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Possible Implications of Draft ICRP Recommendations

NUCLEAR ENERGY AGENCY
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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- to achieve the highest sustainable economic growth and employment and a rising standard of living in Member countries, while maintaining financial stability, and thus to contribute to the development of the world economy;
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- to contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations.

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NUCLEAR ENERGY AGENCY

The OECD Nuclear Energy Agency (NEA) was established on 1st February 1958 under the name of the OEEC European Nuclear Energy Agency. It received its present designation on 20th April 1972, when Japan became its first non-European full Member. NEA membership today consists of 28 OECD Member countries: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, the Netherlands, Norway, Portugal, Republic of Korea, Slovak Republic, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The Commission of the European Communities also takes part in the work of the Agency.

The mission of the NEA is:

- to assist its Member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally friendly and economical use of nuclear energy for peaceful purposes, as well as
- to provide authoritative assessments and to forge common understandings on key issues, as input to government decisions on nuclear energy policy and to broader OECD policy analyses in areas such as energy and sustainable development.

Specific areas of competence of the NEA include safety and regulation of nuclear activities, radioactive waste management, radiological protection, nuclear science, economic and technical analyses of the nuclear fuel cycle, nuclear law and liability, and public information. The NEA Data Bank provides nuclear data and computer program services for participating countries.

In these and related tasks, the NEA works in close collaboration with the International Atomic Energy Agency in Vienna, with which it has a Co-operation Agreement, as well as with other international organisations in the nuclear field.

FOREWORD

The NEA Committee on Radiation Protection and Public Health (CRPPH) has, throughout its existence, been interested in the development of recommendations by the International Commission on Radiological Protection (ICRP). Recently, this interest has included a very active CRPPH programme to develop ideas and suggestions that the ICRP can take into account in its work. The CRPPH has also become an active partner with the ICRP to provide the views of regulators and experts from the NEA's 28 member countries.

The latest products of CRPPH work in this area include four reports. The first identifies in which ways the current system of radiological protection (as per ICRP Publication 60) could be usefully improved. The second report discusses the policy-level aspects of how stakeholder involvement can affect decision making in situations involving radiation exposure to the public or to workers. The third report proposes concrete approaches for modifying the current system of radiological protection in order to make it more transparent, clear and easy to implement. The fourth report is a "road test" of the key ideas developed in the third report. The titles of these reports are as follows:

- *A Critical Review of the System of Radiation Protection: First Reflections of the OECD Nuclear Energy Agency's Committee on Radiation Protection and Public Health* (OECD/NEA, 2000).
- *Policy Issues in Radiological Protection Decision Making*: *Summary of the 2nd Villigen (Switzerland) Workshop, January 2001* (OECD/NEA 2001).
- *The Way Forward in Radiological Protection: An Expert Group Report (*OECD/NEA, 2002).
- *A New Approach to Authorisation in the Field of Radiological Protection: The Road Test Report* (OECD/NEA, 2003).

Collaborative efforts with the ICRP have included the organisation of joint forums. The first NEA/ICRP Forum was held in order to assist NEA member countries and the ICRP in developing a policy basis for radiological

protection of the environment. Held in Taormina, Italy on 12-14 February 2002, the first Forum helped the NEA member countries to better understand the approach proposed by the ICRP, and to provide input to the ICRP on how the direction it is taking could be refined to better serve the needs of policy makers, regulators and implementers. The resulting documents were published by the NEA:

- *Radiological Protection of the Environment: Summary Report of the Issues* (OECD/NEA, 2003).
- *Radiological Protection of the Environment: The Path Forward to a New Policy?* Workshop Proceedings, Taormina, Sicily, Italy, 12-14 February 2002 (OECD/NEA, 2003).

Following this Forum, the CRPPH developed a process and structure for continuing its contribution to the evolution of the system of radiological protection. Following reviews of early-draft ICRP recommendations within the NEA family, further views of the ICRP and other stakeholders are collected in the format of a Forum or workshop. In close collaboration with the ICRP, the focus of review is on the possible IMPLICATIONS of the ICRP draft recommendations SHOULD they be published. In this fashion, the CRPPH felt that it could maximise the value of its feedback to the ICRP, while at the same time bringing CRPPH members up to date on the evolution of the ICRP's thinking. As such, once final ICRP publications are approved by the Commission, the policy makers, regulators and experts of the CRPPH will already have had the opportunity to read and understand the recommendations, and to provide input towards the direction taken by the ICRP in developing its recommendations.

To accomplish this, the Committee created, at its March 2002 meeting, the Expert Group on Implications of ICRP Recommendations (EGIR), and agreed to the following review process:

- In collaboration with the ICRP, it was agreed that the Commission would send its draft General Recommendations (which will replace ICRP Publication 60), and its draft Framework Recommendation on the protection of non-human species to the NEA for comment.
- The CRPPH would then co-ordinate the collection of comments on these recommendations within the relevant NEA standing technical committees:
  - the Committee on Radiation Protection and Public Health (CRPPH);

- the Radioactive Waste Management Committee (RWMC);
- the Committee on Nuclear Regulatory Activities (CNRA);
- the Nuclear Development Committee (NDC).

- The CRPPH Expert Group on Implications of ICRP Recommendations would:
  - review draft ICRP recommendations, focusing on their possible implications, as described above;
  - provide specific suggestions as to textual changes to the draft ICRP recommendations;
  - collect comments, solicited from other NEA standing technical committees, on the draft ICRP recommendations and include these in their discussions;
  - develop a draft summary report of their views, and those of the NEA standing technical committees, on the possible implications of the draft ICRP recommendations.

The EGIR submitted its draft report to the CRPPH at its March 2003 meeting. A broad discussion was held in which representatives of other NEA standing technical committees were invited to participate.

In parallel with these activities, the CRPPH organised the second NEA/ICRP Forum, during which a broad spectrum of stakeholders, including representatives from the above-mentioned NEA standing technical committees, and radiological protection specialists discussed the implications of the draft ICRP recommendations.

This report is the result of the work prepared by the EGIR, presented during a special session of the March 2003 CRPPH meeting, again presented during the second NEA/ICRP Forum in April 2003, and modified as per comments received on these occasions.

Both the CRPPH and the RWMC have strongly endorsed the executive summary of this report. The body of the report, which represents more detailed views and is reflected in the executive summary, although not representing the full consensus of the CRPPH and the RWMC, was also strongly endorsed by both Committees as useful views to be taken into account by the ICRP when drafting its new recommendations. To this end, this work, and all the specific comments that were received by the CRPPH from other NEA standing technical committees, have been transmitted officially to the ICRP for information and use.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The International Commission on Radiological Protection (ICRP) has embarked on a broad programme of consultation in order to collect concepts, ideas and views regarding how radiological protection should be managed at the start of the 21st century. The results of this consultation will be a new set of comprehensive ICRP recommendations, updating and consolidating ICRP Publication 60 and all subsequent ICRP recommendations. It is expected that the new ICRP general recommendations will be published in 2005, with additional, more detailed "building block" recommendations being published in subsequent years.

The Nuclear Energy Agency (NEA) has for some time been interested in this area, and has developed a series of documents and report, through its Committee on Radiation Protection and Public Health (CRPPH), discussing its views (see Annex). The objective of the CRPPH in this work has been to contribute actively to the development of new ideas and approaches that could help the internationally accepted system of radiological protection respond better to the needs of policy makers, regulators and practitioners. As such, its work has been offered to the international community, including the ICRP, as forward-looking "food for thought".

In this context, the NEA and the ICRP have established a collaborative effort, whereby the NEA has analysed draft ICRP materials specifically looking at the implications that might arise should the ideas and concepts in the draft material be implemented in the form of a recommendation. Two such high-level ICRP draft documents have been submitted for this process, which was carried out by the Expert Group on the Implications of Draft ICRP Recommendations (EGIR), and discussed and updated in plenary by the CRPPH itself. The two documents submitted by the ICRP were:

- The Evolution of the System of Radiological Protection: The Justification for New ICRP Recommendations, Roger Clarke, 22 November 2002.

- 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.

The CRPPH appreciates the openness of and collaboration with the ICRP to advance radiation protection for the benefit of society. This report raises a number of issues and makes a number of suggestions to enhance the understanding and transparency of the ICRP recommendations that will result from the framework documents that have been reviewed. The CRPPH looks forward to continuing its relationship with the ICRP to address and contribute to the resolution of issues. The Committee will also continue to contribute to the creation of a new set of ICRP recommendations, having strong scientific foundations and broad stakeholder acceptance that will result in accelerated and efficient implementation of the final ICRP recommendations.

