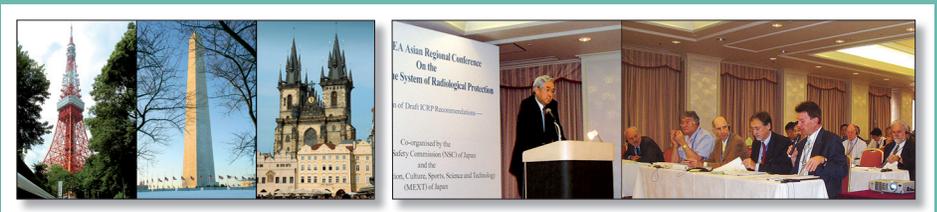


A Stakeholder Dialogue on the Implications of the ICRP Recommendations

Summary of the Three
NEA/ICRP Conferences



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on the Implications of
the ICRP Recommendations**

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The Third NEA Asian Regional Conference on the Evolution
of the System of Radiological Protection
Tokyo, Japan, 5-6 July 2006

The NEA North American Regional Conference
on the Evolution of the System of Radiological Protection
Washington, DC, USA, 28-29 August 2006

The Third NEA/ICRP Forum on the Evolution
of the System of Radiological Protection
Prague, Czech Republic, 24-25 October 2006

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FOREWORD

The Committee on Radiation Protection and Public Health (CRPPH) of the OECD Nuclear Energy Agency (NEA) organised three conferences in 2006 dedicated to discussions on the new draft recommendations of the International Commission on Radiological Protection (ICRP) issued in June 2006. These conferences were held in Asia (Tokyo, Japan, 5-6 July), in North America (Washington, DC, USA, 28-29 August) and in Europe (Prague, Czech Republic, 24-25 October). The main scope of these conferences was to evaluate and to discuss the draft ICRP recommendations with the stakeholders of each region.

The objectives of each conference were:

- to discuss how the new ICRP recommendations could best serve the needs of national and international radiological protection policy makers, regulators, operators, radiation workers and the general public in respect to each regional community;
- to continue the open and broad dialogue among stakeholders in order to achieve consensus and the highest possible level of understanding of the issues included in the draft;
- to contribute in a positive and constructive manner to the evolution of the system of radiological protection.

Based on the discussions and proposed modifications during these conferences, this summary report identifies the key issues that were raised.

Acknowledgements

The CRPPH is grateful to the ICRP, and particularly to its Chair, Dr. Lars-Erik Holm, for having welcomed open discussions during these conferences and for having accepted and implemented the comments from stakeholders into the draft recommendations.

The CRPPH and the ICRP would also like to thank Professor Henri Métivier for having written the reports of each conference which were used to prepare this summary report.

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EXECUTIVE SUMMARY

Introduction

Since its inception in 1957, the NEA Committee on Radiation Protection and Public Health (CRPPH) has been involved in the assessment and implementation of the recommendations of the International Commission on Radiological Protection (ICRP). The current initiative of the ICRP to develop its new general recommendations, to replace Publication 60 approved in 1990, unsurprisingly incited the active involvement of the CRPPH. This report summarises the key results of the Committee's most recent dialogues with the ICRP.

Beginning in 1999 with the open dialogue on new approaches proposed by the ICRP Chair, the CRPPH launched a broad programme of work addressing the evolution of the system of radiological protection. Over the subsequent years of ongoing dialogue with the ICRP, this work included seven international conferences to discuss the evolution of the system, two direct discussions between the CRPPH membership and the ICRP Chair, a series of expert groups and meetings resulting in 13 relevant NEA publications, and three detailed and constructive assessments of various draft ICRP recommendations. This work has mobilised over 100 experts from 17 countries, coming from 25 national governmental organisations, national nuclear industries and international organisations.

The latest manifestation of this "partnership in dialogue" between the NEA and the ICRP has been three conferences (of the seven mentioned above) to discuss the June 2006 ICRP draft recommendations, referred to as RP06. Two regional meetings (Tokyo, 5-6 July 2006; Washington DC, 28-29 August 2006), and an international forum (Prague, 24-25 October 2006) were held to assess in detail the draft ICRP recommendations and to suggest changes and additions to the ICRP to improve the clarity and applicability of the recommendations. The Prague meeting included the presentation of a "line-by-line" assessment of the RPO6 text made by an NEA Expert Group, with detailed and supported suggestions for modification.

This report is the summary of the results of work performed during 2006. It includes a presentation of the key points of the RP06 draft recommendations, a summary of the suggestions made during the three conferences, and an assessment of the significant evolution that has been seen in the ICRP presentation of its draft recommendations over the course of the three meetings.

Key points from participants

The overall tone of the meetings, and stakeholder comments, were positive, particularly regarding the open nature of the ICRP process to collect and act on comments. This process of dialogue with stakeholders was seen as a significant improvement over the previous, more closed-circle preparation of ICRP recommendations, and the ICRP was strongly encouraged to continue along these lines for the preparation of all future recommendations.

Particularly regarding the RP06 text, it was seen as a significant advancement over earlier draft recommendations, notably from 2004, but was still perceived as needing a fair amount of polishing in terms of its overall organisation, and the clarity and consistency of its description of key elements. Among the areas most discussed over the course of the three meetings were the concept of dose constraints, the LNT model and low-dose effects, the use of collective dose, the three principles of RP, stakeholder involvement and the increased focus on optimisation, exclusion and exemption, exposure to natural radiation, medical exposure, radiological protection of the environment, and the cost of implementing the new recommendations.

Many concrete suggestions to improve the recommendations were made, in the form of proposals for specific textual changes, the identification of internally inconsistent or contradictory paragraphs, and questions regarding apparent policy choices by the ICRP. The most significant messages passed to the ICRP, however, were somewhat more limited in scope, and had to do broadly with clarity of reasoning and presentation.

