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PROGRESS IN REGULATION FOR GEOLOGIC DISPOSAL SINCE CORDOBA - AN INTERNATIONAL OVERVIEW

This document reviews the regulatory developments in the field of geologic disposal since the Cordoba Workshop of 1997.

This document supports the Tokyo workshop of the RWMC Regulators' Forum (20-22 January 2009) as well as other activities of the RWMC-RF.

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FOREWORD

This document reviews the regulatory developments in the field of geologic disposal since the Cordoba Workshop of 1997. It was prepared by the German GRS (Cologne) on behalf of the Core Group of the RWMC-RF. It has benefitted from the review of the RWMC Regulators' Forum Core Group and the NEA Secretariat.

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1. INTRODUCTION

In January 1997, the NEA workshop "Regulating the Long-term Safety of Radioactive Waste Disposal" (known as "Córdoba Workshop" [1]) set an important milestone concerning regulatory issues in the field of final disposal of radioactive waste, such as the regulatory framework at the national and international levels, the understanding of what is meant by demonstrating regulatory compliance, and approaches to an appropriate regulatory process. This paper aims to depict the evolution of these issues during the following decade, focusing on the major areas addressed in Córdoba, notably

- radioactive waste disposal criteria,
- performance assessment trends, and
- the conduct of the regulatory process.

For these three areas, accounts will be given of the regulation and guidance development at national and international levels, international and multi-national initiatives for developing recommendations and common views on regulatory questions, as well as experience from a regulatory perspective on some of the safety assessment reports and safety cases produced during the last decade.

With regard to regulatory development at international level, the Safety Requirements WS-R-4 "Geological Disposal of Radioactive Waste" (issued in 2006 and jointly sponsored by the IAEA and the NEA, [2]) will be addressed in particular. National regulations and guidelines in NEA member countries addressing the long-term safety of deep disposal facilities which were developed or revised during the last decade include the CNSC guides (Canada, [3]), the STUK guidelines (Finland, [4]), SKI and SSI regulations (Sweden, [5, 6, 7]), and general and site-specific (Yucca Mountain) NRC regulations (USA, [8, 9]). In addition, a number of regulations have been presently being developed, i.e. in the Slovak Republic and Switzerland [10], were presently developed or revised, including the Guideline G03/d in Switzerland [39], French "Basic Safety Rule" RFS III.2.f of 1991 [11] as guide [42], Draft Guidance on Requirements for Authorisation in UK [41], and the EPA 40 CFR 197 rule for Yucca Mountain of 2008 [43] or are under revision like the German BMI Safety Criteria of 1983 [12].

Amongst the numerous international projects and initiatives for developing recommendations as well as common views and opinions, the work of the ICRP is probably the most influential. ICRP 81 [14], stemming from 2000 and explicitly addressing radioactive waste disposal, is frequently referred to in regulatory work. The recently issued ICRP 103 [44] accounts for a number of recent developments but in a much broader perspective; concerning questions specific to disposal, it explicitly refers to ICRP 81. Many of the problems related to regulations and guidance concerning the long-term safety of radioactive waste repositories were addressed in numerous NEA projects and initiatives, important examples being the development of the Safety Case concept which is fundamental for repository development including related regulatory activities [16, 17], work addressing the question of timescales including regulatory issues such as compliance timeframes [18, 19], analyses of criteria and compliance issues [20], and an exploration of the role of regulators and regulatory activities in a broader societal context [21]. Recently, a group of European safety authorities and technical support organisations performed a Pilot Study in which regulatory expectations were specified in relation to the development stage of a disposal programme and the associated safety case [22, 23].

In the meantime, safety assessment reports and safety cases that have been developed include the SAFIR 2 report compiled by the Belgian ONDRAF/NIRAS in 2001 [24], OPG's Third Case Study from 2004 (Canada) [25], the Finnish safety report TILA-99 [26] and the Safety Case Plan in 2008 [40], the "Dossier 2005" produced by the French Andra [27], the Japanese H17 report [28], the "SR-Can" assessment published by the Swedish SKB in 2006 [29], the "Opalinus Clay" safety report submitted by the Swiss Nagra in 2002 [30], the Yucca Mountain Total System Performance Assessment prepared by Bechtel SAIC Company for US DOE in 2001 [15], and the US-DOE's 2004 Compliance Recertification Application for the Waste Isolation Pilot Plant (USA) [31].

2. INTERNATIONAL DEVELOPMENTS IN REGULATION

The development process of geological disposal can be mirrored on the development of the ICRP Recommendations, the Safety Standards of the IAEA as well as the wide-ranging publications of the NEA. In parallel to the ICRP and the IAEA, the NEA has widely articulated in many discussions, questionnaires, workshops and summarising statements the importance of the results and has thereby made a major contribution to a harmonisation both at international and national level. Above all, it consistently followed up the idea of the "safety case", which already emerged at the workshop in Cordoba [1] in 1997, and established it as the key item for the demonstration of the long-term safety of a repository. Eventually, this led to the demand to involve all stakeholders in the repository implementation process.

2.1 Developments on the part of the ICRP

In 1985, the ICRP first commented on the problem of final disposal in its Publication 46 [45] and recommended dose/risks limits (1 mSv/year; 10^{-5}) and the optimisation of protection in terms of ALARA for final disposal.

With ICRP 60 [46], recommendations providing guidance on fundamental principles as base for appropriate radiological protection, which were groundbreaking for radiation protection, were issued in 1991;this was a concept which until this day represents the foundation - albeit modified to consider recent findings - of general radiation protection. One major aspect of ICRP 60 was that the standard of environmental control applied to protect man should also ensure that other species would not be put at risk, either.

Taking the demands of the Rio Conference of 1992 [47] into account and issuing ICRP 77 [48] simultaneously with the publication of the Joint Convention in 1997 [32], the ICRP also considered the idea of sustainability and recommended the following assessment criteria for long-term safety:

doses and risk constraints (0.3 mSv/year or 10^{-5}), the optimisation of potential exposure, the use of BAT, and the protection of future generations.

Groundbreaking for the development of final disposal was ICRP 81 [14], which was published in 1998, confirming the doses and risk constraints (0.3 mSv/year or 10^{-5}) of ICRP 77. The quantification of assessment criteria is made for different periods. Dose and risk are quantitative values in timescales from 1000 to 10 000 years, beyond this timescales dose and risk are only reference values. The comparison with natural analogues is integrated into the assessment of long-term safety. Further characteristics of the ICRP approach for the assessment of the long-term safety of a repository are i.a. demands for: constrained optimisation, technical and managerial principles, defence in depth, quality assurance, iterative safety assessment, a safety case, multiple lines of reasoning, and a stepwise approach.

The most recent recommendations of the years 2006 and 2007 confirm and intensify the recommendations of ICRP 81 with respect to final disposal: As concerns principles for the optimisation of final disposal, ICRP 101 [15] recommends "a broader process reflecting the increasing role of individual equity, safety culture and stakeholder involvement into the decision-making process".

ICRP 103 [44] describes optimisation of protection as a forward-looking iterative process aimed at preventing or reducing future exposures. It expressly point out that "optimisation of protection is not minimisation of dose". Dose estimates beyond several hundreds of years "represent indicators of protection afforded by the disposal system". As a novelty, an approach for a framework to demonstrate protection of the environment is formulated.