The key observations, issues and implications raised by the CRPPH as a result of its analysis of these documents are the following;

- There is broad agreement that the ICRP should clarify and consolidate its recommendations. However, the goal of the ICRP to publish new recommendations by 2005 is seen as being ambitious, and not absolutely necessary.
- Both of the documents from the ICRP are “framework” documents. While they provide discussions of the guiding principles and overall concepts that the ICRP is proposing to use as the bases for its recommendations, the details that would be necessary to fully understand the implications and ramifications of the new recommendations are not presented. It is assumed that the ICRP will modify, based on the views and opinions it is currently collecting, its framework appropriately and use this to develop detailed recommendations. In this context, it is also suggested that some of the details of the “building block” support recommendations should be developed and reviewed in parallel with the general recommendation document.
- The current efforts of the ICRP to clarify its framework and principles, and to consolidate the recommendations it has made since the issuance of Publication 60, are very much supported. Many aspects of the body of the ICRP’s recommendations are difficult to interpret and implement, and simplification would be greatly appreciated. However, the framework documents suggest that some significant changes in its fundamental principles are being

contemplated by the ICRP. In presenting its new framework, and subsequently its new recommendations, the ICRP will need to provide a clear and compelling argument as to why any significant changes are needed at this time. In view of the potentially large direct and indirect costs of translating ICRP recommendations into national legislation and international agreements and standards, it is suggested that the demonstration of the value of the new recommendations, through the use of road tests and/or case studies, should be considered before the recommendations are finalised and issued.

- Given that these documents present simply the framework for future recommendations, it is understandable that they do not present their ideas and concepts with a great amount of detail. However, some of the key ideas and concepts seem to be either completely new, or to have significantly evolved from their previous manifestations (in ICRP Publication and its subsequent supporting documents). Thus, in order to fully understand the Commission's proposed direction, there is a need for presenting much more detail regarding various key issues, such as:
  - Three basic principles, presented in the draft texts as Justification, Constraints to Optimisation, and Authorised Levels.
  - The concept of exclusion, that is, how and why natural and artificial sources and exposures are included in the system, or considered as not entering within the system of radiological protection.
  - The reference flora and fauna approach to establishing radiological protection criteria.

Further, more specific questions and possible implication regarding these important aspects of the draft framework are provided in the body of this report.

- The ICRP has suggested in its draft framework that radiological considerations will form only one element, and often not the deciding element, in decisions regarding radiological protection options and optimisation. This implies that the final recommendations will be written in a way to allow national authorities the flexibility to appropriately address local issues. The balance that the ICRP strikes between international harmonisation of numerical criteria and the flexibility necessary for local approaches is very

important, and will be a key consideration in the review of final ICRP recommendations.

- In discussing the role of radiological protection aspects in decision making, the ICRP has hinted at the distinction between the scientific aspects of risk assessment, the social aspects of risk evaluation and management, and the regulatory aspects of risk management. This distinction is seen as important to understanding the context of ICRP recommendations in the broader process of risk governance.

- Addressing the question of risk transfers, particularly within the optimisation process, has 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 will complicate this even further. It will be essential for the Commission, 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.

- ICRP publications 77 and 81 provided some guidance from the Commission on radiological protection issues in the context of radioactive waste management options. The draft material that was reviewed provided no discussion of waste management issues at all. Potential exposures, which had been used with regard to waste management issues, was also not mentioned. The Commission will need to provide guidance for the long-term management of radioactive waste, particularly with regard to the protection of non-human species.

- Since the 1990 issuing of ICRP Publication 60, radiation protection policy makers, regulators and practitioners have become familiar with the meaning and use of several fundamental tools, including the concepts of dose limits, ALARA and collective dose. These three concepts, as well as such other ideas as the use of risk as a basis for numerical protection criteria, and potential exposures, are not discussed at all in the draft texts from the ICRP. There is broad agreement, but not full consensus, that these concepts should be kept as parts of the system of radiological protection because of their usefulness and their widespread use in regulatory and guidance texts at the national and international levels. At the very least, the ICRP should explain how these concepts, if by another name, are included in their new proposals.

- A key aspect of risk assessment and management is the addressing of uncertainties. Both assessment and management require the use of assumptions, biological models, environmental transport models, dose-effect models, etc. All of these assumptions and models include uncertainties, implying that the end result of such models also has a given level of uncertainty. At this point there is still very little knowledge, relatively speaking, of various ecosystems, implying that some margins of conservatism will be used. Although the ICRP has, in the past, provided some guidance as to how uncertainties should be addressed in regulation and practice, further guidance is certainly necessary. This should begin with general guidance with respect to the overall approach to uncertainty, and continue with more specific guidance as to how such uncertainties should be understood in practice (policy, regulation and application). The need for and use of margins of safety, in regulation and practice, should be part of this discussion for the protection of both humans and non-human species.

1. INTRODUCTION

Since 1990 when it issued its most recent general recommendations for a system of radiological protection its Publication 60, the International Commission on Radiological Protection (ICRP) continued to clarify and update its position by issuing subsequent, subsidiary recommendations on specific topics. Approximately ten years after the issuing of Publication 60, a period during which the Commission has issued 25 subsidiary recommendations, the ICRP began the process of consolidating its recommendations, and, more importantly, updating their recommendations to better reflect modern scientific and social views of risk and risk management, and to more specifically address the radiological protection of non-human species. The most obvious manifestation of this updating is the Commission's active, and successful, attempt to develop a broadly based consensus on not only the type of recommendations it should be making, but on the details of these recommendations.

The result of this process should be at least two-fold. First, the Commission should develop consensus within the radiological protection community on its new recommendations. This will help to assure that the new recommendations are much more transparent than those produced in 1990, and that they are more clear, precise and more directly useful to national regulatory authorities and radiological protection practitioners. What's more, the broad consultative process that the ICRP has undertaken has gone well beyond the radiological protection community, and has included the radioactive waste community, the broader nuclear regulatory community, the nuclear development community, as well as environmental groups. Second, by using a process of consensus building, the Commission should follow, rather than completely led, an evolutionary trail by which all participants in discussions have had the opportunity to develop ideas together. In this way, it is hoped that the recommendation that is finally published will be simplified, much easier to understand and accept, and will be much more likely to find its way into national regulations in a timely fashion.

It should be noted that the development of these general recommendations has included specifically the protection of non-human species from ionising radiation. Here, the Commission is expanding on the simple statement

it made in Publication 60 (paragraph 16), which suggested that the appropriate protection of man will assure the appropriate protection of the environment.

In this context, the NEA Committee on Radiation Protection and Public Health has contributed to this discussion, and to the development of new ICRP recommendations. This document represents the views of the CRPPH, as well as those of several other NEA Standing Technical Committees, with regard to the two latest draft ICRP recommendations: on the general recommendations for a system of radiological protection at the start of the 21st century; and for a framework recommendation for the protection of non-human species from ionising radiation.

The views expressed here focus on what implications these draft recommendations would have if they were to be approved, as written.

2. COMMENTS ON THE DRAFT ICRP GENERAL RECOMMENDATIONS

In December 2002 the NEA Secretariat received, from the ICRP Chair, a draft version of the framework document that will be the basis for the new ICRP General Recommendations. This document, titled "The Evolution of the System of Radiological Protection: The Justification for New ICRP Recommendations", was distributed to the NEA, for limited distribution within the CRPPH, before the ICRP Main Commission had had the opportunity of review. The document was circulated within the NEA, and comments were solicited with regard to the possible implications that the presented concepts would have should they be implemented.

The objective of this review is to help the ICRP to find an appropriate balance in its new recommendations to best serve the needs of national and international radiation protection policy makers, regulators and implementers.

2.1 Expectations

The draft ICRP document presents the new concepts as a consolidation and updating of the recommendations from ICRP Publication 60 and all subsequent recommendations. The comments received on this ICRP draft material, and the discussions of the Expert Group, indicate that there is broad agreement that it is timely to try to simplify the system, and to work towards a unified set of coherently and clearly expressed recommendations. This view encompasses a desire for the simplification of terminology, the need to build in transparency of process, and the need to have a less complicated structure.