The concept of dose constraints raised the most concern during the three meetings. It was suggested that philosophically, a single approach to radiological protection in any circumstances, focused on the use of optimisation and dose constraints for all exposure situations (e.g. planned, emergency and existing), was an improvement over the previous, divided approaches to practices and interventions. However, the RP06 text is not consistent or coherent on dose constraints, and dose constraints are not clearly defined. The draft presents several different “flavours” of dose constraints, some being closer to action levels (the old intervention concept) than to tools for optimisation (the apparent new concept). It presents dose constraints as being uniquely

prospective in nature, when participants saw dose constraints as useful tools for planning, but also as benchmarks for the retrospective assessment of the success of radiation protection actions. It presents dose constraints in many different places but with an inadequate logical structure (e.g. they could be presented initially in a broad philosophical description, followed by application details for each exposure situation). These issues made the text hard to follow and internally inconsistent.

It was also noted that dose constraints are already widely used in the nuclear industry, if under various other names, where they are routinely fixed by operators. There was great concern expressed at the possibility of constraints for occupational exposure being fixed by the ICRP, and transposed into national regulations, leading to de facto new worker dose “limits”. This also raised the point that, for the most part, optimisation and ALARA have resulted in very good protection in the nuclear industry, and that there is thus no reason to “fix” what is not broken by changing ICRP recommendations at this point. Further, such a change would most likely be expensive, both for regulatory authorities and operators, while not providing any additional safety.

Participants also expressed their opinion with regard to exclusion and exemption as presented in RP06. It was suggested that these topics are very important to regulators and operators alike, and that guidance from the ICRP, in terms of the type of criteria that should be considered when making decisions, was very welcome. However, setting numerical values for exclusion and exemption was seen more as more of a job for national regulatory authorities, and international organisations in terms of broad standards, than for the ICRP. This was tied to participants’ views on optimisation in general. There was general agreement with the RP06 text’s increased focus on optimisation as the central tool for risk management within the RP system. Optimising protection under the prevailing circumstances, with the involvement of stakeholders, better reflects what is actually being done than did Publication 60. Participants felt that this could be best served by “flexibility” from the ICRP, particularly in not overly focusing on specific numerical guidance intended to be equally relevant in all situations. Management of risks using optimisation, under the prevailing circumstances and with stakeholder involvement, was broadly supported, to the point that stakeholder involvement was suggested as the fourth principle of radiological protection.

Discussions of optimisation also focused on the new proposal to approach all exposure situations in the same fashion, broadly using the success of optimisation and dose constraints in planned situations also for emergency and existing situations. While suggesting that the recommendations needed much more clarity and consistency in this area, and emphasising the need not to

overly impact the current, well-functioning process in the nuclear industry, participants felt that this new general approach was a great improvement over interventions and practices. However, further detailed discussion of application, particularly in the area of emergencies, was seen as necessary.

The more scientific aspects of the ICRP recommendations were also discussed, in particular the use of the linear non-threshold (LNT) hypothesis and collective dose. In the view of most participants, LNT remains the most appropriate tool for exposure management, although it should not be used in place of well-founded scientific knowledge in specific situations. Similarly, collective dose is seen as an effective exposure management tool (i.e. optimisation, comparison of radiological technologies and protection procedures), but there was general agreement that collective dose should not be misused (i.e. for prediction of cancer rates in large populations exposed to very small doses, for epidemiological risk assessments, for risk projection). The ICRP was encouraged to clearly state the fields of applications of this concept. However, participants acknowledged that this presents a problem of some ambiguity in the use and validity of the LNT hypothesis, and that discussion of these issues should continue.

Another general comment made at all three fora concerned the terminology used by the ICRP, particularly new terms. It was strongly suggested that the ICRP should carefully consider the wording of newly introduced terminology (particularly dose constraint) to assure clarity and avoid misinterpreted translations into other languages. It has also been suggested to use a more “sentence definition” style than a “single word term”.

Finally, participants expressed their views with regard to exposure to natural radiation and the radiological protection of the environment. The increased emphasis on natural exposures, by including them, in general, in the category of existing situations, was appreciated. Again though, there was a demand for a clear explanation of how dose constraints would be used. Concerning the radiological protection of the environment, this was seen as an important subject meriting mention in the new recommendations but not yet mature enough to include specific recommendations by the ICRP.

The evolution of ICRP presentations

While the RP06 draft recommendations did not themselves change during the course of the three conferences, the presentation of the key issues by the ICRP Chair evolved considerably. Over the course of the three meetings, the ICRP Chair increasingly clarified those aspects that will not change, as well as the novelties of the new recommendations. This continuity was manifested in

the maintenance of previous dose limits, of the three key principles (Justification, Optimisation, Limitation), and of the validity of other existing numerical guidance unless specifically noted. Repeatedly it was noted that national regulations and international standards in compliance with Publication 60 would not require significant change.

In more direct answer to the various comments made by participants, the ICRP Chair noted several significant modifications to the RP06 approach that he had taken on board as a result of meeting suggestions. The dialogue organised by the NEA was seen by the ICRP as having been very fruitful, and would thus be a process likely to continue for future ICRP publications. In fact, in view of the significant changes expected in RP06 as a result of the broad consultation process, the NEA suggested that a last round of consultation would be valuable and appropriate, and the ICRP Chair agreed that this was a good idea and would likely occur.

The ICRP Chair suggested that the NEA meetings had assisted in clarifying various aspects of dose constraints. These optimisation tools are based on projected dose or actual residual dose, and represent the level of dose above which, for any exposure situation, it is planned not to go, and below which one strives to reduce all actual exposures. Dose constraints were seen as useful prospective planning tools, as well as retrospective assessment benchmarks, although in both cases it was stressed that dose constraints are intended to be guidance values for optimisation, not regulatory values with legal significance. In this context, it was also stressed that competent organisations, such as those responsible for the operation of nuclear installations, should be the ones to set numerical values of dose constraints for workers, and report these to regulatory authorities as part of their optimisation programmes. Other organisations, with less radiation protection competence, could well ask the assistance of regulatory authorities in fixing such values. Regulatory authorities should fix dose constraints for public exposures.