2.2 Developments on the part of the IAEA

The main task of the IAEA is to develop and specify internationally binding safety standards, the so-called Basic Safety Standards. The SS-99 [49] of the year 1989 containing the demands for responsibility to future generations by minimisation of burden independence of safety from institutional control, and dose and risk upper bounds represent to this day the basic safety standards of final disposal. The responsibility of today's generation for future generations is the prime demand in all subsequent IAEA recommendations, especially in the S-Fundamentals 111-F [50] of 1995, which formulates central demands: protection of future generations, no undue burden and intergenerational equity, and protection of the environment in addition to human protection. In the Joint Convention of 1997 [32], this demand is specified in: provision for effective protection of individuals, society and the environment, and avoidance of actions that impose reasonably predictable impacts on future generations greater than those permitted for the current generation, all of which is summarised under the heading 'sustainability'. The most recent IAEA Safety Standard WS-R-4 [2], too, contains responsibility for the current and future generations as a central principle. However, WS-R-4 also considered the developments of geological disposal that have occurred both internationally and nationally in the meantime, especially with respect of the fulfilment of the protection goals (endpoints) and the demonstration of long-term safety in a safety case. The concrete demands of WS-R-4 include as a central approach constrained optimisation as a judgmental process, with social and economics factors being taken into account. Regarding the long periods after closure, "indicators of safety other than dose or individual risk are demanded". Further characteristics of WS-R-4 are: reduction of the likelihood of events by suitable siting and design; stepwise decision-making by adequate level of confidence, management system for QA, multiple safety functions, safety case. +

SF-1 [19], which were published simultaneously with WS-R-4 in 2006, put the Safety Fundamentals of 1995 in a broader context. Apart from the fundamental demand that people and the environment, present and future, must be protected against radiation risk, it points out above all that governments/regulators have to be provided with technical as well as managerial competence. The optimisation of protection is promoted to become a central demand.

2.3 Developments on the part of the NEA

The Radioactive Waste Management Committee (RWMC) of the NEA has been a major driving force in the shaping and promotion of the development of requirements for final disposal and its acceptance by starting many initiatives and setting up working groups for the clarification of specific issues. The RWMC has always promoted the dialogue between regulators, policy makers, implementers, and R&D specialists and has in the end brought about the involvement of an even wider set of stakeholders. The importance of the 'safety case' as a safety demonstration for a repository was recognised and already made an issue at the Cordoba workshop in 1997. Further major topics at Cordoba were: long-term safety issues and the dialogue between regulators and implementers, regulatory assessment framework, objectives and criteria for long-term safety, measures to demonstrate compliance with regulatory requirements (see: Regulating the long term of radioactive waste disposal [1]).

In the years after Cordoba, the idea of the safety case was developed further and first defined in the brochure "Confidence in the long-term safety" [38] published in as a collection of arguments; these were to comprise "the findings of a safety assessment and a statement of confidence in these findings as well as natural analogues for the qualitative evaluation and enhancement of confidence". In the same year, two further reports were published. The report "Progress Towards Geologic Disposal of Radioactive Waste: Where Do We Stand?" [51] refers to the task of "ensuring that confidence in geologic disposal is communicated to, and shared by, the public at large" as the biggest challenge for the implementation of final disposal. The report "Geological Disposal of Radioactive Waste: Review of Developments in the Last Decade" [52] states the following: "There is a need to demonstrate and communicate to a wider public the consensus and confidence that exists within the waste management community in the concept and technical feasibility of deep geologic disposal." The foundation for the deliberate involvement of the stakeholders in the repository development process has thereby been laid.

In the year 2000 the report “Lessons Learnt” from “Regulatory Reviews of Assessments of Deep Geologic Repositories” [57] was published. This report presents the lessons learnt from the review experiences of regulator and implementer regarding regulatory reviews of integrated performance assessments (IPAs) of radioactive waste repositories, and provides recommenddations to aid future regulatory decision making.

The role of the regulator is further defined in NEA No. 4428 [21], published in 2003: "Key function of regulators: communication with the public to gain public trust and provide decision makers with all information on relevant matters."

In the reports NEA No. 3679 [16] and NEA No. 4429 [53] that followed in 2004, the safety case is defined more comprehensively as an "integration of arguments and evidence that describe, quantify and substantiate the safety, and the level of confidence in the safety, of the geological disposal facility." The involvement of the stakeholders calls increasingly for the stepwise approach with option to make decisions in a way that they are reversible.

In the arrangement of the safety case, the handling of timescales plays an essential role, especially with regard to the long-term safety demonstration. The committees of the NEA have also debated the "different lines of argument at different times or in different time frames" [18], coming to the following conclusions: "safety and performance indicators other than dose and risk should be used: indications of safety are independent of both limited predictability of the surface environment and, on a far longer timescale, limited predictability of the geological environment".

"The policy of openness towards the general public became more and more important"; the main insights on this topic were summarised in NEA No. 6041 [54], which was published in 2005.

The NEA Report No. 6182 [20] published in 2007 was of particular importance in the area of safety criteria.

The Workshop Proceedings NEA No. 6423 [55], which were published in 2008, take stock of the developments at regulatory level in the 10 years since Cordoba with regard to regulatory requirements for long-term safety. The points of agreement include: limitation associated with the long-term; existence of different time frames based on geoscientific resp. sociocultural aspects. Other key points are: confidence-building, stepwise approach, optimisation and BAT, numerical criteria only for defined periods, complementary indicators.

The documentation of the results of the Safety Case Symposiums of January 2007 in NEA No. 6319 [17] shows that the safety case concept has been understood, accepted and adopted by radioactive waste management programmes worldwide. It provides more than calculated numerical results (in terms of radiological dose indicators, for example) to demonstrate safety or regulatory compliance. The safety case provided the scientific fundamentals and serves as a basis for the design of a repository system.

The latest status of final disposal was presented by the Radioactive Waste Management Committee (RWMC) in 2008 in a Collective Statement [56].

3. RADIOACTIVE WASTE DISPOSAL CRITERIA

3.1 Risk/dose criteria for protection of human beings

At the Córdoba workshop, the role and applicability of so-called calculation endpoints (often also referred to as safety indicators), i.e. the final outcomes of numerical assessments which can then be compared to regulatory criteria, were widely discussed. The discussion covered issues such as

- the appropriate choice of indicators, namely of dose and/or risk, and associated criteria, benchmarks or yardsticks,
- the degree of rigour to which associated criteria should be applied and their relationship to other arguments for safety, and
- the question of timeframes for their use.

With regard to the choice of indicators (namely dose versus risk), the workshop concluded: “It was recognised that risk is in principle a more fundamental and perhaps more appropriate criterion than dose since analyses of radioactive waste disposal will yield ultimately estimates of potential exposures, with varying degrees of probability of occurrence of exposure. However, the risk concept is difficult to understand and use in practice when applied to far future events, the probability of which may be affected by large uncertainties. Suggestions were made to use dose as the main indicator/criterion for the most likely evolution scenarios; and to consider risk for more uncertain scenarios with the recommendation that risk figures should be disaggregated into probabilities and consequences in order to give a better perspective of the two components of risk. Such scenarios may be judged more appropriately on the basis of relatively 'soft' information, with multiple lines of reasoning." [1]

The ICRP recommended that "assessed doses or risks arising from natural processes should be compared with a constraint of no more than about 0.3 mSv per year or its risk equivalent of around 10^{-5} per year." [14] It also acknowledges: "Doses and risks, as measures of health detriment, cannot be forecast with any certainty for periods beyond around several hundreds of years into the future … . Instead, estimates of doses or risks for longer time periods can be made and compared with appropriate criteria … in a test to give an indication of whether the repository is acceptable given current understanding of the disposal system. Such estimates must not be regarded as predictions of future health detriment." Similarly to the conclusions of the Córdoba workshop, the ICRP recommended a disaggregated presentation of potential doses and associated probabilities.

