acknowledged qualitative basis for the dose constraint values provides support for the advice of the ICRP to the effect that the application of dose constraints must depend on local circumstances (§ 42, ICRP, 2008).

BIOGRAPHIES OF THE AUTHORS

Dr. Richard V. Osborne

Richard Osborne received his B.A. with Honours in Natural Sciences from Cambridge University in 1959, after which he undertook post-graduate research with Professor W.V. Mayneord at the Institute of Cancer Research, London, gaining his Ph.D. in biophysics from London University in 1962. He then accepted a research fellowship with Dr. M. Eisenbud at the Institute of Environmental Medicine in the New York Medical Center.

In 1963 he joined AECL at Chalk River as a research officer in the Health Physics Branch. He was appointed Manager of the Environmental Research Branch at Chalk River Laboratories (CRL) in 1981 and in July, 1988 accepted a special assignment as Executive Assistant to the President of the AECL Research Company in Ottawa. He returned to CRL in November 1989 as Director of Health & Environmental Sciences Division. From 1991-1994 he had responsibility for all the programmes in occupational safety and health protection in AECL Research in addition to the responsibility for directing the research programme in health sciences. From 1994 until he retired from AECL in 1998 he directed the AECL research programmes in radiation biology, health physics and environmental research. He chaired the AECL Health and Environment Working Group and also served on AECL's Safety Review Committee, and the AECL Environmental Panel. He is now President of Ranasara Consultants Inc., working in the general area of radiological protection. Clients have included Natural Resources Canada, the Canadian Nuclear Safety Commission, the US Agency for Toxic Substances and Disease Registry, Atomic Energy of Canada Limited, SENES Consultants Limited, the International Atomic Energy Agency, the Nuclear Energy Agency (OECD), Natural Resources Canada, SRB Technologies, Ecometrix Incorporated, the Canadian Nuclear Association and the Canadian Nuclear Workers' Council.

Dr. Osborne received the Elda E. Anderson Award of the Health Physics Society in 1975, was a member of the Society's Board of Directors from 1976-1979, was the Society's G. William Morgan Lecturer in 1992 and the Robert S.

Landauer Lecturer in 2004, and was elected a Fellow of the Society in 2005. He founded and was first President of the Canadian Radiation Protection Association in 1979. He was Vice-President of the International Radiation Protection Association from 1992-1996.

He served on Committee 4 of the International Commission on Radiological Protection from 1980 to 1993 and from 1997 to 2001 when he was Vice-Chairman of that Committee. In 1989, he chaired the ICRP Task Group on Radon in Buildings and from 1997 to 2001 chaired the ICRP Working Party on controllable dose. Dr Osborne has worked with committees and advisory groups of the Nuclear Energy Agency (OECD) in Paris, the NCRP in the USA, the International Atomic Energy Agency in Vienna (including the Radiation Safety Standards Advisory Committee), and various Canadian Agencies, including the Advisory Committee on Radiological Protection of the Canadian Nuclear Safety Commission. He was a member of the US National Research Council's Committee on Radiological Safety in the Marshall Islands. He was the Canadian Representative to UNSCEAR in 1996 and 1997, and in 1997 was the Task Leader for Tritium Safety and Environmental Effects for the IEA Implementing Agreement on Environmental, Safety and Economic Aspects of Fusion Power. In the late 1990s, he served as a member of the Research Advisory Committee for the National Institute of Radiological Sciences in Japan.

Dr. Osborne's early research and papers were on the behaviour and measurement of natural radioactivity in the biosphere. Later he led an R&D programme on tritium health physics which resulted in many papers on topics ranging from biokinetics through instrumentation to operational protection. In his work for various agencies he has been responsible for writing and editing many reports on the practical application of radiological protection principles.

Wendy P. Bines OBE

Following a varied career in the Department of Employment Group (covering adjudication of benefit claims, youth employment, economic planning, skill centre training and marketing of training opportunities), Wendy Bines joined the Health and Safety Executive's (ionising) radiation policy section in 1983 in time to see through the finalising of the Ionising Radiations Regulations 1985 (implementing BSS Directive 80/836/Euratom, as amended by 84/467/Euratom) and related guidance. These Regulations were the first piece of UK radiation protection legislation to apply across the board. In 1986 she edited A Guide to Radiation Protection in the Use of X-Ray Optics Equipment (Science Reviews Ltd with Hughes). From 1986 she was secretary to the Health and Safety Commission's Working Group on Ionising Radiations, which later became the Ionising Radiations Advisory Committee. She was a member of the joint HSE/Department of Transport Secretariat of the Advisory Committee on the Safe Transport of Radioactive Material (ACTRAM) becoming the main author of ACTRAM's first report, on the Transport of Radioactive Materials for Medical and Industrial Use. Mrs Bines led the UK negotiating team for the Outside Workers Directive (90/641/Euratom), also the Council Regulation on Shipments of Radioactive Substances between Member States (1493/93/Euratom), subsequently playing a key part in preparing the implementing legislation and supporting guidance for the former and co-ordinating preparation of the necessary supporting procedures and guidance for the latter.

In 1992 she prepared the HSE Discussion Document on recognition of Radiation Protection Advisers and chaired a subsequent Workshop in 1993. She later led the UK team for negotiation of the revised Basic Safety Standards Directive adopted in 1996 (96/29/Euratom). Her contribution to the subsequent preparation of the UK implementing legislation, the Ionising Radiations Regulations 1999, focused on the authorisation, reporting (notification), justification and, initially, recognition of qualified experts aspects. She co-ordinated the UK implementation of the BSS Directive, including liaison with Northern Ireland and Gibraltar as well as GB Government Departments and associated liaison with the European Commission. She was a *de facto* member of the EC's Article 31 Group Working Group on Training and Education in Radiation Protection, which developed a Basic Syllabus for Qualified Experts and prepared the way for subsequent EC actions relating to the harmonisation of recognition of qualified experts and initiated discussions with the Netherlands

Authorities regarding mutual (UK/NL) recognition of qualified experts. She retired as Head of the ionising radiation policy section within HSE in October 2003, having been appointed an Officer of the Order of the British Empire (OBE) in 2002.