Importantly, it was suggested in the Prague Forum that the term “dose constraint” is in fact hard to translate and somewhat difficult to understand. While the ICRP would most likely choose to keep this term for planned situations, particularly as it was initially defined in Publication 60 for this purpose, the Commission would most likely change to something like “reference level” for emergency and existing situations. In spite of this change in terms, however, the concept of using dose constraints or reference levels would be the same for all situations.

To further clarify this, as well as to improve the overall readability of the text, the ICRP Chair suggested that the RP06 table of contents would be

significantly restructured to more clearly present an overview of the recommended system of radiological protection (including a clear presentation of justification, optimisation and dose constraints/reference levels, and limitation), and then more specific sections on planned, emergency and existing exposures situations. In particular as a result of presentations during the Prague Forum, where a more detailed view was for the first time presented of how reference levels would be applied in emergency situations, the ICRP Chair suggested that the detailed aspect of this would be presented not in the next draft general recommendations, but in another document currently in preparation by a Task Group of ICRP Committee 4. Another Committee 4 Task Group is also working on detailed aspect of applying the new system of radiological protection to existing situations.

Implications for the CRPPH

Based on these discussions, it is clear that, as with previous ICRP recommendations, there will still be the need for some interpretation for application. The CRPPH has successfully contributed to this process in the past, and several areas in these draft recommendations have emerged where the CRPPH could again contribute. This will be primarily focusing on implementation aspects. These areas include the use and application of dose constraints, the broad concept of regulatory authorisation, particularly in terms of exclusion and exemption, collective dose, potential exposure, emergencies, the consideration of science in decision making, in parallel with a discussion of the ties between scientific research and judgements made in radiation protection policy and regulation.

INTRODUCTION

In recent years, the ICRP launched an open process to broaden, elaborate, and consolidate the current set of radiological protection recommendations. The ICRP is presenting new draft of recommendations to the broad radiological protection community, and is seeking a dialogue with all interested parties and stakeholders. The objective of this open process is to issue the new generation of ICRP recommendations that are broadly understood and accepted, and what can consequently be effectively and efficiently implemented. The publication of these new recommendations is foreseen in 2007 time frame.

The preliminary focus of this ICRP development was on new general recommendations which should replace ICRP Publication 60. As part of this process, the ICRP identified a need to clarify and update its views on the radiological protection of non-human species. Both of these areas are of significant interest to the member countries of the NEA.

The CRPPH, as the international committee formed of nationally nominated radiation protection authorities and technical experts, has for most of its history actively followed the work of the ICRP. This interest continued throughout the development of new recommendations.

Shortly after the ICRP introduced its new ideas,¹ the CRPPH began work on task how the system of radiological protection could be made more responsive to decision makers, regulators, practitioners and the public. Through a series of expert groups, topical session discussions with the chair of the ICRP, and broad stakeholder dialogue fora, the CRPPH developed a comprehensive series of documents discussing relevant issues, and proposing possible directions. Since the appearance of the new ICRP ideas in 1999, the CRPPH has developed and published 13 reports specifically dealing with development of a new system, all of which are available from the NEA web site (www.nea.fr).

In order for any new radiation protection recommendations to be successful, they must be welcomed and accepted by policy makers, regulators,

1. Roger Clarke, "Control of low-level radiation exposure: time for a change?" 1999 *J.Radiol.Prot.* 19, 107-115.

industry, stakeholders, scientists and radiation protection professionals. They have to enhance worker safety and health, protect the environment and deliver an understandable, easy to implement and cost effective system. They need to maintain stability in the policy and system of radiological protection to avoid the waste of limited resources. Since the proposed change in radiation risk is small, and the risk is in fact decreasing, it could be understood that the current system already protects both workers and public properly.

The most recent draft, posted on the internet for public comment in June 2006 represents a considerable evolution and improvement from the earlier draft. It is apparent that the ICRP has addressed many, if not all, of the comments provided by the worldwide stakeholders.

Through the three conferences organised by the NEA, the Third Asian workshop held in Tokyo in July 2006, the North American workshop in Washington in August 2006, and the third NEA/ICRP Forum in Prague, the ICRP agreed to expand, revise and consolidate the current set of radiological protection recommendations through an open dialogue with stakeholders in order to better meet the health and safety needs of national radiological protection programmes. Regulators, as key users of ICRP recommendations, greatly appreciated the opportunity to express their views during these conferences.

The key objectives of these conferences were:

- To evaluate and to discuss the draft of ICRP recommendations.
- To discuss how the new ICRP recommendations can serve the needs of national and international protection policy makers, regulators, operators, radiation workers and the general public in respect to each regional community.
- To continue open and broad dialogue among stakeholders in order to achieve broad consensus and the highest possible level of understanding of the issues included in the draft.
- To contribute in a positive and constructive manner to the evolution of the effective system of radiological protection.

Key presentations in all three conferences focused on key aspects of the new ICRP recommendations, and on views and reactions on the draft recommendations from various stakeholders. To complement these presentations, the panel discussions (in Washington) and breakout sessions (in Prague) were held to discuss key points. These discussions were primarily focused on framing the key issues and their implications on various stakeholders since reaching consensus among stakeholders was seen essential for the development of the new ICRP recommendations.