A recent review undertaken on behalf of NEA's RWMC Regulators' Forum has found "significant differences among the criteria used in various member states, with a range of up to two orders of magnitude in the reference numerical values." [20] Indeed, recently developed or revised criteria do not show convergence with regard to such reference numerical values. In fact, a variety of dose, risk, combined, and other criteria with a range of reference values can be observed (Appendix 2 of [20], for single criteria cf. also [4-13]).

This finding is, however, less alarming than it seems because criteria used in all countries are well below levels at which actual effects of radiological exposure can be observed and the way reference values are defined (limit, target, constraint) varies, as do the ways indicators are being calculated [20]. Compliance with regulations is increasingly, in accordance with the evolving safety case concept [2, 16, 17], seen as an issue going far beyond compliance with reference numerical values. Consequently, compliance evaluations are losing importance compared to other, "softer" issues such as good siting, design, and engineering, optimisation issues, usage of best available technique, implementation of adequate management principles, etc. All of the safety reports referred to in the introduction place considerable weight on these issues, and so do the regulations recently developed or revised.

The latter observation is consistent with the Córdoba workshop's request for 'softer'approaches to compliance: "It was noted in this respect that, in a decision making context, single 'high-level' criteria like dose or risk indicators, coupled with a pass/fail decision process, have the appeal of being transparent and easy to understand by the public, but that a more sophisticated approach taking account of multiple factors is more appropriate." Requests for "multiple factors" or "multiple lines of evidence" in national regulations include the requirement for "confidence-building arguments" and the "development of a safety case, which includes a safety assessment complemented by various additional arguments" in Canadian regulatory guidance [3], the "Design principles" formulated in Finnish regulations [4], the request for "best available technique" (BAT) in Sweden [7], and supportive arguments for overall safety assessment [39]. The revised guidance in UK [41] mentioned the "use of multiple lines of reasoning based on a variety of evidence, leading to complementary environmental safety arguments." and "Examples of environmental safety indicators that might be used to strengthen the environmental safety case include radiation dose, radionuclide flux, radionuclide travel times, environmental concentration and radiotoxicity."

The above discussion leads to the observation that, despite varying reference numerical values, there is an evolving joint understanding about the nature of the safety case in connection with compliance issues in the community in general as well as amongst regulators in particular. Consequently, a number of regulators and technical support organisations recently concluded: "Although regulatory frameworks differ considerably between countries, …regulatory practice differs to much less an extent." [22]

3.2 Protection of the environment

In the years after the Córdoba Workshop, many initiatives were started on the part of the radiation protection authorities to challenge the established approaches that were exclusively directed at humans (protection of the individual) and to broaden the point of view to include protection of the non-human environment. How and in what way protection of flora and fauna will be taken into account in the national regulations regarding the long-term safety of a repository is at present still an open question in many countries.

On the topic of protection of the environment, national and international developments over the last ten years include:

- several conferences and congresses, especially on the initiatives of ICRP, IAEA, IUR and NEA,
- the formation of independent teams and working groups,
- the placement of many research programmes and
- the development of different evaluation models and basic approaches, e.g. on the basis of the Reference Animals and Plants (RAP's) of the ICRP or specifically defined reference organisms in the individual programmes.

In the same period, the following documents were published:

- in 1999 and 2002 two technical reports of the IAEA [34, 35],
- in 2003 "A Framework for Assessing the Impact of Ionising Radiation on Non-human Species" of the ICRP [36] and
- in March 2007 new recommendations of the ICRP. Among its major features is: "an approach for developing a framework to demonstrate radiological protection of non-human species, noting that there is no detailed policy provided at this time." [37]

The development of extended protection of the environment including flora and fauna has already been considered in the regulations of the following countries:

- The Swedish SSI [7] stipulates "The organisms included in the analysis of the environmental impact should be selected on the basis of their importance for the ecosystems, but also according to their protection value according to other biological, economic or conservation criteria. .... The assessment of effects of ionising radiation in selected organisms, deriving from radioactive substances from a repository, can be made on the basis of the general guidance provided in the International Committee for Radiation Protection's (ICRP) Publication 91."

- The guideline of the Finnish Radiation and Nuclear Safety Authority (STUK) [4] provides the following: "Disposal of spent fuel shall not affect detrimentally to species of fauna and flora." .... "Moreover, rare animals and plants as well as domestic animals shall not be exposed detrimentally as individuals"

- The Canadian Regulatory Guide G-320 [3] stipulates: "Since the NSCA and regulations specify protection of both the environment and persons, long term assessments should address the impact on humans and on non-human biota from both radioactive and hazardous non-radioactive constituents of the radioactive waste…."

- The UK Draft Guidance [41] requires: "Measures are needed not only to protect people, but also to protect the environment. The aim is to maintain biological diversity, conserve species, and protect the health and status of natural habitats and communities of living organisms. For non-human species the general intent is to protect ecosystems against radiation exposure that would have adverse consequences for a population as a whole, as distinct from protecting individual members of the population."

- The Draft Guideline G03/d of Switzerland [39] stipulates: "The environment as the natural basis for the existence of humans and other creatures is to be protected. The biodiversity must not be endangered by deep geological storage."

Beside the assessment of the radiological risk, there has been an increasing demand for a uniform evaluation standard for the collective registration of the effects of radioactive and other pollutants. This is already anchored in the aforementioned Canadian Regulatory Guides [3]. The UK Draft Guidance [41] mentioned: "The environmental safety case will need to show that members of the public and the environment are adequately protected from non-radiological hazards, but this may be straightforward given the nature of the disposal facility, in other words, the extent to which the waste is separated from the accessible environment.". The French Guide [42] requires that the assessment of the future repository development should also include the risks due to the release of chemotoxic compounds. "…..la modélisation du comportement futur du système de stockage pour un jeu de scénarios représentatifs de la situation de référence et des situations altérées, ainsi que l'estimation des risques radiologiques et chimiques associés à chacun de ces scénarios."

3.3 Timescales

An issue on which opinions certainly diverge is the question of compliance timeframes. Arguments frequently used refer to the question of the obligation to protect future generations on one hand, and on the other hand to the practical limitations of human undertakings such as compiling a safety case in general or forecasting repository evolution in particular. With regard to the former, the requirement of the Joint Convention [32] that "… individuals, society and the environment are protected from harmful effects of ionizing radiation, now and in the future, in such a way that the needs and aspirations of the present generation are met without compromising the ability of future generations to meet their needs and aspirations" has often been interpreted as a requirement to analyse repository performance and its associated safety for the time the waste remains hazardous. Given that "… even though the hazard potential of spent fuel and some long-lived wastes decreases markedly over time, these wastes can never be said to be intrinsically harmless" [19], this interpretation would lead to a demand for demonstrating safety for practically indefinite timeframes and, in the extreme, for doing this by showing compliance with reference numerical values.