At the same time, however, there is a certain level of caution regarding some of the proposed approaches, particularly those that seem to represent significant change from the previous system (e.g., no use of dose limits, no ALARA). There is also broad agreement that changes with respect to the current system should result in a net benefit, and that they should not be made unless they can be shown to be an improvement. In this context, benefit should

balance not only improvements in the level of protection, but the direct and indirect costs of change.

The draft document is seen as a framework that will be used as the basis for more complete recommendations. The Expert Group thus feels that the comments from this analysis, and input from other stakeholders, will help the ICRP to expand these draft concepts into more detailed explanations of the new approaches, that will further clarify understanding of the new ICRP recommendations.

In this spirit, a summary of the more general comments that have been made has been compiled. These do not present each of the comments provided, but rather represents the common ideas that were seen in one or more of the responses received.

2.2 Comments

The draft ICRP text on the general recommendations is seen as a framework document, which seems to be intended to describe the Commission's direction, and the rational behind this direction. In reviewing this document, there was broad agreement within the Group on the following points:

The goal of the ICRP to publish new recommendations by 2005 is seen as being ambitious, and not absolutely necessary. There are many national and international standards and regulations that already exist, and which should be taken into account in one way or another. The time necessary to appropriately take these aspects into account should be taken.

Following the development of new recommendations, it has also been suggested that a period of "road testing" should be envisioned. This could include the use of case studies, as has been done by the NEA in the context of its "The Way Forward" document. It could also include publishing the new recommendations in an interim form for an extended "trial period" during which specific studies could be made in national contexts.

Direction and the need for change

In general the EGIR feels that there is a need for much more clarification of the directions that the Commission is proposing to take, and of the rational that is being used for changing at this time. Some specific examples of this are given here.

- There was general agreement that there is no need to put much emphasis on the use of ethics as a rational for changing the system of radiological protection. The relative importance placed on individual and societal rights/needs/views is very country-specific, and is by no means homogeneous around the world.
- There is no discussion of those aspects of the current system that are in need of "fixing". Such a discussion should be a significant part of the introductory text. The NEA "Critical Review", and "The Way Forward" have discussed these issues, and could be considered as input for such introductory material.
- There is no real discussion of why it is reasonable to shift from the concept of an individual dose limit (exposures from all sources) to a source-related individual dose constraint. If such a shift were to be proposed, a clear approach to dealing with exposures to multiple sources would be necessary.

The fundamental principles

General

- There were many comments regarding how the ICRP system of protection should be applied in different cultural and development settings. There were some that suggested that the level of protection afforded to populations should be equal, regardless of a country's developmental status. Others argued that some cultural flexibility would be necessary to take into account a broader context of risk management. In general, it was requested that the ICRP provide guidance on its philosophy regarding the need, or not, to achieve a homogeneous level of protection across all types of national and cultural borders.
- There is broad agreement that there is a need to mention, in some fashion, the protection of non-human species in the discussion of the System's three fundamental principles.
- The Group noted that the identification of a common basis for protection of humans and non-human species is particularly difficult. It should be specified that protection of the individual applies to humans, while the protection of non-human species generally focuses on protection of the ecosystem, of reproductive success, or other criteria. It should also be stated that some species are protected

at the individual level. Philosophically, the ICRP should address this difference in protection bases.

- Focusing the optimisation of protection on the most exposed individual was strongly supported.
- The disappearance of ALARA was broadly remarked. The return of this concept, which is well understood and appreciated, was supported by most Group members.

Justification

- There is very little explanation of what is meant by the "new" concept of justification, and how this differs from the "old" concept of justification. Any new, detailed ICRP recom-mendation will need to clearly address this important topic.
- In referring to the responsibility for introducing a new practice (paragraph 24), the ICRP suggests that the responsibility lies with the appropriate regulatory authority. There was broad agreement that this definition is not sufficiently precise. It was rather suggested that the justification of practices should take place at the appropriate publicly accountable level which can take a balanced view of all relevant benefits and detriments. A caveat discussing Justification as it refers to medical doctors could also be included in the general description of this principle.
- Justification is presented as only needed for the introduction of new practices. This seems too limiting. Appropriate national authorities might wish to revisit the justification of an existing process or practice based on new science, technology, or social factors. The case-specific use of justification should, it was strongly felt, not be limited to the medical field.

Constraints to optimisation

- There is broad agreement that there is a need for both an overall "dose limit" as a planning and regulatory tool, as well as source-related dose constraints. Both of these concepts are seen as very useful dose management tools for both the regulator and the practitioner.

- The Group felt that overall public and worker dose limits are needed for international harmonisation of radiological protection levels, but that the need for flexibility could be best applied through the use of constrained optimisation. Both concepts, however, were seen as necessary.
- As with justification, there is very little explanation of what is meant by the "new" concept of dose constraint, and how this differs from the "old" concept of dose constraint. Any new, detailed ICRP recommendation will need to clearly address this important topic.
- In explaining the Commission's new recommendations for dose constraints and optimisation, it will be important to very clearly explain how they should be applied to planned, existing and cleanup situations.
- There will be a need for clear guidance in the use of dose constraints by both regulators and operators.
- There is broad agreement that there is a need to protect both the individual and society. As such, most EGIR members feel that collective dose is very useful tool in the process of optimising protection for both workers and the public. Although the use of the concept of collective dose should be much more clearly explained (as in the IRSN document for example), the concept of collective dose should be retained as part of the ICRP's protection system.
- In the context of collective dose, if this concept is not retained, the new recommendations will need to give some guidance with respect to dilution.

Stakeholders

- It was broadly agreed that the ICRP should not recommend methods by which stakeholder involvement in the optimisation of protection can be achieved (paragraph 48). However, ICRP recommendations should be formulated so as not to hinder the involvement of stakeholders in national decision-making processes.
- In a very broad sense, the Group agreed that the ICRP should much more clearly set out the distinction between those parts of its recommendations that are based on science, and those parts of its recommendations that are based on social choice through appropriate stakeholder involvement. The NEA "Critical Review",

and “The Way Forward” have discussed these issues, and could be used as reference material.

- The judgement of what level of dose is “safe” or “unsafe” is a social decision. As such, the ICRP recommendations should not make this judgement in society’s place, and should clearly point out the judgmental nature of phrases such as “low concern” and “high concern” should these continue to be used.

Levels for numerical criteria

- There was broad agreement that fixing of the numerical levels of protection criteria should not be solely based on the level of concern over natural background exposure. In fact, several aspects should be considered, including the ICRP 26 concept of using the level of risk in “safe industries” as a reference point for fixing numerical levels of worker protection criteria was supported.
- In presenting Table 3, levels of concern and annual natural background dose, the draft states that “the concern that can be reasonably felt about annual dose from natural sources” can be used as a starting point for the selection of numerical values for constraints. This use was not seen as necessarily reducing public confusion. In addition, the levels provided seemed to be based on public concern, and thus would not necessarily be applicable to fixing criteria for workers. As such, the explanation of any new criteria is not necessarily facilitated.
- Most Group members agreed that risk should be considered as a reference for the fixing of public dose constraints.
- There was broad agreement that the number of numerical criteria that ICRP has promulgated in and since Publication 60 should be reduced. However, it was noted that using a dose constraint of 0.3 mSv in a year for public exposures may pose practical difficulties in certain cases, such as mines, at the site boundary, or for on-site exposure of non-nuclear workers. In this context, guidance with respect to the amount of conservatism used in models and their assumed parameters was seen as essential.

Exclusion

- As with other concepts, there is insufficient explanation of what is meant by the "new" concept of exclusion, and how this differs from the "old" concept of exclusion. Any new, detailed ICRP recommendation will need to clearly address this important topic. For example:
  - Why is exclusion applied differently to natural and artificial radionuclides?
  - What level of international agreement should be suggested on what is or is not "controllable"?
  - What types of issues or contexts should be considered when deciding whether a natural sources is or is 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., are other factors that could have important roles in the decision.
- It was suggested that the exclusion of the residual doses resulting from an optimisation process (whether this is an assumed optimisation or an active assessment) does nothing to enhance protection or ease the burden on regulatory authorities. In fact, excluding these low doses may be detrimental in terms of the image that such exclusion gives to the public.
- In this same context, it was not seen as useful for the ICRP to declare, 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 will always "assess" doses, even if they are low. The assessment may not be as detailed for a very low dose as for a higher dose, but the regulator will not always, a priori exclude low dose situations from consideration. Considering these two last points, it was suggested that the overall need for the concept of exemption could be revisited.
- In terms of exclusion of natural sources based on specific activity (Bq/kg), it was agreed that it is hard to control the health impact of radionuclides by only considering the specific activity. In different

situations, the same specific activity could lead to very different doses.