During each forum, the chairman of the ICRP presented the last version of the draft recommendations updated after receiving a considerable number of comments during the preceding web consultations and conferences. Each new document, significantly advanced from each previous version, incorporated substantial number of comments from reviewers throughout the world. The final ICRP presentation was seen as more comprehensive, and seems to be more accepted by stakeholders. The only exception is the area of dose constraints where some uncertainty regarding the intent and use still exists.

The draft recommendations are based on the LNT assumption, while recognising new scientific data may challenge this hypothesis in the future. Relatively few modifications appeared in the radiation and tissue weighting factors, with the exception of tissue factor for gonads, which is affected by a change in the estimation of genetic risk and for breast.

Based on the discussions that took place during this forum, this summary report identifies the key issues that were raised. The CRPPH is grateful to the ICRP for the open discussions held during these fora, and for acceptance of the comments made by various stakeholders, including regulators, industrials and professionals.

THE NEW ICRP GENERAL RECOMMENDATIONS

Digest of Changes

The first ICRP recommendations were issued in 1928 and were aimed at the protection of medical staff against occupational exposure. General recommendations have subsequently appeared in 1959 (Publication 1), 1964 (Publication 6), 1966 (Publication 9), 1977 (Publication 26) and 1991 (Publication 60). Over the evolution of these recommendations, the dose limits have been reduced from 1 000 mSv in 1928, to 500 mSv in 1934, (for medicine), then to 150 mSv in 1950, to 50 mSv and 5 mSv in 1964 (for worker and public respectively) and finally to 20 mSv and 1 mSv in 1991 (for workers and public, respectively).

The ICRP Publications 26 and 60 focused on preventing deterministic effects and minimised stochastic effects. The dose limits in the 1977 and 1991 recommendations were mainly based on cost benefit analysis and judgements on acceptable risk.

Since 1991, nearly 30 different numerical dose restrictions appeared in a number of ICRP publications leading to some confusion among users and stakeholders. The ICRP prepared new draft recommendations to simplify its advice on dose restrictions and to consolidate general principles described in ICRP Publication 60 (1991).

It is noted that most ICRP recommendations will remain valid because they are functioning and are clearly understood. Some others may change or be added because they require additional explanation or more guidance, they are missing, or because their scientific background has evolved.

Since 1991, radiation risk estimates have not changed substantially. While new results of scientific research are challenging the general concepts of the radiological protection system, they are not sufficiently consolidated to indicate a need for drastic change of the system. The system is considered successful, and since there is no urgent need for imminent change, the ICRP wishes to broadly keep current wording in the proposed recommendations as long as it is

consistent with new scientific information. This was among main requirements expressed during the former consultations in Asia (Tokyo, 2004), Europe (Lanzarote, 2004), and during the IRPA 11 congress in Madrid (2004). This approach was also agreed and reinforced in all three conferences in 2006. Thus, in the area of radiation risk estimate there is more continuity than change.

During last decades the ICRP has always kept close contact with the United Nations Scientific Committee for the Effects of Atomic Radiation (UNSCEAR) as a main scientific source, as well as with the international BSS as a key regulatory benchmark before standards are adopted in national regulations.

The new recommendations maintain the fundamental principles of radiological protection and clarify how they apply to sources and individuals. The new recommendations update weighing factors, radiation detriment and maintain dose limits but expands the concept of dose constraints in source-related protection to all exposure situations.

One of the main changes in the draft recommendations is shift from the use of “practices and interventions” as situation specific approach. The new recommendations note that there was no fundamental difference in applying the system to practices and interventions, and now prefer to use a single approach for all situations and sources:

- There is a level of dose above which the regulator will demand an action.
- Optimisation of protection is always applied to reduce exposure.

These concepts are applied to three types of exposure situations identified in the new recommendations:

- Planned situations – everyday situations involving a planned operation.
- Existing situations – situations that already exist and a decision on control has to be taken, including natural background radiation and residual radiations from past practices.
- Emergency situations – unexpected situations requiring urgent action that occur during the operation of a practice.

The draft recommendations continue to cover exposures to both natural and artificial sources that are controllable, and apply to the control of sources or pathways leading to individual doses.

In support of the draft recommendations, the ICRP published foundation documents resulting from the discussions of the different Committees of the ICRP. These source documents include:

- Biological and epidemiological information on health risks attributable to ionising radiation (C1).
- Basis for dosimetric quantities used in radiation protection (C2).
- Low-dose extrapolation of radiation-related cancer risk (C1).
- Radiation protection in medicine (C3).
- Optimisation of protection (C4).
- Assessing dose to the representative individual (C4).
- The scope of radiation protection regulations: exclusion and exemption (MC).

The quantities for radiological protection remain unchanged but the radiation and tissue-weighting factors used in the calculations of these quantities underwent some revision:

- W_R for protons decreases from a value of 5 to 2.
- W_R for neutrons is a continuous function (instead of step function in ICRP Publication 60) and is approximately halved for low energy (below 10 keV) and for high energy neutrons (above 100 MeV).
- W_T for gonads decreases from 0.2 to 0.08. This difference is mainly due to the change of reference for genetic risk estimate: previously extrapolated to the theoretical equilibrium (many generations), while currently is limited to first 2 generations (based on the Hiroshima and Nagasaki survivors).
- W_T for breast increases from 0.05 to 0.12.
- W_T for bladder, oesophagus, liver and thyroid slightly decrease from 0.5 to 0.4.
- W_T for other organs (brains and salivary gland) are introduced, and the splitting rule for remainders ($W_T = 0.12 - 0.05$ in ICRP Publication 60) is omitted.

The ICRP clearly defines the use of effective dose, E:

- E is calculated by using reference values for reference person or group (it is not based on data from individual person).

- E should be used for planning of prospective situations.
- E should not be used for retrospective dose and risk assessments of exposure of individuals.
- E should not be used for epidemiological studies.

Equivalent dose should be considered as a step in effective dose calculation.