However, it is precisely the calculation of dose and risk indicators that relies most heavily on assumptions concerning the evolution of surface-near aquifers and the biosphere, which can only be forecasted reliably for very limited timeframes (some 10s to 100s of years) [18]. Such forecasts are feasible and reliable for longer times for other system components: "… for a well-chosen site, the evolution of the broad characteristics of the engineered barrier systems (EBS) and the host rock are reasonably predictable over a prolonged period (10^5 or 10^6 years, say, in the case of the host rock). There are uncertainties affecting the engineered barrier systems and the host rock over shorter timescales, but these can, in general, at least be bounded with some confidence." [18] This has led to suggestions of using indicators located in the vicinity of these components rather than dose or risk, but even if this were successful, an apparent discrepancy between ideal and reality would remain, sometimes referred to as the "regulatory dilemma".

At the Córdoba workshop, a number of points to address the issue were made, including doubts that there is real justification for "hard" cut-off times, the possibility of moving from essentially quantitative to more qualitative approaches in the very long term, and the necessity of clarifying the meaning and interpretation of timescales and cut-off times. Since then, it has been possible to observe a general trend that many regulations and safety cases today address timeframes up to one million years rather than some 10 000 years. Probably the most spectacular and widely noticed evolution concerning this issue happened in the United States, where, amongst other things, the compliance timeframe of 10 000 years fixed in EPA regulations [13] was questioned in court. EPA has then advised by the court revised its regulation based on National Academy of Science (NAS) recommendations, which name a timeframe on the order of one million years as a period for which assessments are feasible at Yucca Mountain [43].

Recent discussions, especially in connection with the NEA work on long-term safety criteria [20], show that the above-mentioned interpretation of the Joint Convention requirement (i.e. the request to analyse for the entire time the waste remains hazardous) is, from an ethical point, at least debatable.

"Most ethicists accept that one generation has responsibilities towards succeeding generations, though views differ on the nature of these obligations and on their duration. There is the view that this responsibility extends so long as the impact persists, i.e. there is no cut-off. This absolutist view is countered by the more pragmatic position that responsibility necessarily must diminish in time reflecting capacity to discharge the responsibility. Even if it is argued, in the context of responsibility towards future generations, that the duty of protection does not change over time, it is clearly accepted that our capacity to fulfil the duty is time dependent." [20]

The fact that uncertainty increases with time and that this increase varies from component to component can be, and is, addressed in a number of ways in regulations and safety cases. The most pragmatic but perhaps a bit simplistic way is using a so-called "hard" time cut-off for times when forecasts become unreasonable. It must also be noted that a demand for "forecasting" impacts in a stronger sense of the word implies the demand for sufficient support for aquifer and biosphere models, which is achievable only for comparably short times (cf. above). Instead, an understanding has evolved that dose or risk estimates "… should not be regarded as measures of health detriment beyond times of around several hundreds of years into the future" but instead "… represent indicators of the protection afforded by the disposal system." [14]

There are various, and sometimes combined, ways of "softening" a cut-off or of replacing it by an approach varying over time, the implications of which in terms of ethics and safety philosophy are widely discussed in [20]. The usage of, and the weight placed on, different kinds of quantitative indicators and more qualitative arguments might change over time. STUK sets a dose limit for early times and limits on radionuclide fluxes for later times [4].The UK Draft Guidance [41] mentioned: "Where environmental safety needs to be assured over very long timescales, it is likely this will only be achieved through multiple lines of reasoning based on a variety of evidence, leading to complementary environmental safety arguments." The Swiss guideline G03/d [39] stipulates: "The safety demonstration includes also an evaluation of the methods of the safety analysis and the data used. If necessary, it can refer to further supportive arguments for the basis or results of the safety analysis." This approach can be seen as an aspect of the broader and now widely accepted concept of building a safety case from multiple lines of evidence, a concept which has evolved in such a way that increasing emphasis is placed on the demonstration of appropriate performance of the system, indicated e.g. by recent discussions of indicators more directly related to safety functions such as isolation [33].

In summary, it can be stated that recent work at the NEA as well as in national programmes has led to progress but the Córdoba demand "… to clarify the meaning and interpretation of proposed timescales or cut-off times" remains valid and indicates the necessity for further effort. The obligation of protecting future generations from harmful effects of radiation and the duty of solving the issue of radioactive waste management at the present without imposing a liability on future generations leads to an ethical conflict with respect to the current limited practical abilities of demonstrating the protection of future generations over virtually indefinite timeframes. This still open basic question has been discussed lasting recent years, especially in the NEA RWMC Regulators' Forum, where further work is being pursued. .

4. PERFORMANCE ASSESSMENT TRENDS

General statements about the role of performance assessment (PA) at the Córdoba conference show that PA results are the most significant and essential part of the technical and scientific basis to be provided in a safety case, and that they imply the need for sufficient understanding of system behaviour and care in the use of quantitative approaches in a context of uncertainty. Therefore they can not be regarded as predictions but rather as *conservative illustrations* of the long term behaviour of the repository system. PA analyses may be carried out for different purposes (to identify R&D priorities, as boundary calculations, to assess parameter sensitivities, or for license applications). It is noted that there are always remaining (irreducible) uncertainties. Thus, the interpretation of PA results requires caution and appropriate qualifications on the results must be supplied [1].

4.1 General development of performance assessment/safety case

Significant progress has been achieved by integrating PA in the broader context of an overall safety case [16, 17] and by specifying the different roles of the safety case elements 'performance assessment', 'safety assessment' and 'safety analysis'. Two years after the Córdoba workshop, a first systematic definition of the required content of performance assessment and its role in a safety case was documented by the NEA confidence paper [38] and was reviewed by a NEA working group in the year 2000 [57]. The proposals and results in these reports strongly focused on the idea of confidence building In 2004 and 2006 two important publications [16, 2] were issued with more comprehensive and technical definitions of the terms "safety assessment", which can be regarded as the safety related conclusion of the performance assessment; and "safety case", as the integration of all arguments and evidence (including the results of PA) that "describe, quantify and substantiate the safety and the level of confidence"… [16].

In a more or less close interrelation with the general development towards broader based safety evidence strategies the following important changes, developments and trends in ensuring and demonstrating the required safety of a repository system can be observed at the international level:

The predictive character of PA analyses results (calculated doses/risks) is restricted to a short time period (<1 000a), beyond which time they can only be used as indicators for the safety related system behaviour in terms of potential exposure or as indicators for the isolation potential of a repository system. In this context problems in communicating the fact that PA is not a prediction of the future can be observed (evidenced e.g. in LTSC discussions) [20]; better communication between PA specialists and radiation protectionists may perhaps be needed.

In connection with the problem of PA predictability for long times, the usage of multiple lines of argument and of multiple or parallel criteria (e.g. natural analogues, groundwater residence times) became more important evidence to support the results of safety analyses carried out within the framework of PA [2]. Due to the increasing meaning of multiple lines of arguments and evidences complementary to dose and risk, the role of the safety analyses and their end points in the overall context of a safety case has recently been under discussion. The role of PA embedded in a safety case is still crucial, but its weight is dependent on the different steps of repository development, an issue which is addressed from the perspective of regulatory review in the European Pilot Study [22, 23].

It is internationally widely agreed that a step-wise procedure in the safety case decision making process, including public involvement and the possibility of reversal or modification of decisions made at previous steps (cf. 4.2), is essential to manage the complex and long-running decision procedure for radioactive waste repositories efficiently (also with respect to economic funding and taking into account the ongoing technical and scientific progress), as well as to achieve the required confidence of the general public and the stakeholders by involving them in the step-wise iterative process [21].