- For natural sources, it was suggested that activity 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 was suggested that a very clear explanation of why particular levels had been selected. The use of activity level, as opposed to dose level, was supported.
- Paragraph 22 of the document suggests that only two counter-measures (relocation or extensive rebuilding) would be possible in certain natural exposure situations. It was also noted that other countermeasures (ventilation for example) are possible. The two options presented should not be assumed to be the only possible approaches.
- In a specific comment, with regard to the exclusion of air-flight doses, there seem to be national approaches that consider this occupational, and others that consider it excluded. The ICRP should take this into account and allow sufficient flexibility for national views.

Radiological protection of non-human species (also see Chapter 3)

- The Group welcomed the ICRP's involvement in this important area, and feels that this new, more detailed approach to this area is needed to achieve a comprehensive framework.
- The Group felt that the radiological protection of non-human species is inherently interdisciplinary, and encouraged the ICRP's openness to co-operation, particularly in the spirit of achieving an approach that is coherent with other environmental protection approaches and goals.
- There was also broad agreement that, for the most part, the current system of radiological protection is probably not resulting in the under-protection of non-human species, and that this aspect should be more clearly expressed in any new recommendations.
- There is broad agreement that the inclusion of a framework table for the numerical values of non-human species protection criteria is

premature. Such a table implies that the scientific and social knowledge needed to support the designation of levels of harm and levels of concern already exist in detail. This is not yet the case.

- The Group was concerned that there is virtually no discussion of how the new recommendations on the protection of non-human species would affect the disposal of waste and the release of effluents (gaseous and liquid). It was suggested that guidance in these two areas, particularly as to how optimisation could be performed, would be essential to allow the practical implementation of the new recommendations.
- There was agreement on a need to discuss elements and aspects to consider in balancing the protection of humans with the protection of non-human species in the optimisation process.
- In a more detailed context, it was noted that the ICRP should specifically discuss the level of conservatism that should be used when developing models and protection criteria for non-human species.
- The further clarification of the issues of protection of non-human species should be included in the bullet points for paragraph 48.

Dosimetric quantities

- Several respondents commented on the ICRP's proposals for its work with dosimetric quantities. Although there was general agreement on the need to move forward in this area, it was suggested that the ICRP and the ICRU should work closely together to define the dosimetric quantities that the new recommendations will employ. Also, the relationship between W_r and Q should be clearly explained.

2.3 Implications

In making new general recommendations, the ICRP states in paragraph 12 that its primary aim is "to be contributing to the establishment and application of an appropriate standard of protection for human beings and now explicitly for other species." The Commission specifies that "This is to be achieved without unduly limiting those desirable human actions and lifestyles that give rise to, or increase, radiation exposures." Paragraph 13 goes on to provide another important detail: "While the primary emphasis is now on protection of individuals, it is then followed by the requirement to optimise protection to

achieve the best level of protection available under the prevailing circumstances."

These new recommendations are presented as a consolidation of recommendations from Publication 60 and those published subsequently in order to give a single, unified set of recommendations that can be simply and coherently expressed. The opportunity has also been taken to include a coherent philosophy for natural radiation exposures and to introduce a clear policy for radiological protection of the environment.

In developing a recommendation to attain these aims, the ICRP will certainly impact the making of national and international policy, the setting of national regulation and international standards, and in general the implementation of radiological protection.

In reviewing the draft framework document that has been prepared for the ICRP Main Commission, several areas have been noted that, if carried forward as described, would have various implications, as suggested in the previous paragraph. The following is a non-exhaustive list of the implications that were felt to be potentially the most significant.

Flexibility

Paragraph 12 of the document suggests that; "All those concerned with radiological protection have to make value judgements about the relative importance of different kinds of risks and about the balancing of risks and benefits." This implies that the ICRP expects to build into its next recommendations a fair amount of flexibility to allow such judgement to be exercised. In particular, the draft talks about reducing the number of numerical criteria that the ICRP will recommend, which implies that national authorities will need to be prepared to develop their own, case specific numerical guidance. If the ICRP expects that competent authorities will need to develop their own, case-specific dose constraints, some guidance will be needed with regard to the scientific issues and aspects that should be taken into account when arriving at numerical values.

Evolution of protection

In paragraph 13, the last sentence provides a somewhat new view of optimisation, suggesting that; "While the primary emphasis is now on protection of individuals, it is then followed by the requirement to optimise protection to achieve the best level of protection available under the prevailing

circumstances." This seems to imply that achieving doses that are "As Low As Reasonably Achievable" is no longer the goal of optimisation of protection. Paragraph 33, which uses these same words to describe the "optimisation of protection", also implies that ALARA will no longer be a main part of the Commission's description of protection. If the Commission intends to replace ALARA, this would be taking away what is widely regarded as a useful and well-understood radiological protection tool. This would also imply that the ICRP would need to provide detailed guidance on the "new" goals of radiological protection and optimisation.

In addition, the use of "prevailing circumstances" as guidance for protection and for optimisation seems to imply that protection will be more strongly linked with the "current" situation. As such, national authorities should be prepared for their objectives to evolve as prevailing circumstances change, necessitating perhaps a more periodic or programmed revisiting of objectives and regulations than now employed.

Exclusion

Paragraph 16 suggests that, for "…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." Paragraph 20 suggests that, ^{222}Rn, and now also for all other natural sources, "Exposures below the designated action level are then excluded from the system of protection."

These paragraphs suggest the ICRP will, 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 will never be of sufficient concern to be taken into account by regulatory authorities. Although low doses from natural radio-nuclides may, in many cases, not provoke any regulatory reaction, it is difficult to judge that this would be the case, de facto, in all situations.

In addition, taken together, these statements could be viewed as implying that ANY doses below a designated Action Level (that is, optimised doses) should be excluded from the system of protection. This would imply the use of truncation of exposures 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. Such a position by the ICRP would not necessarily aid regulatory authorities or practitioners.

It should also be noted that the statement from paragraph 16 talks about an assumed optimisation. Optimisation is 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 is a somewhat technical point, given the view expressed in paragraph 9, that the new recommendation is 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.

The level of protection afforded

Paragraph 24 explicitly states that the intention of the new system of protection is "to provide a higher standard than the previous one." Many radiation practitioners feel that the current system provides an appropriate level of protection to the public, workers, and in many cases the environment. It is thus assumed that the Commission is here referring to the somewhat broader protection afforded, in the new draft recommendations, to non-human species, and to the more explicit discussion of exposures from natural radiation.

This being said, the assertion that the new system provides a higher standard could be taken, in the courts, to imply that the previous system was not safe enough (such an argument has been used in American courts in the past with regard to safety improvements). While this concern might not arise, the general implication is that a legal review of these recommendations should be undertaken before they are finalised to minimise any legal confusion their publication might cause.

In addition to possible legal concerns, suggesting that the new system provides a higher standard could also provoke concern in the public, implying that regulatory authorities would need to be very careful in explaining the reasons for the change, and its end results. It is also felt that abandoning the use of risk as a benchmark for numerical radiological protection criteria could add to public concern over the level of protection afforded by the new system, again implying that the explanation of the new approach will require great care.

Justification

Paragraphs 26 describes the Commission's current view of Justification for practices, and for natural sources that are controllable. This implies that there will need to be some discussion, and perhaps criteria developed, with respect to what is considered to be a controllable natural source. This will apply to an area that has already caused some conflicts, that of Naturally Occurring

Radioactive Material (NORM – that has also been referred to as Technologically Enhanced Naturally Occurring Radioactive Material – TENORM). As such, the text that is finally developed by the ICRP will need to be clear, precise and convincing.

Paragraph 26 also implies that justification will be a very broad process, in which radiological considerations are not always the determining feature of the decision. This suggests that the Commission should discuss the nature of the radiological input that could be of value to such decision processes, and should perhaps reference other work, such as that of the NEA Villigen workshops, that could also provide regulatory authorities with some insights in this area.

Paragraph 27 goes on to describe the justification of patient exposures, specifying that this will be a two step process: one generic justification for, e.g., the broad use of X-rays in medicine, and the second for the specific use of an irradiation for a specific patient. This implies that for patients, the case-specific aspects of an irradiation are essential to the overall justification. For Practices, however, the Commission does not make this two-step distinction, implying that, for example, the siting of a new dose-causing facility does not invoke any question of justification. This implies that the Commission will need to much more clearly discuss its views on Justification and Optimisation, and their inter-relationship, such that national regulatory authorities can appropriately decide how they should interpret and apply the Commission's recommendations.