The LNT hypothesis remains fundamental for averaging and summing up of doses, for the concept of effective dose and for the system of dose record keeping. The ICRP maintains that LNT is a good tool for managing risk.

New biological information is challenging the current system but is still not comprehensive enough in order to be applied in radiation protection. At low doses, a simple proportional relationship between dose and risk still remains the best approximation. As for genomic instability, bystander effects and adaptive response, these phenomena do not provide sufficient impetus to cause changes in the Commission's recommended radiation protection strategy. The ICRP considers that LNT remains a pragmatic, realistic and conservative tool for radiological protection.

For non-cancer diseases the ICRP maintains that most of these are observable at high doses, and no sufficient scientific data can confirm any relevance at dose levels considered in radiological protection (below 1 Sv).

Genetic risk estimate is currently based on the UNSCEAR 2001 Report and on the doubling dose (dose required to produce the same amount of additional mutations as those that occur spontaneously in a generation; relative mutation risk per unit dose is the reciprocal of the doubling dose).

The nominal risk coefficients for stochastic effects ($\% \text{ Sv}^{-1}$) decrease from 6.0 to 5.5 for cancer and from 1.3 to 0.2 for heritable effects for the whole exposed population, but the ICRP estimates that this decrease is small and does not justify the change of the values of dose-limits. In fact, the lasting problem of uncertainty remains, and is particularly remarkable for low doses and low dose rates. The criticism raised that ICRP recommendations should be based on the published data and that the latest Life Span Study (LSS) results have not been yet published in peer-reviewed journal. To answer this criticism, the ICRP mentioned that the recent data will be published very soon in the Radiation Research journal. Some criticism was caused by the fact that the studies of Hiroshima and Nagasaki taking into account the new dosimetry methods are not completed.

The ICRP continues to assume that the overall risk coefficient of 0.05 Sv^{-1} is appropriate for purpose of radiological protection.

Overall risk is now based on cancer incidence rather than on mortality.

In spite of the decrease of heritable risk, the ICRP continues strong recommendation of keeping gonadal doses as low as reasonably achievable.

Although LNT remains a sound basis for radiological protection, the ICRP acknowledges that in certain specific situations, other dose-effect relationships are possible including some threshold or threshold-like methods. These are not however seen as universal, and LNT remains the primary tool for the radiation protection purposes.

The three basic principles of radiation protection – Justification, Optimisation and Limitation are maintained and consolidated.

- Justification is source related, and relates to any action that changes the radiation exposure situation, for example by introducing a new radiation source, or by reducing exposure from a particular pathway.
- Optimisation is aimed to achieve the best level of protection from a particular source by justified actions under the prevailing circumstances.
- Limitations are based on assumption that in planned situations, the dose to any individual from all regulated sources should not exceed the dose limits specified by the ICRP.

In the draft of new recommendations the ICRP reinforces the concept of dose constraints, stating that it is the most fundamental level of protection for the most exposed individuals from a single source within a type of exposure situation. Dose constraints apply to any exposure situation (planned, existing and emergency). It is used in conjunction with optimisation of protection along with the ALARA principle. In planned situations, dose constraints are lower than limits and the ICRP assumes that individual dose limits are adequate to ensure reasonable dose equity.

Dose constraints represent a level of ambition for operators in a prospective approach and are not any form of retrospective dose limitation.

Dose constraint in prospective situation could be used to determine which protection option is the most appropriate and the predicted dose distribution is then compared to the pre-selected constraint.

Retrospectively, in emergency or existing situations where an exposure occurred and doses were measured or assessed for identifiable population, the constraint is used as a benchmark against which protection options can be judged. In the case of emergency situation, the dose constraints should be revisited in order to see whether selected values continue to address protection needs. They should represent the level of dose/risk where action is “almost always” warranted.

Constraints should be established at the national or local level by regulators and operators.

Some recent practical examples show that this concept is already implemented in industry (for example the construction of the new European reactor). For potentially contaminated territories, a benchmark for optimisation is needed, partly to assist public in understanding the rationale behind any protection actions.

In the case of irradiation beyond the constraint, the ICRP suggests that this should not necessarily be regarded as a failure of protection, but should lead to re-consideration of the optimization and perhaps of the chosen dose constraint numerical value.

The ICRP states that the numerical criteria recommended in ICRP Publication 60 and thereafter can be regarded as constraints (three defined bands: 0.01-1 mSv, 1-20 mSv, 20-100 mSv). These three bands are explained in the text with examples given. For radon, the constraints are set as values in which an action is “almost always” warranted (600 Bq.m⁻³ for dwellings and 1 500 Bq.m⁻³ for home and work)

In the new recommendations the ICRP clearly defines the collective dose and describes limitations of its use. Collective dose is an instrument for optimisation and for evaluation of radiological technologies and protection procedures. It is not intended as a tool for epidemiologic risk assessment. Calculation of cancer deaths based on collective dose involving trivial exposures to large populations is not justified and should be avoided.

Concerning exclusion and exemption, the ICRP refers to several years of inter-agency dialogue, and does not intend to interfere in these discussions.

The legislators should exclude from particulars legal systems those subjects that cannot be regulated and the regulator should be authorised to define the exemptions from regulations.

Examples of exposure situations that can or should be excluded include cosmic rays at ground level, radionuclides of natural origin in the body, as well other exposure situations that the legislator considers as uncontrollable.

Principles that should govern the process of definition of exemption are:

- The practice must be justified and its sources inherently safe.
- Radiation protection must be optimised.
- Individual risk must be insignificant.

For the protection of the environment, the key question is “How can we demonstrate that the environment is adequately protected?”. This new approach is not driven by concern of existing radiation hazards, but rather aims to fill a conceptual gap. Some of the issues include the fact that the assumptions of ICRP Publications 26 and 60 are not explicitly demonstrated, humans are likely to be the least exposed species, and that not all habitats have a human presence. The ICRP is waiting for the results of Committee 5 (Environment) in order to further develop its recommendations for protection of environment. The draft recommendations currently refer to ICRP publication 91 (2003), which describes a framework for assessing the impact of ionising radiation on non-human species.