Methodologically associated with the step-wise decision making process is the principle of optimisation of repository safety and potential exposures, which originates from the ALARA radiation protection principle. The idea of optimisation was primarily taken up in ICRP 81 and subsequently defined in ICRP 101 [15] "as the source related process to keep the magnitude of individual doses, the number of people exposed, and the likelihood of potential exposure as low as reasonably achievable below the appropriate dose constraints, with economic and social factors being taken into account." Within the international community, the term optimisation is often used in a broader sense, i.e. less restricted to radioprotection requirements, e.g. the requirement of the application of state-of-the-art techniques and methodologies, verified at each safety case step or even retroactively at the end of the licensing procedure (e.g. plan-approval procedure Konrad mine, Germany), as well as the step-wise reflection about appropriate measures which can contribute to an improvement of the system safety. ICRP 103 [44] recommended: "The optimisation of protection is a forward-looking iterative process aimed at preventing or reducing future exposures. It is continuous, taking into account both technical and socio-economic developments and requires both qualitative and quantitative judgements. The process should be systematic and carefully structured to ensure that all relevant aspects are taken into account. Optimisation is a frame of mind, always questioning whether the best has been done in the prevailing circumstances, and if all that is reasonable has been done to reduce doses. It also requires the commitment at all levels in all concerned organisations as well as adequate procedures and resources."

Thematically linked with the concept of optimisation is the requirement for the application of best available techniques (BAT), which has been implemented in the Swedish regulation rules [7]. At the international level there is still a need of clarification concerning the significance of optimisation and BAT and their limitations in regulatory processes in the field of radioactive waste disposal.

A broad consensus can be noticed concerning the need for a more sophisticated approach to uncertainty management, which includes a more critical attitude towards conservatisms (data and assumptions etc.), favoured application of probabilistic methods and the need to communicate the impact of any remaining non-reducible uncertainties on the safety statements. A safety case should show that uncertainties that do have a potential to compromise safety can be adequately dealt with in future project stages via an appropriate research programme and management strategy [2]. In this context the requirement of system robustness became more and more important. Crucial criteria for achieving system robustness are, e.g., a sufficient distance from active tectonic areas and a sufficient depth, limited natural resources which might attract future generations, as well as a multi-barrier concept with complementary contributions to the overall system safety [2].

It is also common understanding that there is a need for better communication between the "actors" and parties not directly involved in the licensing process. This includes sufficient accessibility of information needed, a comprehensible and traceable documentation and explanation of the safety system concept, scientific and technical information, the assessment methods (e.g. computer tools and databases) applied, the assessment basis and the safety case in general [2], as well as a clear definition of the regulatory rules and a justification of any decisions made [21] (cf. 4.1). Necessity of shared understanding and definition of the basic terms, such as safety, protection and of the basic objectives of disposal is called for in [20]

4.2 Further technical, scientific and methodical aspects

At the Córdoba workshop some additional technical and scientific topics, which are not covered by the discussion above, were identified as also requiring discussion, clarification or improvement:

- Event probabilities: There is a necessity to address this issue, which is strongly related to the regulatory framework. For example, the Swedish risk criterion [6] and recent safety case [29] often use upper estimates in order to avoid estimating probabilities. , which are indeed an example for which credible probability estimates can be achieved on a scientific basis, are explicitly taken into consideration. Other safety reports which were produced under different regulatory conditions put less weight on event probabilities.

- Human intrusion probabilities: There is an increasing consensus that human and societal evolution cannot be forecast for long terms on a reasonably scientific basis. Thus, assigning probabilities to human intrusion actions is not regarded as sensible, as evidenced by the absence of such estimates in most of the recent safety cases.

- Stylised approaches: Development work on biosphere models can be observed at the international level. Two international research projects to be highlighted are aiming at a structured compilation of methodologies for the creation of reference biospheres under steady conditions (BIOMASS, IAEA) and under consideration of climate changes (BIOCLIM, EU). There are significant differences among the OECD member countries concerning the implementation of stylised biosphere models with respect to the degree of site specific considerations. Recently, it has been possible to observe diverging views of PA specialists and radiation protectionists concerning the significance of stylised biosphere models in PA because of the lack of predictability of biosphere developments over long time periods.

- Deterministic vs. probabilistic approaches: The complementary role of both approaches is now widely accepted. Nevertheless, the relative weight assigned to each of the approaches in recent safety cases varies depending, amongst other things, on the regulatory context. Although the majority of regulations do not explicitly prescribe the choices to be made with regard to deterministic vs. probabilistic approaches (notable exceptions: [4, 5, 13]), risk-based regulation is often interpreted as a demand for probabilistic approaches.

- Retrievability or reversibility (R&R): The issue of retrievability and reversibility has been a widely debated question to this day, especially under ethical and socio-economical aspects. Reversibility is closely related to the stepwise approach, which today represents the basis of repository implementation or the licensing procedure in all countries. In some countries, such as France, the US and Switzerland, R&R is stipulated in the regulations for the phase prior to the closure of the repository [42, 8, 9, 10]. In no country, however, are there any specific requirements of retrieval for the post-closure phase.

5. THE CONDUCT OF THE REGULATORY REVIEW PROCESS

The third section of the Córdoba workshop was devoted to more high-level regulatory topics such as how the licensing process is conducted in practice by regulators to judge compliance with regulatory requirements and, ultimately, the acceptability of the proposed waste disposal facilities from a technical point of view. Although the workshop was not intended to cover non-technical issues in detail, their importance was recognised and their influence on the conduct of the regulatory review process discussed.

5.1 The technical review process

At the Córdoba workshop, questions concerning the relationship between implementer and regulator, the degree of prescriptive regulation, the definition of the "rules of the game" and the need for technical competence of the regulator were discussed. General ideas and proposals concerning the regulator's role and image in a licensing procedure within the framework of a changing modern society, dealing with the topics mentioned above, were developed by the NEA Forum on Stakeholder Confidence (FSC) and published in [21]:

- Relationship between the regulator and implementer: “As the Finnish experience has shown, regulatory feedback may, in all cases, be fruitfully ensured during the siting process by creating some reporting review milestones. This model of ‘informal’ dialogue between implementer and regulators requires strong social trust in the regulatory authorities. It also requires a well-defined interaction process that secures public confidence and ensures that decision-making in regard to licensing is not subsequently constrained or compromised in the legal or ‘quasi-judicial’ sense (p. 10).” The last requirement was emphasised by the definition of the regulators’ attributes (p. 14): “Regulators need to be independent of organisations of the nuclear energy industry in regard to licensing decisions, and of any other organisations likely to be affected by such decisions. Independence has to be demonstrated by visible actions.”

- Degree of prescriptive regulation: In [21] a range of different regulatory philosophies is notified: More prescriptive regulation provides clear messages to the implementer and the general public. However, if unduly restrictive, it may hamper the development of techniques and procedures. Less prescriptive regulation provides more opportunity for a constructive dialogue between regulator and implementer and could be beneficial for the development of technical procedures, but it could leave too much to interpretation and perhaps give the impression of insufficient control by the authorities.

- Definition of the “rules of the game”: In accordance with the demands of the Córdoba workshop, FSC stated in [21] that “the ‘rules of the game’ for the regulatory process should be known as soon as possible and in any case in advance of a licensing application.” Beyond that it is regarded as ideal if the general public could perceive the overall system of regulation, including the formulation of relevant policy by government, as being impartial and equitable. At a minimum, regulators should communicate the basis of their decisions.