Dose constraints

Paragraph 29 describes the concern felt about annual dose from natural sources as what the Commission considers to be "the starting point for selecting the levels at which any revised constraints are set". Paragraph 31 states that "annual doses far below the natural annual dose should not be of concern to the individual." These two statements imply that the context of an exposure (i.e. situation history, costs, benefits, etc.) is considered by the Commission to be less important than the absolute level of dose. This view is reinforced by the statement in paragraph 31 that: "The Commission is satisfied that protection is already optimised if the effective dose to the most exposed is, or will be, less than about 0.01 mSv in a year. Taken in conjunction with the Commission's views about Exclusion (see paragraph 3 above), this implies that the flexibility of national regulatory authorities may be reduced, rather than enhanced as the Commission has stated.

Potential exposures

The concept of potential exposures, that have been applied to accident situations, waste disposal situations, nuclear safety questions, etc., has not been included in the new draft recommendation framework. This is also true of risk constraints (which were mentioned in paragraph 112 of Publication 60). It is not clear whether this implies that these concepts are no longer viewed by the Commission as useful, or whether these will be discussed when more detailed recommendations are drafted.

Should the concepts of potential exposure and risk constraints be abandoned, this would imply that the Commission should provide guidance for addressing the various risk transfer situations that were previously addressed, in part, through the use of potential exposure. The tools for such situations would be particularly necessary for the optimisation.

The cost of change

While it is evident that regulatory changes come only at a certain cost, the cost implications that would result from the proposed changes to ICRP's recommendations are significant. The more direct costs would involve the modification of international agreements and standards, of national regulations and of license and/or technical specification documents needed by users of radiation and/or radioactive materials. Such simple modifications as changing ALARA to "best available protection under the prevailing circumstances" could be quite time consuming, as the ALARA concept has become pervasive in many regulatory and operational documents. Indirect costs, such as the expenditures of political and social capital, or some loss of public trust in the face of such significant change, could also be quite high.

The implication of these potential costs is that the ICRP will need to be quite clear with respect to the benefits from change, in order to optimise the efforts and costs involved with this change.

To assist in the assessment of the regulatory changes that might be necessary following the issuance of the ICRP's new recommendations, it would be very useful to have a "Map" of concepts from Publication 60, and subsequent ICRP Publications, to the new recommendations.

3. COMMENTS ON THE DRAFT ICRP FRAMEWORK RECOMMENDATION ON THE PROTECTION OF NON-HUMAN SPECIES FROM IONISING RADIATION

In early June 2002, the NEA received from the ICRP its draft framework recommendation on the radiological protection of non-human species. As had been agreed to by the NEA Committee on Radiation Protection and Public Health, this document was widely circulated within the NEA family, and comments on it were sought. Comments were specifically requested regarding the philosophical basis from which national policy on the radiological protection of non-human species should be built.

In order to promote and establish a process of developing a policy for radiological protection of the environment that is as broadly informed as possible, and to foster information exchange between various initiatives, the NEA conducted, in close collaboration with the ICRP, a forum on radiological protection of the environment. This first NEA/ICRP forum: Radiological Protection of the Environment, The Path Forward to a New Policy?, was held from 12-14 February 2002, in Taormina, Italy.

The Forum achieved the following conclusions, which were taken into consideration during the discussion of this document's implications:

- The major objective of any system of radiological protection of the environment is to prevent harm.
- There was broad consensus that the environment is, in general, sufficiently protected against harmful effects of ionising radiation, however, the current system fails to demonstrate the level of protection.
- One has to create a consistent Radiological Protection system for man and the environment, which should also be consistent or at least harmonised with the protection systems which are in place against other stressors, such as chemicals.

- Radiological Protection of the environment might have different solutions on a global, regional and national level, depending on the context.
- Meeting participants agreed that the ICRP is the appropriate international organisation to develop recommendations, but that a broad dialogue with various interested parties is important.

Following the 1st NEA/ICRP Forum, it was widely agreed that the radiological protection of the environment should be addressed in co-ordination with the radiological protection of man. Subsequently to this meeting, the ICRP developed a new draft Framework Recommendation. The following comments on this latest draft have taken into account the conclusions from the 1st NEA/ICRP forum. The objective of this review is to help assure that final ICRP recommendations in this area will best serve the needs of national and international radiation protection policy makers, regulators and implementers.

3.1 Expectations

The ICRP has embarked on this new area using a broad consultation and consensus building process. Within the NEA family discussions have begun to identify the best approach to this issue. The first questions that have arisen are why do we need a new recommendation, what is the most practical way forward, and what are the implications on these new steps. Based on comments sent to the NEA by members of its various Standing Technical Committees, and based on discussions within the CRPPH Expert Group on the Implications of Draft ICRP Recommendations (EGIR), this section presents views on what is expected from an ICRP recommendation for the radiological protection of non-human species.

Firstly, a clear statement of the rationale behind the wish to protect non-human species from ionising radiation is an essential part of any ICRP recommendation on this issue. Therefore, the needs and objectives for the protection of non-human species must be clearly defined and completely explained in the recommendation.

The objectives of protection are strongly based on societal views, and the ICRP has stated that it is not developing these objectives itself, but simply reflecting society's will. However, because the details of any system of protection will depend upon its objectives, the ICRP will have to clearly express these social objectives, in particular, "what do we want to protect?".

Depending on who is asked, the answer to this question may be very different. Some may focus on bio-diversity, while others might also wish to define different ideas or endpoints, for example, the protection of endangered species. The maintenance of the level of reproductive success, and sustainable development are other possible goals of protection. The protection against deterministic and/or stochastic effects will also need to be addressed. One approach to defining the objectives of protection could be to group endpoints, or reference endpoints. Whatever the approach taken by the ICRP Recommendation, the endpoints it addresses, and the criteria for assessing the degree of attainment of these objectives, will need to be defined.

The system of protection will need to be based on up-to-date knowledge. This input will be provided by related research projects and studies, such as the FASSET project, which will finish its programme in 2003, the continuing work at UNSCEAR, as well as follow-up to the FASSET project.

Based on a scientific foundation, the system should, as for the radiological protection of humans, rest on clearly defined principles. The newly proposed system for humans is 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. In this context, it is felt that this parallelism refers more to the achieved level of protection than to the details of its application.

For coherence and simplicity, there is agreement that these principles should be, at the very least, broadly similar for the radiological protection of humans and non-human species. It should be recognised, however, that the application of these parallel principles may well be different for humans and non-humans. Optimisation of the radiological protection for non-human species, for example, may be achieved de facto through the application of other environmental protection initiatives. In any case, the current draft recommendation framework discusses only justification. The ICRP will need to define any other principles it recommends, and address how these should be applied to the protection of non-human species.

A key aspect that will need to be addressed by the ICRP involves the simultaneous protection of humans and non-humans. The optimisation tools and criteria necessary to demonstrate compliance with human and non-human radiological protection objectives will need to be developed, and guidance will be needed with regard to their use.

There is general agreement that the resulting system for a radiological protection of non-human species has to be transparent, easy to understand and

easy to implement. In order to enhance the acceptance of such a system, a somewhat flexible, reference-based approach would be necessary to accommodate solutions that may differ at the global, regional and local levels.

The application of the new system should allow for a graded approach based on the level of concern identified through an environmental impact assessment process. In practice, any situation would be examined with a view to the most appropriate reference species, and protection criteria could be used as screening values. If no identified non-human species presents concern, a simplified approach based on the protection of man could be sufficient.

3.2 Comments

It is understood that this document is no more than a framework for the future development of an ICRP recommendation in this area, and will be used as the basis for a short text in the Commission's general recommendations. In this context, it was felt that the document is, on the whole, well written and easy to read. It provides important background information as a basis for the development of an ICRP recommendation in this field. The introduction of an executive summary, however, would help to highlight the key points of the document.

The ICRP is seen as the appropriate international body to develop and publish a recommendation on radiological protection of the environment. However, during the process of developing these recommendations, broad consultation with the relevant stakeholders is seen as essential. ICRP has embarked on this path by providing early drafts of the recommendations to the radiological protection community and to other stakeholders. The NEA has offered its structures to facilitate the collection of some of this input for the ICRP. With a view to a harmonised international approach, the involvement of all relevant international organisations is key.