Finally, following this latest round of consultations, the ICRP believes that the final adoption of the new recommendations will be completed by the end of March 2007 and published subsequently. However it has been noted that numerous different suggestions and comments have been received during the last web consultation. The ICRP assumes that in the optimal case, these new recommendations could be transformed into the next international BSS revision in 2010 and followed by their implementation in 2015.

COMMENTS AND SUGGESTIONS FROM STAKEHOLDERS AND INTERNATIONAL ORGANISATIONS

(As summarised from three conferences)

This chapter summarises and highlighting the main points of presentations and discussions from all three conferences. The first part represents the comments and view of participants (stakeholders, regulators, scientists, etc.) as they were raised during presentations, discussion and break out sessions. The second part compiles the views, those adopted and those rejected, as these were presented by the ICRP.

Views from the participants

Dose constraints (Tokyo, Washington, Prague fora)

The concept of dose constraints remains the most controversial issue in the draft recommendations, and was discussed in all three fora. Participants raised many specific points:

- It was questioned whether it is necessary to introduce dose constraints into the regulation system for all types of exposure situations, because this could make the system more complicated and confusing.
- This being said, dose constraints were seen as potentially useful tools if they were clearly and consistently explained. In particular
 - Dose constraints in RP06 are not consistently defined, causing significant confusion.
 - The relationship between dose constraints and dose limits, in planned situations, is unclear. It seems that dose constraints would be difficult to implement along with dose limits, in that dose limits are considered as legal boundaries. Dose limits are thus the “fundamental” tool of protection of an individual in planned situations, not dose constraints.
 - The application of dose constraints in all three types of exposure situation (planned, existing and emergency) needs to be explained.

- Constraints are already in use for the control of occupational exposures in nuclear installations. At the very least, this experience should be taken into account by the ICRP when recommending any numerical bands for constraints. Further, however, the RP06 description of dose constraints and the optimisation process match, in fact, what operators are currently doing. Radiation protection measures based on the ALARA concept have been implemented since the end of the seventies. Such optimised radiation protection has resulted in significant decreases in occupational exposures. In fact, the optimisation process would result in doses below any reasonable dose constraints, and therefore if the optimisation process is followed, dose constraints may appear redundant. As such, the ICRP should rather focus on the enforcement of the optimisation principle rather than on dose constraints. Dose limits should remain the clear and only regulatory boundary.
- There is a concern that if an assessment shows that a relevant constraint has been exceeded then this could be regarded as a failure of protection.
- Based on operational experience with ALARA and optimisation, it was clearly expressed that, for nuclear installations and worker protection, the operator is the most competent organisation to fix operational dose constraints. In planned situations the dose constraints should be set by the licensee and reviewed by the regulator. The ICRP should not make such judgements.
- Although dose constraints are presented as source-related criteria, the precise definition of a source can cause confusion. For example, in the nuclear industry there are many “itinerant workers” exposed to several plants, and on a particular site there may be several units.
- The ICRP should clearly explain the rationales behind its proposed numerical values, and promote public education and information on dose constraints. Constraints could be a good opportunity for ICRP or other organisations to promote education of radiation risk. For example 1 mSv/year is the variation of natural background dose in the world and this level of dose could be explained as a marginal increase above the natural background.
- Finally, there is a concern arising from the terminology. Term “constraint” may cause problems when being translated to languages other than English.

Collective dose (Tokyo, Washington, Prague fora)

It is generally appreciated that the ICRP retains the concept of collective dose. It is also appreciated that the limits of this concept are more clearly explained, which will hopefully help to avoid future misuses of the concept, as it happened in the case of prediction of deaths after the Chernobyl accident. The clarification that collective dose is mainly an instrument for optimisation will be welcome.

It is agreed that the use of LNT hypothesis, if extrapolated to calculate collective dose for large groups where population characteristics are poorly defined, is inappropriate and thus cannot be considered as a valid prediction of health effects from very small doses.

The ICRP claims that collective dose is mainly an instrument for optimisation, for comparison of radiological technologies and for protection procedures. Collective dose is not intended as a tool for epidemiological risk assessment and it is therefore inappropriate to use it in risk projection based on epidemiological studies. The computation of cancer deaths or hereditary effects based on collective dose involving trivial exposures to large populations is not reasonable and should be avoided.

The ICRP is encouraged to provide stronger statements to further discourage misuse of this concept, and to provide recommendations on applications where collective dose may be appropriate and important. The ICRP should clarify applications in which it is not appropriate to use collective dose. Without such additional guidance the new recommendations are not likely to have an impact on practical regulation and risk communication.

However, in spite of this consensus on the use of collective dose, participants found an interesting contradiction in the use of the LNT as a fundamental tool for risk management, and the imposition of restrictions on the use of collective dose. The ICRP was encouraged to address this issue.

Types of exposure situations (Tokyo and Prague fora)

The new draft replaces “practice and intervention” with three exposures situations:

- **Planned exposure** – everyday situations involving the planned operation of practices.
- **Existing exposure** – situations that already exist when a decision on control has to be taken, including natural background radiation and residues from past practices.

- **Emergency exposure** – unexpected situations that occur during the operation of a practice requiring urgent action.