- Technical competence [21] (p. 14): “Competence is both statutory and effective. Statutory competence is granted by the mandate defined for regulators in the national programme. It is a prerequisite for legitimacy and action. Effective competence relies on the training of regulatory staff and the resources of their institution. The regulatory staff must have the required expertise and sufficient resources for careful scrutiny of the implementer’s proposals and arguments. Achieving and maintaining adequate effective competence within regulatory authorities means they must be able to attract and retain capable staff.”

Significant progress regarding regulatory technical review within the framework of step-wise decision making processes is achieved by the European Pilot Study [22, 23], which substantiates the respective steps’ content in licensing procedures, namely the conceptualisation stage, siting stage and design stage. The group proposed that at each development stage the facility design and the evolving safety strategy, the demonstration of site and engineering suitability, the impact assessment and the adequacy of management systems should be considered. In this respect, the safety case presenting the arguments and supporting information and assessment related to the above aspects will have to be comprised of clear information, from the very beginning of a disposal project, covering the design options and the key elements upon which safety relies, together with a description of the preferred strategy to acquire progressively enough knowledge of the factors governing the containment and isolation capacity of the disposal system.

5.2 Non-technical aspects and their impact

Super-ordinate non-technical topics addressed at the Córdoba Workshop concerned transparency and confidence building (trust) within the framework of a licensing procedure [1]. In particular, this pertains to a distinct definition of the role of the general public in a regulatory process and to the question of which of the institutions/bodies involved is responsible to communicate to the public and bring in confidence building elements in a step-wise approach.

In general a new dynamic of dialogue and decision making process has been observed, characterised by the FSC as a shift from the traditional "decide, announce and defend" (DAD) model, focussed exclusively on technical content, to one of "engage, interact and co-operate" (EIC), for which both technical content and quality of the process are of comparable importance to a constructive outcome [21]. One important element in the EIC strategy is public involvement in the regulatory process, which is a usual practice in some cases (e.g., the USNRC), and is being incorporated by other regulators (e.g., the CNSC, HSK, SKI and SSI). According to the national legal framework, approaches differ between countries, varying from open public and stakeholders' comments to open licensing meetings and hearings. Irrespective of the degree of involvement, there is a broad consensus that the involvement of the public and stakeholders is essential, and needs to be implemented from an early stage to allow sufficient exertion of influence.

In accordance with different legal constraints, the regulator's role as a communicator to the public varies from country to country. In [21], FSC defines the role of regulatory bodies on the basis of a common regulatory self-conception, wherein "regulators should be 'guarantors' of safety and the 'peoples' expert', acting as an accessible resource to stakeholders addressing safety concerns. Regulators should thus establish good contacts with the different stakeholders. Open channels of communication should be maintained with the general public, implementers, government departments, parliament, concerned action groups and others." At a minimum it is expected that the regulators communicate the basis of their decisions.

A current and concise overview of the mechanisms and attributes required to achieve public confidence from the regulators' point of view is given in [20], whereupon three pillars were identified to be crucial to gain the required level of trust: Trust in the institutions involved in decision-making (clearly and comprehensibly defined in their roles, independent, credible, honest, transparent, open), trust in the decision-making process (clear and consistent decisions, step-wise decision making process including public involvement, possibility of reversal or modification of decisions made, criteria tailored to each step, usage of multiple lines of argument and of multiple or parallel criteria), and trust in the technical concept and control measures (usage of adequate, verified and transparent methods, usage of additional assessment criteria, such as robustness, passive safety, land use, retrievability, monitoring abilities etc., development of a clear "road map" of the process even at an early step, design of a system that can assure an acceptable level of safety even in the absence of future control).

6. CONCLUSIONS

Since the workshop in Cordoba in 1997, significant progress has been made in the regulatory area both internationally and nationally. The major developments include the following:

The strict compliance with quantitative limit values for the fulfilment of the protection goals as the only demonstration of long-term safety is increasingly questioned, mainly in view of the long time periods. The handling of the timescales and possible cut-off times requires further clarification. The demonstration of long-term safety is extended by multiple lines of evidence and confidence-building arguments. Softer aspects such as good siting, design and engineering, optimisation issues, usage of best available technique, implementation of adequate management principles, etc. are gaining more and more importance. Next to the protection of man, the protection of the environment may be demanded in addition.

Performance assessment (PA) was placed in the context of a comprehensive safety case. This is defined as the integration of all arguments and evidence (including the results of PA). After a few hundred years the results of the PA analysis (calculated doses/risks) lose their predictive character and ought afterwards be considered as indicators of isolation. Internationally accepted in connection with the safety case is a step-wise decision-making process with the option of reversing the individual steps. Stakeholders and the general public have to be involved in this process. This is a further element of progress since Córdoba, where the dialogue was mostly called for only between implementers and regulators.

The principle of optimisation of the safety of the repository and of potential radiation exposure closely linked to this decision-making process. The idea of optimisation is based on the ALARA principle applied in radiation protection, but is today placed in a wider context internationally, e.g. by the requirement of the application of state-of-the-art techniques and methodologies and the constant enhancement of the safety of the repository system. The latest recommendations of the ICRP published in 2007 take this development into account by stating that the optimisation of protection is a forward-looking iterative process aimed at preventing or reducing future exposures. The handling of uncertainties has to be closely examined. It has to be shown as part of the safety case how uncertainties are dealt with (demonstration of robustness). The concept is not, however, well defined in national regulations and some basic questions remain.

The step-wise execution of the licensing procedure is considered to be effective. The respective steps in licensing procedures are the conceptualisation stage, the siting stage and the design stage. At each decision point, the corresponding status of repository development has to be demonstrated by preparation of a safety case. The stakeholders demand that "rules of the game" for the regulatory process be laid down as soon as possible. There is a trend showing a movement away from the traditional "decide, announce and defend" (DAD) model with its exclusively technical background towards the "engage, interact and co-operate" (EIC) model that provides involvement of the general public. The regulator should maintain good contact with the stakeholders and open common communication channels.

In its Collective Statement of 2008, the NEA presents the current status of final disposal and outlines the development of its earlier statements and opinions through the times before, during and after the Cordoba workshop.

7. REFERENCES

1. Joint CNRA/CRPPH/RWMC Workshop "Regulating the Long-term Safety of Radioactive Waste Disposal". Proceedings of an NEA International Workshop held in Córdoba, Spain, 20-23 January 1997. OECD, Paris, 1997. http://www.nea.fr/html/rwm/reports/1997/cordoba.html

2. Geological Disposal of Radioactive Waste. Safety Requirements Jointly Sponsored by The International Atomic Energy Agency and the OECD Nuclear Energy Agency. IAEA Safety Standards Series No. WS-R-4, Vienna, 2006. ISBN 92-0-10570-9, http://www-pub.iaea.org/MTCD/publications/PDF/Pub1231_web.pdf

3. Canadian Nuclear Safety Commission – Commission canadienne de sûreté nucléaire (CNSC-CCSN): Regulatory Guide – Assessing the Long Term Safety of Radioactive Waste Management, G-320, 2006 http://www.nuclearsafety.gc.ca/pubs_catalogue/uploads/G-320_FinalPaper_e.pdf

4. Radiation and Nuclear Safety Authority (STUK, Finland): Long-term safety of disposal of spent nuclear fuel . STUK Guide YVL 8.4, 2001, http://www.stuk.fi/saannosto/YVL8-4e.html