Wendy Bines joined the Society for Radiological Protection as an Associate Member in 1984, becoming a full Member in 1994 and a Fellow in 2001. She chaired the Organising Committee for the 1999 International Symposium (Southport '99). She was elected President of SRP for the term 2005/06, completed a second spell on the Strategic Planning Committee in 2007, is still a member of the Qualifications and Professional Standards Committee and is Chairman of the BSS Revision Working Group.

Professor Henri Métivier

Professor **Henri Métivier** PhD is Emeritus Professor of Radiation Protection at the National Institute for Nuclear Sciences and Technology (INSTN) in Saclay. He was Director of Research of the former IPSN (Institut de Protection et de Sûreté Nucléaire) and assistant to the Director for Protection of Man and Environment.

After obtaining his first degree (master of sciences) in the chemical sciences at Paris University (La Sorbonne), he obtained a speciality in radiochemistry in Curie Institute, then a PhD at the University of Paris in radiochemistry. He joined the Atomic Energy Commissariat, Military Branch, becoming Deputy Head of Experimental Toxicology in 1972, and in 1982 he became Head of the Toxicology and Cancerology unit of the IPSN. In 1989 he joined the Director of Nuclear Safety Research of the IPSN, then became in 1995 Director of Research and took the responsibilities of IPSN-University relationships and the responsibility for Fellows doing PhDs. In 1999 he was nominated Professor at INSTN.

His research work has been mainly concerned with actinides, speciation of plutonium at low levels for human extrapolation, biochemistry linked to the effects of plutonium in lungs, and connective tissues pathologies of the lung whether linked to radiation or not, biokinetics (after inhalation and ingestion) and carcinogenesis of actinides compounds. He has also been responsible for the creation, in France, of protection rule of workers experimenting with HIV viruses in animals, more especially in monkeys. He has published more than 200 papers, more than 50 as first author in international journals, and 40 as first author in French journals.

He has acted as a consultant of ICRP in different task groups. He was member of ICRP Committee 2 (1989-2005) and chairman of human ICRP Alimentary Tract Task Group (ICRP Publication 99). He was a member of a scientific Advisory Group to the EC Radiation programme. Today, he is evaluator of several of EC's programmes. He is consultant of the OECD/NEA CRPPH (Committee for Radiological Protection and Public Health), for which he wrote several reports/reviews, the last being the reference NEA, 2008c. He is chairman of the scientific committee of the Department of Radiation Measurements and Units of the CEA and member of the French Metrology

Committee (LNME). He is consultant for French Academy of Sciences and for the French Nuclear Safety Authority (ASN).

He has participated in organising several international symposia and he has published a collection of about 20 scientific books devoted to nuclear protection and safety. He is chairman of the editorial board of Radioprotection, the journal of the French Radiation Protection Society (SFRP). He obtained Academic palms in 1992.

Tetsuya Oishi

Mr. T. Oishi received his master's degree at the Muroran Institute of Technology in Japan and he joined the Japan Atomic Energy Research Institute (JAERI) in 1994. He belonged to the Health Physics Division in JAERI, and developed calibration sources simulating a filter paper with ion-exchange membrane for the airborne dust monitors. He determined the dynamic response of radioactive gas monitors to a pulse-like injection of radioactive gases and established the calibration techniques for radioactive gas monitors. For the purpose of measuring the characteristics of radioactive wastes for the purpose of clearance, he also developed three fundamental techniques, which were specifically developed for identifying radionuclides, detecting the location of the radioactivity and determining the activity with high efficiency, respectively. These results are useful for improving the reliability and the measurement accuracy of a wide range of radiation monitors.

In 2004 he moved to the secretariat of the Nuclear Safety Commission and contributed to the radiation protection policy in Japan as a regulator. In 2006, he returned to the Japan Atomic Energy Agency (the Japan Atomic Energy Research Institute and the Japan Nuclear Cycle Development Institute were unified on October, 2005 and became JAEA).

At present, he works in the Environmental Radiation Control Section of the Department of Radiation Protection and is involved in monitoring environmental radiation and the assessing dose to the public.

In this document, as one of the radiation protection experts in Japan, he commented on the discussions of the Asian Regional Conferences and on the influence of the Conferences on the decision making process throughout the evolution of the ICRP recommendations.

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The NEA Contribution to the Evolution of the International System of Radiological Protection

Since the International Commission on Radiological Protection (ICRP) initiated a dialogue in 1999 on the evolution of the system of radiological protection, the NEA Committee on Radiation Protection and Public Health (CRPPH) has actively engaged in providing the ICRP with input and views. The Committee's work on this subject has included eight expert group reports, seven international conferences, and four detailed review and comment assessments of draft ICRP recommendations. This report presents a chronological summary of the issues, views and concerns raised by the CRPPH as the ICRP issued various draft versions of its new recommendations (ICRP Publication 103, published in December 2007), and of the response by the ICRP as seen in its subsequent draft recommendations. The interest of this summary report is that it will not only assist readers in understanding the main themes and concepts of the new ICRP recommendations, but also why and how the changes from the previous ICRP Publication 60 recommendations came about.

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