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 is present and protected, is biota then also protected? What would be needed to answer this question should be addressed. The scope of the recommendation's objectives should also be clearly stated, particularly with respect to consistency with existing international and national environmental protection policies, agreements, standards and regulations, in the chemical domain for example. The intent of the

recommendation to be consistent with the protection of humans should also be clearly stated.

Radiological protection of the environment must not be in conflict with internationally agreed general principles of environmental protection. A basis of environmental protection already exists in national regulations and international conventions.

As such, the protection of the environment should be seen as an evolution of the current system of radiation protection, which already provides a certain level of protection for the environment, but does not yet consider explicitly situations where humans are not a good reference.

Going into increasing detail, the proposed development of reference flora and fauna, based on dose quantities, was seen, especially if divided in three tiers, as very complex, and therefore as difficult to implement. As part of a more pragmatic presentation of these principles, it was suggested that the concept of protection, and its criteria, should be based on detriment, involving some type of dose-effect relationship. A separate aspect is then the management of radiological protection, which could be based on activity concentrations. Activity concentrations could also be used as screening criteria for the identification of further hazard and detriment studies, and as regulatory limits. The objective of protection should be the improvement of safety.

3.3 Implications

In developing a recommendation on the radiological protection of non-human species, the ICRP will certainly impact the making of national and international policy, the setting of national regulation and international standards, and in general the implementation of radiological protection of the environment. As a result, governments will consider changes to their policy and regulation, and will be required to clearly present and implement their positions. This implies that the ICRP will have to very clearly present its own recommendations such that regulatory choices based on these recommendations will have a valid and understandable basis. To this end, in making recommendations for the protection of non-human species, the ICRP clearly states that its aims are to:

- Define how the ICRP can contribute to the attainment of society's goals of environmental protection by developing protection policy;

- suggest a framework for the assessment of the impact of ionising radiation in the environment, and protection of the environment against harmful effects of ionising radiation, based on scientific and ethical-philosophical principles; and
- show how such a proposal for protection of the environment can be interfaced with or integrated into an overall system of radiological protection.

In reviewing the draft framework document that the ICRP Task Force has prepared for the ICRP Main Commission, several areas have been noted that, if carried forward as described, would have various implications, as suggested in the previous paragraph. The analyses of these implications have been partly predicated on the following assumptions regarding this new framework:

- The protection of ecosystems is the objective that has been established by society for the radiological protection of non-human species.
- The approach to the assessment of hazards is the use of Reference Flora and Fauna, including Primary, Secondary and Tertiary level organisms, beginning at the Family or Order taxonomic level.
- The regulatory framework is based on Derived Considerations Levels, which in turn are based on bands of consideration as orders of magnitude above and below background.

The following is a non-exhaustive list of the implications that were felt to be potentially the most significant.

The life-cycle perspective

Paragraph 49 of the document suggests that in order to appropriately embrace the concept of sustainable development, it will be necessary to take a "life-cycle perspective" with respect to the analysis of practices. Although the meaning of this perspective is not explicitly presented, this suggests a very broad approach to the analysis of impacts. In this context, broad is intended to imply that environmental stresses can not be analysed in isolation. Specifically, along with radiological impacts, other impacts such as chemical pollutants or human and social stresses (population growth, deforestation, agriculture, etc.) will have to be considered. While this is obviously necessary and desirable, it is practically speaking often very difficult, even simply from the scientific standpoint. If such an approach continues to be suggested, additional discussion

of what is meant should be provided. This should include discussions of how policy should address the need for these broader analyses, how regulators should interpret the appropriateness of the scope of analyses presented to them for consideration, and how implementers should rationalise the scope of their approaches.

Because of the complex interrelationships in ecosystems, taking the very broad view of life-cycle perspective also implies that dose (or activity concentration) could not be taken alone as a criteria, but would in fact need to be considered on a case-by-case basis along with the other existing stressors to adequately reflect the true hazard. Such an approach seems to be well beyond our current level of ecosystem understanding, and could thus be taken as an aspiration. Even admitting as such our level of understanding, this view would imply that all ecosystem stresses should be assessed, radiological stresses being only one of these.

Should parallelism between the approaches to human and non-human protection be considered by the ICRP, as suggested in the aims of this report (also see below), this would suggest that a similar broad approach should be adopted for the protection of humans. This might have a profound affect on the assessment of risks to the public from, for example, radioactive emissions, or site and/or material release. Here again, the ICRP should consider, if there is an intention for the approaches to human and non-human protection to be parallel, providing guidance as to how such a broad approach to risk assessment and analysis could and should be applied to the protection of humans. Policy, regulatory and applicational aspects should be considered.

Parallelism

One of the stated aims of the ICRP's work in this area is to show that integration, or at least an interface with the system for protection of humans can be made. Paragraphs 57, 58 and 97 are a bit more specific in this area, suggesting that a strong parallelism should be sought between the approaches to the radiological protection of humans and non-human species. Looking in more detail, parallelism could have several significant implications.

- Paragraphs 57 and 58 suggest that environmental protection is tending towards a Best Available Techniques (BAT) approach to steady reduction, with a further trend towards minimisation. Although arguments have been made that BAT and ALARA are compatible, minimisation seems to go beyond the optimisation that is implied by ALARA and to a certain extent by BAT. Minimisation,

particularly with respect to radioactive discharges, has been used in cases where harm is difficult to assess. Should a parallelism between the approach to humans and non-human species be invoked, this could be interpreted as tending to lead towards a minimisation approach in human protection, particularly that of the public.

In any case, the approach that is finally taken here (ALARA, BAT, best protection under the prevailing circumstances) should be consistent with that taken in the general recommendations.

- Paragraph 97 says that the ICRP should not develop an ethical basis for the protection of non-human species, suggesting instead that this should be a societal consensus that has already been built to a large extent. This could suggest, from a parallelism viewpoint, that the ICRP should also not develop an ethical basis for the protection of humans. The recent NEA report, "The Way Forward in Radiological Protection" suggests that the social, and thus ethical, aspects of justification and optimisation are very important in the resolution of stakeholder concerns in reaching an accepted decision on radiological protection solutions. The implication of not developing, or at the very least not discussing, the ethical basis for the protection of non-human species is then that a similar approach should be taken for development of the ethical basis for the protection of humans.

In the recent NEA publication, "The Way Forward in Radiological Protection", the distinctions between the social aspects of risk assessment and management, the scientific aspects of risk assessment, and the regulatory aspects of risk management are noted as being very important. In the context of the ethical basis for the protection of non-human species, this would imply, as the publication suggests for human protection, that the fixing of any quantitative norms (guides, PALs, etc.) should be based largely on social acceptance of the practice causing the risk, and the level of risk. Paragraph 97 suggests that, in recommending quantitative norms, the role of the ICRP is not to determine what is socially acceptable, but to rather interpret consensus on such norms as a reflection of social acceptance. The approach taken with regard to the bases of ICRP numerical recommendations should be consistent for the protection of humans and non-human species.

Nominal approach

Section 5.3, as well as paragraph 88, suggest that Reference Man is a "nominal" framework that is used as a basis for the development of norms,

standards and regulations. In this sense, Reference Man is not an "average" individual, but the sum of a series of models. More specific models, for example addressing variability due to age, sex, origin ("Western" versus "Asian") have also been used. Since the development of Reference Man, the radiological protection community has adopted approaches to "appropriately" use this nominal data, and the ICRP has provided guidance as to how policy makers, regulators and implementers can interpret Reference Man. A similar "nominal" approach is suggested in section 5.3 for the protection of non-human species. To assure that this approach would be exploited in the intended fashion, the ICRP would need to provide guidance with respect to the interpretation of nominal values (reference flora and fauna), particularly as these apply to the development of policy and regulations, and in application. Should this continue to be advocated by the ICRP, its implications could be significant.

In a general sense, there seems to be a great inter-species variability in both flora and fauna. This being the case, the number of Reference Flora and Fauna needed to appropriately serve as the scientific basis for decision making could be fairly large. Section 5.3 of the report suggests that there may be a need for Primary, Secondary and even Tertiary level Reference Flora and Fauna (to account for inter-species and even geographic variability). This could well result in a very large number of reference organisms, requiring significant long-term research. Should this be the case, the radiological protection community would need guidance from the ICRP with regard to how Reference Flora and Fauna should be interpreted when making policy and recommendations, and in application.