5. The Swedish Nuclear Power Inspectorate's Regulations concerning Safety in connection with the Disposal of Nuclear Material and Nuclear Waste (including General Recommendations concerning the Application of the Regulations). SKIFS 2002:1, March 2002, http://www.ski.se/dynamaster/file_archive/020627/059da393a73a96d33e260aab78a401ac/SKIFS2002%2d1eng.pdf

6. SSI (1998). The Swedish Radiation Protection Institute's Regulations on the Protection of Human Health and the Environment in connection with the Final Management of Spent Nuclear Fuel and Nuclear Waste. SSI FS 1998:1, September 1998, http://www.ssi.se/forfattning/PDF_Eng/1998-1e.PDF

7. SSI (2005). The Swedish Radiation Protection Authority's Guidelines on the Application of the regulations (SSI FS 1998:1) concerning Protection of Human Health and the Environment in connection with the Final Management of Spent Nuclear Fuel and Nuclear Waste. SSI FS 2005:5, September 2005, http://www.ssi.se/forfattning/pdf_eng/2005_5e.pdf

8. NRC Regulations Title 10, Code of Federal Regulations, Part 60--Disposal of High-level Radioactive Wastes in Geologic Repositories, 1981, last amendment 2004, http://www.nrc.gov/reading-rm/doc-collections/cfr/part060/

9. NRC Regulations Title 10, Code of Federal Regulations, Part 63--Disposal of High-level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada, 2001, last amendment 2004, http://www.nrc.gov/reading-rm/doc-collections/cfr/part063/

10. Der Schweizerische Bundesrat: Kernenergieverordnung (KEV) vom 10. Dezember 2004 http://www.admin.ch/ch/d/sr/7/732.11.de.pdf

11. Direction de la sûreté des installations nucléaires, Règle Fondamentale de Sûreté III.2.f, Définition des objectifs à retenir dans les phases d'études et de travaux pour le stockage définitif des déchets radioactifs en formation géologique profonde afin d'assurer la sûreté après la

période d'exploitation du stockage - Juin 1991, http://www.asn.fr/sections/rubriquesprincipales/textes-reference/acces-par-type-texte/regles-fondamentales/guides-asn-rfs-relatifs/RFS_III2f/downloadFile/file/rfs_III_2_f.pdf

12. Bundesministerium des Innern (BMI): Sicherheitskriterien für die Endlagerung radioaktiver Abfälle in einem Bergwerk, GMBl. 1983, S. 220 http://www.bfs.de/de/bfs/recht/rsh/bmu

13. Environmental Protection Agency, 40 CFR Part 197, Public Health and Environmental Radiation Protection Standards for Yucca Mountain, NV; Final Rule, 2001, http://www.epa.gov/radiation/docs/yucca/66fr32074.pdf

14. Annals of the ICRP, Publication 81: Radiation Protection Recommendations as Applied to the Disposal of Long-lived Solid Radioactive Waste, Elsevier, 1998

15. Bechtel SAIC Company, LLC prepared for US Department of Energy: Total System Performance Assessment - Analyses for Disposal of Commercial and DOE Waste Inventories at Yucca Mountain – Input to Final Environmental Impact Statement and Site Suitability Evaluation, REV 00, ICN 02, December 2001 http://www.ocrwm.doe.gov/documents/sl986m3b/index.htm

16. OECD/NEA: Post-closure Safety Case for Geological Repositories. Nature and Purpose. NEA No. 3679, OECD, Paris, 2004, ISBN 92-64-02075-6, http://www.nea.fr/html/rwm/reports/2004/nea3679-closure.pdf

17. OECD/NEA "Safety Cases for the Deep Disposal of Radioactive Waste: Where Do We Stand?", Symposium Proceedings 23-25 January 2007, NEA No. 6319, OECD, Paris, 2008, ISBN 978-92-64-99050-0 http://www.nea.fr/html/rwm/reports/2008/ne6319-safety.pdf

18. OECD/NEA: The Handling of Timescales in Assessing Post-closure Safety. Lessons Learnt from the April 2002 Workshop in Paris, France. NEA No. 4435, OECD, Paris, 2004, ISBN 92-64-02161-2 http://www.nea.fr/html/rwm/reports/2004/nea4435-timescales.pdf

19. OECD/NEA: Integration Group for the Safety Case (IGSC): Consideration of Timescales in Post-closure Safety of Geological Disposal of Radioactive Waste, NEA/RWM/IGSC(2006)3 http://www.olis.oecd.org/olis/2006doc.nsf/LinkTo/NT00007642/$FILE/JT03220159.PDF

20. OECD/NEA: RWMC Regulators' Forum (RWMC-RF), Regulating the Long-term Safety of Geological Disposal. Towards a Common Understanding of the Main Objectives and the Bases of Safety Criteria. NEA-6182, OECD, Paris, ISBN-978-92-64-999031-9 , http://www.nea.fr/html/rwm/reports/2007/nea6182-regulating.pdf

21. OECD/NEA: The Regulator's Evolving Role and Image in Radioactive Waste Management. Lessons Learnt within the NEA Forum on Stakeholder Confidence. NEA No. 4428, OECD, Paris, 2003, ISBN 92-64-02142-6, http://www.nea.fr/html/rwm/reports/2003/nea4428-regulator-role.pdf

22. F. Besnus, J. Vigfusson, R. Smith, V. Nys, G. Bruno, P. Metcalf, C. Ruiz-Lopez, E. Ruokola, M. Jensen, K.-J. Röhlig, P. Bodenez: European Pilot Study on the Regulatory Review of the

Safety Case for Geological Disposal of Radioactive Waste, in 17, http://www.grs.de/pilot_study/Paper_NEA_European_Pilot_Study.pdf

23. F. Besnus, J. Vigfusson, R. Smith, V. Nys, G. Bruno, P. Metcalf, C. Ruiz-Lopez, E. Ruokola, M. Jensen, K.-J. Röhlig: European pilot study on the regulatory review of the safety case for geological disposal of radioactive waste. EUROSAFE Forum 2006. "Radioactive Waste Management: Long Term Safety Requirements and Societal Expectations". Paris, 13 & 14 November 2006, http://www.eurosafe-forum.org/products/data/5/pe_439_24_1_seminar2_02_2006_.pdf

24. ONDRAF / NIRAS: Technical overview of the SAFIR 2 report - Safety Assessment and Feasibility Interim Report 2. NIROND 2001-06 E, December 2001, http://www.nirond.be/engels/Safir2_eng.php

25. Ontario Power Generation, Nuclear Waste Management: Third Case Study – Postclosure Safety Assessment. Report No: 06819-REP-01200-10092-R00, March 2004

26. Safety Assessment of Spent Fuel Disposal in Hästholmen, Kivetty, Olkiluoto and Romuvaara – TILA-99. VTT Energy, March 1999. POSIVA 99-07

27. Dossier 2005. Andra research on the geological disposal of high-level long-lived radioactive waste. http://www.andra.fr/interne.php3?id_rubrique=161

28. H17: Development and management of the technical knowledge base for the geological disposal of HLW, JNC TN1400 2005-022, 2005, http://www.jaea.go.jp/04/tisou/english/pdf/H17_KM_Report_E.pdf