In the Prague forum, a stakeholder dialogue on the implications of the ICRP proposals was organised through three presentations by various members of the ICRP Committee 4 followed by breakout sessions. Summary of these ICRP presentations and breakout session's discussions is as follows:

Planned situations

The main points of discussion and the arising conclusions are:

- Dose constraints are already a part of existing optimisation processes.
- The ICRP sets a ceiling on optimisation for the purpose of improving protection and guiding performance.
- Dose constraints for prospective use may also be used to inform decisions.
- Dose constraints should not be considered as a limit and thus the ICRP should not set values for planned exposure situations as there are dose limits.
- Specific doses constraints are based on:
 - Good practice, consistent with dose limits.
 - Generic optimisation.
 - Stakeholder involvement and responsibility.
- The ICRP should consider the wording in order to provide clarity in use of the term “dose constraints” by regulatory authorities (it has been suggested to use “sentence definition” instead of “single word term” since this may lead to misunderstandings when translating to languages other than English).

The further objections are as follows:

- It is difficult to apply the single source concept to outside workers.
- To provide more explanation related gender and age averaging.
- In the case of the “representative individual” both real and hypothetical exposure situations should be considered.

Existing situations

Three distinct types of existing situations were discussed:

- Contaminated territories resulting from a radiological accident, or from residual radioactivity caused by former regulated or unregulated activities.

- Indoor radon in dwellings and workplaces.
- Other natural sources including elevated cosmic and terrestrial exposure, naturally occurring radioactive material (NORM), etc.

The characteristics of the existing situations are:

- There is generally a large distribution of individual exposures.
- Exposures occur where people live.
- Exposures can be difficult to control.
- The level of individual exposure may be influenced by the individual's behaviour.

Key factors for justifying action leading to the reduction of existing exposures include:

- The level of exposure.
- The number of exposed individuals.
- The controllability of exposures without significant disrupting living conditions.

Further factors to be considered include the type of existing exposure situation, past experience in the management of similar situations, the feasibility to control the situation and the intention to return to a "normal situation".

In existing situations, the dose constraints are the prospective level of ambition or the retrospective tool for assessing the effectiveness of protection. It is not mandatory that the constraints must be achieved. The authorities are expected to set dose constraints following consultation process with stakeholders and these constraints should serve for implementation of the optimisation.

The main points of discussion and the arising conclusions are:

- There is general support for the concept of dose constraints in existing situations, for both prospective and retrospective use.
- Doses constraints and the focus on optimisation are seen as important improvements over the previous "practice and intervention" approach.
- The new text should clarify distinctions between the concepts of dose constraints, limits, intervention levels and action levels.
- There was support for using doses constraints as to manage exposures of people living in contaminated territories.
- The value of 1mSv/year should be used as a long-term goal for dose constraints applied in existing situations.

- The importance of stakeholder involvement in determining doses constraints, and for designing and implementing of optimisation is underlined.
- The ICRP should provide clear guidance on dose constraints, but numerical values beyond the three defined dose constraint bands (0.01-1 mSv, 1-20 mSv, 20-100 mSv) should not be specified.
- Guidance on the implications of the concept of dose constraints for regulatory frameworks is required.

Among further proposals there are included:

- Radon should be considered separately as a special situation.²
- NORM exposure situations should be considered as existing situations.
- The guidance on the use of exclusion and exemption should be provided, but no numerical values should be set by the ICRP.

Emergency situations

The objectives of off-site emergency preparedness and response are to provide protection at the individual level by preventing the occurrence of severe deterministic health effects among emergency workers, members of off-site assistance services, and the public. In addition and depending on the specific situation the objective is also to minimise the occurrence of stochastic health effects in workers and the public, and to prepare for the resumption of normal social and economic living conditions.

The key features of dose constraints in emergency situations are:

- Dose constraints are a planning tool defining the dose level above which you plan not to go and above which protective actions are generally warranted.
- Protective actions are always optimised and aim at reducing exposures below the dose constraint.
- The numerical value of constraint will depend on the circumstances of the actual exposure situation.
- Dose constraint should be used as a benchmark for assessment of the effectiveness of protection strategies.

2. ICRP should explain its recommendations in the context of new epidemiological evidence suggesting the observation of statistical significant detriment at 100 Bq/m³. These new results don't change the risk estimates, however, they suggest the need for emphasising optimisation as the key aspect of risk management of radon exposure

It has been concluded that in order to be a stand-alone document the final version of the recommendations should clearly define which numerical values remain valid (e.g. from ICRP Publications 63 and 96) and how these should be interpreted in the context of the new recommendations.

Three principles of protection (Tokyo, Washington, Prague fora)

The new draft is based on, and consistent with the former recommendations. New scientific findings have been introduced and the three principles of protection remain unchanged from ICRP Publication 60 since they are of key importance for regulatory authorities.

- **Justification** is source related, and relates to any action that changes the radiation exposure situation by introducing new radiation source or by reducing exposure. Such actions should do more good than harm, and should yield an individual or societal benefit that is higher than detriment they cause. Justification occurs primarily at a political level, but can be delegated. Recommendations apply to practices once they are declared as justified. In the case of justification of medical radiation this requires separate approach (in three steps, including justification of radiation treatment, irradiation procedure and application to the patient).
- **Optimisation** and the concept of ALARA are well understood and have been well implemented by operators. The average levels of public and occupational exposure have been kept well below the applicable dose limits which are included in national laws and regulations. If the constraints are correctly implemented in the context of radiation protection programme and optimisation of activities, they should contribute to ensure that each individual is adequately protected. However, in the current draft the distinction between dose limit and constraints seems to be unclear and difficult to implement. The clarification is requested for the final document.
- **Limitation** recommended by the ICRP in Publication 60 is implemented in legislation and regulatory materials of most countries as dose limits and these have an important role in radiation protection. According to the concept of ALARA, actual dose levels are kept much lower than dose limits. The values of dose limits in the new draft recommendations are not changed, though detriment-adjusted nominal risk coefficients for cancer and hereditary effects are lower. The ICRP clearly explains that given the level of uncertainty in risk evaluation, the decrease in the new recommendations is too small to justify any changes in dose limits.