The goals of human and non-human protection, as previously discussed, are not necessarily the same, and as such the proposal to "mirror" Reference Man and Reference Flora/Fauna may not be entirely appropriate. For example, if sustainable development and/or ecosystem "health" are the goals of radiological protection of non-human species, then the Reference Flora and Fauna approach may not completely address protection goals. Other more complex indicators, such as affects on inter-species competition, may be important, and would again not be appropriately addressed by the proposed approach. This would imply that the mirroring of the system of human protection into the system for non-human species protection would not necessarily function smoothly, and should perhaps not be forced over and above the defined protection goals.

In general, though, the need for interpretational guidance implies that any recommendations from the ICRP in this area should be flexible, that is, not focusing too much on specific, quantitative Constraints/Limits/Criteria. If local, regional and/or national solutions are necessary to model ecosystems, then

guidelines, rather than more rigid or quantitative approaches, would certainly be necessary.

Flexibility will also be needed should only high-level, generic Reference Flora and Fauna be adequate for policy making, regulation and application. Here, the use of general models would require guidance for the interpretation of specific situations, and the subsequent application of this nominal approach. For this approach to be viable, the starting point for such guidance, as well as the guidance itself, must be inherently flexible. In this context, it should be recalled that the assessment of ecological effects is initially based on specific screening measurements, but that species-level stochastic effect assessment must then be supported by much broader studies.

Section 5.3 also suggests that specific knowledge, such as of a particular organism in a particular ecosystem, should be used when it is available. Secondary and tertiary data sets are mentioned, as well as relationships of Reference Flora and Fauna to specific ecosystems and situations. The use of such an "Expert Approach", that is, the appropriate use of scientific data, when it is available, in place of or in addition to generic data, has been previously discussed by the NEA in the context of human protection (Developments in Radiation Health Science and their Impact on Radiation Protection, NEA 1998). The previously mentioned parallelism between the protection of humans and non-human species could push trends towards an increasing reliance on the "Expert Approach" for the protection of humans, particularly of the public. Such a tendency might push the ICRP to greater use of secondary and tertiary references (children, males, females, etc.), and result in differences in protection recommendations for such specific groups. This could apply to low-dose situations, where specific studies might thus be necessary, or to high-dose situations (intervention) where specific levels for children (thyroid for example) might be necessary. Such approaches would have broad implications on current approaches to regulation.

Level of reference flora and fauna

In addition to the above discussion of the implications of the selection of reference flora and fauna, paragraphs 112 and 113 suggest that it would be appropriate to select these organisms at the Family or Order level taxonomically.[1] Should this be the case, it would imply that such generic

1. The taxonomic declination, from broader to more specific, is: Kingdom, Phylum, Class, Order, Family, Genus, Species.

organisms could be used to interpret the relative "health" of the ecosystem being studied. Guidance would be necessary to assist policy makers, regulators and practitioners in interpreting how these generic organisms could be appropriately used as surrogates for actual organisms, either in actual (Expert Approach) or generic ecosystems.

The suggestion of this type of hierarchical approach could imply that, at lower levels, the Reference flora and fauna could be more thought of as "indicator species". Such a concept implies the selection of a representative "most sensitive" species as a sentinel of possible ecological harm. The ICRP will, in such a case, need to provide a much more detailed description of this approach, and guidance as to the aspects to consider when identifying the qualities of such indicator species.

Bands of derived consideration levels

One of the more specific aspects of the document presents a table describing possible "Derived Consideration Levels" that could be used as one of the bases for making decisions. As with the new ICRP proposal for the protection of humans, a scale based on factors of 10 above and below natural background levels is proposed as a relative scale of "likely effects" and "aspects of concern". While the use of such a scale is seen as useful, as for the protection of humans, there seems to be a sort of "disconnect" between these "benchmarks" and any "observable harm" to individuals, groups or ecosystems. The implication of this is that the ICRP, should it continue to recommend this approach, would need to provide guidance on the interpretation and use of these levels, and particularly in relating them to the scientific aspects of decision making.

A further support that the ICRP could use in this context could be taken from the concepts used for protection against chemical effects. Here, an observed level of harm is identified, and a margin of safety is then applied to define action levels or limits. It should be remembered, however, that there is much scientific uncertainty between the measurement of activity concentrations and the assessment of ecosystem harm. The understanding of this uncertainty is an important scientific aspect to be taken into account when making the social decision regarding acceptable goals for protection. This implies that a clear presentation of uncertainties is essential, as is the clear separation of the scientific and social aspects of protection goals.

The use of a scale of Derived Consideration Levels implies that, at some level of assessed impact to Reference Flora and Fauna, actions will be

considered, presumably that will reduce these impacts. It would be very helpful, to regulators and to practitioners, if the ICRP would provide some examples of what type of actions could be taken to reduce exposures in various situations.

Finally, in terms of any specific numerical criteria that may be developed based on these bands of consideration, guidance will be needed on how the choices of numerical indicators can be made if they are not in line with harmonised values, for example, for case-specific national and local situations. This guidance should focus on scientific aspects:

- Components of the environment, and other aspects to be considered.
- Framework for the numbers developed.
- Approaches to "Optimisation", and/or "ALARA/BAT".

From the viewpoint of operators, in order to implement new recommendations efficiently, precise descriptions and models will be needed in order to appropriately use reference levels for activity concentrations in effluent releases. A graded approach, including concepts such as screening levels and actions levels below regulatory criteria would mirror current approaches to human protection. This implies that some level of international and national agreement on the details of these descriptions and models will have to be reached. Easy to use tools will have to be developed.

Assessment and management

Section 6 of the draft document makes the distinction between assessment and management. Some discussion of what is meant by these distinctions is provided, and seems to be similar to the distinctions made in the recent NEA document, "The Way Forward in Radiological Protection". Further discussion, or reference to other documents, will be necessary for the full understanding of how the ICRP interprets assessment and management, and how these concepts should be applied.

A key aspect of this approach is the addressing of uncertainties. Both assessment and management require the use of assumptions, biological models, environmental transport models, dose-effect models, etc. All of these assumptions and models include uncertainties, implying that the end result of such models also has a given level of uncertainty. At this point there is still very little knowledge, relatively speaking, of various ecosystems, implying that some margins of conservatism will be used. There will certainly also be uncertainties associated with the use of reference flora and fauna. Although the ICRP has, in

the past, provided some guidance as to how uncertainties should be addressed in regulation and practice, further guidance is certainly necessary. This should begin with general guidance with respect to the overall approach to uncertainty, and continue with more specific guidance as to how such uncertainties should be understood in practice (policy, regulation, application and demonstration of compliance). The need for and use of margins of safety, in regulation and practice, should be part of this discussion.

Transitional provisions for application to existing situations

As with any new recommendation, there will be a need to consider whether the new recommendation should be applied to existing situations, and if so, how. Obviously this situation will arise with new recommendations for the protection of non-human species, implying that the ICRP should provide guidance as to how this could be applied in policy, regulation and practice, and through the transition period from the old recommendations to the new.

Optimisation

There is little or no discussion of how optimisation would be applied to the radiological protection of non-human species. As discussed in the NEA publication, "The Way Forward in Radiological Protection", it is suggested that optimisation has scientific and social components when applied to the protection of humans. Again invoking parallelism, this will certainly be the case for the protection of non-human species. As such, an extensive discussion of optimisation will be necessary, particularly with respect to the regulatory and practical application of such things as Derived Consideration Levels.

Looking at this in more detail, adding an explicit recommendation on the protection of non-human species implies that there will be the need to optimise the radiological protection of human and non-human species simultaneously. Given that risk transfer assessments between groups of humans are very difficult, and that the technical bases of protection objectives may not be the same, adding the complex aspect of ecosystems and non-human species to the optimisation process will certainly increase the level of difficulty in identifying an achievable goal.

There are a number of aspects that the ICRP will need to consider when developing guidance in this area. In particular, there will be a need to discuss appropriately "balancing" risks to human and non-human species when making radiological protection choices. The positive and negative effects of "cleanup"

activities on both humans and ecosystems, for example, will need to be considered. ICRP guidance should address this issue at the policy, regulation and application levels. Although the focus of this guidance should be on the scientific elements to consider when making optimisation choices, some discussion of the social importance of these weighting of various elements will also be useful, as would reference to other documents providing more socially oriented guidance.

Particularly in this area, case study examples, and some sort of "road testing" of proposed approaches prior to finalisation, would be of great use.