29. Long-term Safety for KBS-3 Repositories at Forsmark and Laxemar – A First Evaluation: Main Report of the SR-Can Project. SKB Technical Report TR 06 09, Svensk kärnbränslehantering AB, October 2006, ISSN 1404-0344, http://www.skb.se/upload/publications/pdf/TR-06-09webb.pdf

30. Project Opalinus Clay – Safety Report, Demonstration of disposal feasibility for spent fuel, vitrified high-level waste and longlived intermediate level waste (Entsorgungsnachweis), NAGRA Technischer Bericht NTB 02-05, Dez. 2002, http://www.nagra.ch/downloads/ntb_02_05/NTB%2002-05.pdf

31. Department of Energy: 2004 WIPP Compliance Recertification Application - Main Volume, DOE/WIPP 04-3231, March 2004, http://www.wipp.energy.gov/library/CRA/CRA_Index.htm

32. International Atomic Energy Agency (1997), Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, Information Circular INF/546, Vienna, http://www.iaea.org/Publications/Documents/Infcircs/1997/infcirc546.pdf

33. B. Baltes, A. Becker, A. Kindt, K.-J. Röhlig: Focus on Isolation and Containment Rather than on Potential Hazard: An Approach to Regulatory Compliance for the Post-Closure Phase, in: NEA No 6319
http://www.nea.fr/html/rwm/reports/2008/ne6319-safety.pdf

34. International Atomic Energy Agency (IAEA): Protection of the environment from the effects of ionizing radiation. A report for discussion, IAEA-TECDOC-1091 IAEA, 1999 http://www-pub.iaea.org/MTCD/publications/PDF/te_1091_prn.pdf

35. International Atomic Energy Agency (IAEA): Ethical consideration in protecting the environment from the effects of ionizing radiation, IAEA-TECDOC-1270 IAEA, 2002 http://www-pub.iaea.org/MTCD/publications/PDF/te_1270_prn.pdf

36. International Commission on Radiological Protection (ICRP): A Framework for Assessing the Impact of Ionising Radiation on Non-human Species – ICRP Publication 91, Editor: J. VALENTIN Annals of the ICRP, Vol. 33, No. 3, 2003

37. L.-E.-Holm: Lecture on: New results on effects of radiation on man – the new ICRP recommendation, EU-Konferenz im Hotel Berlin, Berlin, 19. Juni 2007

38. OECD/NEA: Confidence in the Long-term Safety of Deep Geological Repositories –Its Development and Communication NEA OECD, Paris, 1999, http://www.nea.fr/html/rwm/reports/1999/confidence.pdf

39. HSK: Spezifische Auslegungsgrundsätze für geologische Tiefenlager und Anforderungen an den Sicherheitsnachweis Entwurf 18. März 2008 Richtlinie für die schweizerischen Kernanlagen G03/d
http://www.hsk.ch/deutsch/files/pdf/Anh_Richtlinie_G03_Mrz_18_2008.pdf

40. POSIVA: Safety Case Plan, 2008
POSIVA 2008-05, July 2008, ISBN 978-951-652-165-0 ISSN 1239-3096
http://www.posiva.fi/publications/POSIVA%202008-05_28.8web.pdf

41. Environment Agency: Deep geological disposal facilities on land for solid radioactive wastes: guidance on requirements for authorisation - Draft for Public Consultation,15 May 2008
http://www.environment-agency.gov.uk/commondata/acrobat/gd_consultation_2052368.pdf

42. ASN: Guide de sûreté relatif au stockage définitif des déchets radioactifs en formation géologique profonde, Version du 12/02/2008
http://www.asn.fr/sections/rubriquesprincipales/textes-reference/acces-par-type-texte/regles-fondamentales/guides-asn-rfs-relatifs/RFS_III2f/downloadFile/file/Guide%20de%20s%C3%BBret%C3%A9%20relatif%20au%20stockage%20d%C3%A9finitif%20des%20d%C3%A9chets%20radioactifs%20en%20formation%20g%C3%A9ologique%20profonde.pdf

43. Environmental Protection Agency 40 CFR Part 197: Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada; Final Rule, October 15, 2008
http://www.epa.gov/radiation/docs/yucca/yucca_mtn_rule_fed_reg_version.pdf

44. International Commission on Radiological Protection (ICRP): The 2007 Recommendations of the International Commission on Radiological Protection ICRP Publication 103, Annals of the ICRP, Vol 37, Nos. 2-4, 2007

45. International Commission on Radiological Protection (ICRP): Radiation Disposal Protection Principles for the of Solid Radioactive Waste, ICRP Publication 46, Pergamon Press Oxford . New York . Toronto . Sydney. Frankfurt, 1985

46. International Commission on Radiological Protection (ICRP): 1990 Recommendations of the International Commission on Radiological Protection, ICRP Publication 60, Pergamon Press Oxford . New York . Frankfurt Seoul - Sydney . Tokyo, 1990

47. United Nations: Report of The United Nations Conference on Environment and Development, Annex I ,Rio de Janeiro, 3-14 June 1992
http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm

48. International Commission on Radiological Protection (ICRP): Radiological protection policy for the disposal of radioactive waste, ICRP Publication 77, Annals of the ICRP Volume 27 Supplement, 1997

49. International Atomic Energy Agency (IAEA): Safety Series No.99; IAEA: Safety Principles and Technical Criteria for the Underground Disposal of High Level Radioactive Wastes, Vienna, 1989
http://www-pub.iaea.org/MTCD/publications/PDF/Pub854e_web.pdf

50. International Atomic Energy Agency (IAEA): IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles, Safety Fundamentals, Vienna, 2006
http://www-pub.iaea.org/MTCD/publications/PDF/Pub1273_web.pdf

51. OECD/NEA: Progress Towards Geologic Disposal of Radioactive Waste: Where Do We Stand? An International Assessment, Paris,1999
http://www.nea.fr/html/rwm/reports/1999/progress.pdf

52. OECD/NEA: Geological Disposal of Radioactive Waste: Review of Developments in the Last Decade , Paris, 1999, ISBN 92-64171944

53. OECD/NEA: Stepwise Approach to Decision Making for Long-term Radioactive Waste Management Experience, Issues and Guiding Principles, NEA No. 4429, Paris, 2004, ISBN 92-64-02077-2
http://www.nea.fr/html/rwm/reports/2004/nea4429-stepwise.pdf

54. OECD/NEA: The Regulatory Function and Radioactive Waste Management: International Overview, NEA No. 6041, Paris, 2005, ISBN 92-64-01075-0
http://www.nea.fr/html/rwm/reports/2005/nea6041-regulatory-function.pdf

55. OECD/NEA: Regulating the Long-term Safety of Geoloical Disposal of Radioactve Waste: Practical Issues and Challenges, Workshop Proceedings, Paris, France, 28-30 November 2006, NEA No 6423, OECD, 2008, IBSN 978-92-64-04812-6,
http://www.oecdbookshop.org/oecd/display.asp?lang=EN&sf1=identifiers&st1=978-92-64-04812-6

56. OECD/NEA: A Collective Statement by the NEA Radioactive Waste Management Committee (RWMC), NEA No 6433, OECD, 2008, IBSN 978-92-64-99057-9
http://www.nea.fr/html/rwm/reports/2008/nea6433-statement.pdf

57. OECD/NEA: Regulatory Reviews of Assessments of Deep Geologic Repositories, Lessons Learnt, OECD, 2000
http://www.oecdbookshop.org/oecd/display.asp?CID=sourceoecd&LANG=EN&SF1=DI&ST1=5LMQCR2KDCJH