Costs

When discussing optimisation, an important factor is cost. Cost considerations have not been mentioned in the draft framework document, but their use as a part of the decision-making process implies that there will have to be ICRP guidance provided as to how costs should be considered in the radiological protection of non-human species. Costs will have a close tie to the optimisation process, as policy makers and regulators attempt to appropriately allocate resources within the bound of socially acceptable objectives and goals. In performing optimisation assessments, all costs (direct and indirect, regulatory/public and private, etc.) should be included. It should also be noted that the weighting of radiological and other health hazards in the optimisation process may vary from country to country based on local assessment of needs. This implies that the ICRP recommendation should be suitably flexible so as not to constrain national approaches.

An important infrastructural element that has a strong bearing on costs is that of qualified personnel. Many approaches to acquire or consolidate the necessary personnel expertise are possible, and specific national solutions will depend upon how protection mandates are divided among competent national agencies. At the current time, however, many radiological regulatory organisations may not include sufficient expertise in the area of radio-ecology and environmental protection. Although this expertise may exist in other regulatory organisations (environmental protection ministries for example) the development of generic and specific Reference Flora and Fauna implies the need for other competencies, either within the radiological regulatory organisation, or through collaboration with other competent authorities. The infrastructure to educate and employ these experts will most likely need to be further developed. Industry will also have need for the same types of expertise, thus further increasing the demands on the educational and research infrastructure.

The cost of change, from current approaches as mentioned in Chapter 2, should also be considered.

Time scale

For the appropriate management of radioactive waste, it is necessary to consider very long time scales. Clearly this implies that guidance will be necessary for the protection of non-human species over time. Paragraph 49 of the document mentions that, "this emphasis on time is essential for sustainable development", but the document presents no other discussion that would be of value when developing waste management policy, regulation or application based on the protection of non-human species. It will be very important for the ICRP to provide a System that is applicable to the management of radioactive waste, as well as guidance for the application of the System. In this area, the BIOMASS programme has provided some scientific basis for developing policy in this area, and should be considered.

It should also be noted that no mention is made of potential exposures (either in this recommendation or in the general recommendation), which has been a tool used in assessing waste management options. The ICRP will need to provide guidance with respect to the tools that will be needed by regulators and practitioners to take very long time scales into account, and appropriately weight their decisions.

Geographic scale

Many mechanisms can result in the far-reaching dispersal of radioactive materials in the environment: gaseous emissions, liquid emissions, accidents, etc. At the same time, installations that create and/or use radioactive materials exist within an environment. These facts imply that the ICRP will need to provide guidance for the assessment of environmental impacts at the facility (e.g., the effects of radioactive materials on the on-site biota or on biota passing through the site - birds), and the impacts of radioactive materials released from the site (gaseous and liquid effluents, groundwater transport, etc.). Particularly with regard to off-site transport, some guidance with regard to "how far" should be provided. The ICRP could also discuss whether its recommendations will be harmonised to the extent to provide a "universal minimum level of protection". The use of Environmental Impact Assessments, which are generally required for such installations for other regulatory reasons, could be suggested as a way to address at least some of these questions.

Harmonisation

The general nature of the proposed framework, and the ICRP's aim to apply the framework in a generic fashion, implies that some level of harmonisation will be needed. There are several levels of harmonisation that will need to be further discussed.

In relation with the protection of humans, as was previously discussed, there will be a need to harmonise, in some fashion, protection goals to establish, for example, balanced levels of protection.

In relation to the protection of non-human species, the generic application of the framework implies that some "upper levels" could be established to define a common level of protection around the world. On a more detailed level, the need to harmonise upper-level reference organisms, and specific recommendations will have to be considered. The latitude in the interpretation and recommended application of the system will have to be discussed by the ICRP. On the geographic level, it will be necessary to provide guidance on the need to harmonise at the international, regional, national and local levels. This guidance will need to take into account the previous discussions of flexibility. Guidance will also be necessary for the development of specific approaches that may not be in line with an overall harmonised approach, particularly for numerical guidance.

From the practical level of regulation development and application, harmonisation implies that guidance will be necessary. This will include the general aspects discussed in the previous section, but more specifically must include the use of "derived consideration levels", "dose limits", "dose constraints", or whatever regulatory indicator is recommended by the ICRP.

Operator and compliance issues

Any new recommendation on the protection of non-human species will have implications on regulators as discussed above but also on operators of nuclear installations, workers in the nuclear industry (the workforce), the economy, locally and regionally, and on research and development. Among these stakeholders, the operators of nuclear installations will certainly be the most directly confronted with any new recommendation regarding the protection of non-human species.

The new recommendations on the protection of non-human species have to be clearly presented and transparently developed to help to assure their appropriate interpretation and use by all stakeholders.

As a result of any new recommendation, nuclear facility operators will need to review and possibly update their detailed environmental impact assessments. Depending on these reviews, the environmental monitoring programme may have to be updated. Such assessments could also lead to a decrease in authorised release levels as a result of the increased breadth of impact assessments. Both of these would have significant implications for operators.

To most efficiently frame any issues that might arise from new environmental impact assessments, regulators and operators will need to identify the most highly affected species, human or non-human, for each given situations. This will establish the boundaries for operational reference levels for activity concentrations in effluent releases. Guidance for making these judgements will need to be developed.

In this context, it should be noted that compliance with regulatory requirements must be manageable for operators, using simple and inexpensive tools. A regulatory framework based on reference flora and fauna, and on activity concentration values may facilitate the demonstration of compliance. Should protection objectives focus on ecosystem health and sustainability, operators would need clear tools and models to link their compliance objectives to these broader objectives.

In order to perform this assessment, measurement and compliance work, trained experts are needed for the development and implementation of new programmes. Many nuclear installations may not currently have sufficient numbers of appropriately qualified staff in this area. Training will be necessary to allow the workforce to deal with the new requirements. The introduction of complex models to assess the environmental impact might put additional workload on the staff and might require additional educational qualifications.

If these recommendations result in the reduction of effluent releases from a nuclear installation, this could have a significant influence on the amount of radioactive waste retained. In such a case, workers involved in the management of these wastes would most likely receive higher exposures.

A broadly flexible approach in protecting non-human species as has been proposed may result in different local requirements in different countries or regions.

Research needs

There is a lack of data regarding the impact of ionising radiation on most non-human species, which will require specific and detailed research. This lack of knowledge may be even more pronounced for tropical environments that are not included in the studies carried out by the FASSET programme.

This lack of knowledge implies that there is a need for further research in this area. In addition, study of existing contaminated sites may be needed. To accomplish this at the level necessary to support the policy and regulation that will be based on the broad ICRP framework, a co-ordinated global effort, including benchmarks and milestones, would be the most effective approach. Unfortunately, few laboratories capable of carrying out this currently exist, again implying that a global co-operation will be essential to the success of these research efforts. This will require governmental and private funding organisations to prioritise their resource allocations.

4. CONCLUSIONS

The NEA CRPPH continues to be interested in helping to assure that the internationally accepted system of radiological protection is fully and clearly understood, and remains at the service of society through radiological protection policy makers, regulators and practitioners at the national and international levels. As such, the efforts that are currently being made by the ICRP to actively collect views, concepts and ideas for improving the content and presentation of the current system are extremely well appreciated.

The effort that the CRPPH has undertaken has, it is hoped, contributed to this ICRP process, and will result in the final draft recommendations being increasingly representative of good radiological protection practice and understanding. In addition, however, the CRPPH analysis exercise has fostered much more active participation of the members of the CRPPH in the ICRP renewal process, and has helped the CRPPH members to hone their own personal and national concepts in radiological protection as it continues to evolve. The process will also, it is hoped, result in the development of new ICRP recommendations that, even at the final draft stage, already enjoy a broad base of understanding and support. Such understanding and support should greatly facilitate any revision and/or updating of national and international regulations, standards and guides that will ultimately result from the issuance of new ICRP recommendations.

The CRPPH appreciates the openness of and collaboration with the ICRP to advance radiation protection for the benefit of society. This report raises a number of issues and makes a number of suggestions to enhance the understanding and transparency of the ICRP recommendations that will result from the framework documents what have been reviewed. The CRPPH looks forward to continuing its relationship with the ICRP to address and resolve issues, and to create a new set of ICRP recommendations having strong scientific foundations and broad stakeholder acceptance that will result in accelerated and efficient implementation of the final ICRP recommendations.

Annex 1

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Annex 2

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