Japanese, American as well European authorities consider international standards as an important input into their regulatory framework. Scientific knowledge based on UNSCEAR, and policy and principles based on the ICRP provide a basic and practical model for national regulation systems. The universality of ICRP recommendations is therefore an important contribution to world-wide radiological protection.

Stakeholder involvement (Prague forum)

Stakeholder involvement is well recognised by regulators and some think that in addition to the three principles described above, the stakeholder involvement should become the fourth radiation protection principle.

Authorities are now convinced that public participation in regulatory matters is the best way in achieving success. Indeed, one cannot protect people against their will to be protected. From this point of view, the communication is for the ICRP, but also for regulators a major challenge.

Radiation dose, call for research on low dose effects (scientific background) (Tokyo, Washington and Prague fora)

The LNT hypothesis remains the fundamental management tool for the ICRP risk evaluation system despite the fact that the relation among dose, damage and detriment may be much more complex than a simple linear relationship. While risk assessment is mainly based on epidemiological studies of A-bomb survivors where detriment has been statistically well established, risk from low doses is uncertain. It is also important to recognise the statistical limitations of epidemiological studies (for example the regional variation in cancer mortality in different Japanese prefectures is over 10%). One conclusion arising from the fora is that risk assessment at low doses requires continuing research before any changes in the current approach can be introduced.

In radiological protection practice, there is a need for quantities applicable to the management of exposures and regulations. The ICRP defines a single quantity (effective dose), specifying an “amount” of exposure and related to the probability of stochastic effects for all types of radiation exposures, acute and chronic exposures, and for external and internal exposures. While use of a single quantity for all types of exposures is not scientifically justified, it is a pragmatic and conservative approach in radiological protection.

A significant confusion in the current system is presented by the existence of definition of two concepts – “*equivalent dose*” and “*effective dose*”, both using the same unit – Sievert (Sv). Moreover the equivalent dose is applied for

limits of deterministic effects such as to the lens of the eye and to skin, but it uses weighing factors that are based on stochastic effects. As these limits are only controlled for skin, and estimated for the lens of the eye, another approach could be to define equivalent dose as simply a step in the estimation of effective dose. Effective dose should be described as a double weighed concept, using the unit Sv, while the other quantity for regulation should be the absorbed dose, measured in Gray (Gy).³

The ICRP has significantly changed several radiation weighting factors and the tissue weighing factors, two key components in calculating the dose. For the gonads it should be notified that the weighting factor decreased continuously since ICRP Publication 26 (using a tissue weighting factor of 0.25), through ICRP Publication 60 (using a tissue weighting factor of 0.20), to the new draft recommendations (using a tissue weighting factor of 0.08). This results from scientific observation among the A-bomb survivors and their progeny and from the resulting decrease of the probability of hereditary effects.

Furthermore, it is anticipated that the new recommended tissue weighting factors for cancer and hereditary diseases will have the most significant impact on dose assessment of not only internal exposure, but also of external exposure, and will influence national regulations. As the latest A-bomb data are expected to be published in peer-reviewed literature in a short time frame, it is proposed that the ICRP should postpone the finalising of the draft recommendations and should not adopt a new set of tissue weighing factors until the assessment of the A-bomb data is completed and published.⁴

Differences in radiation risks due to gender differences have been reported in the last UNSCEAR and BEIR reports. However, the ICRP does not recommend gender-specific data for the purpose of radiological protection and continues to present gender-averaged tissue weighing factors and numerical risk estimates. Majority of participants agree that the proposed approach provides adequate protection and is better manageable. However it is requested that the ICRP clearly explains its rationale for this decision, and how it accounts for gender differences in radiation sensitivity.

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3. As for the skin dose is concerned, the Council On Radio-nuclides and Radio-pharmaceuticals (CORAR) proposes to ICRP a very specific modification of the ICRP recommendations concerning the annual equivalent dose limit for skin, 500 mSv averaged over 10 cm² area of skin instead over 1 cm². This new recommendation would be compatible with the dose limits of 500 mSv for extremities and for the entire skin. (Washington forum)
 4. The ICRP agreed with this proposal but noted that the new data will be published soon in the Radiation Research journal.

In relation to the protection of the foetus against radioactivity intake by the mother, it was suggested that the ICRP should clarify the apparent inconsistency between the proposed ICRP recommendations and the former ICRP Publication 84, Pregnancy and Medical Radiation.

Exemption and exclusion (Washington and Prague fora)

The ICRP presents a number of recommendations related to small quantities of material; and the concepts of exemption and exclusion. However, in the present draft these concepts appear to be internally inconsistent, and could lead to misinterpretations. The present text implies that exemption should only be appropriate when the individual dose is very low, while according to some participants an exemption may be logical regulatory solution even if individual doses are greater than the values given.

Guidance on exclusion and exemption appears to be presented in a “stand alone” fashion, rather than systematically through the application of justification, optimisation and limitations principles. Exclusions represent those actions which are taken *a priori*, thus bypassing the control of a practice. It is sometimes difficult to understand all radiological aspects *a priori*, and this implies that certain forms of control may be excluded without any systematic assessments.

10 μSv value seems to be inappropriately considered as a boundary between significant and insignificant doses.

Several participants noted that some international values, such as those for foodstuffs and drinking water following an accident, are appropriate for generic exemption. Although the views of participants were not unified on what type of guidance the ICRP should provide, in general participants felt that the ICRP should provide guidance or the criteria to use for exclusions and exemptions, but not numerical values.

Natural exposure, radon (Tokyo, Washington and Prague fora)

The ICRP Publication 60 already states that natural exposure, when controllable, should be incorporated in the radiation protection system. This was viewed as the progress in the system of radiological protection, providing sufficient explanation to the general public that the radiation effects arising from natural and artificial sources do not differ. The new recommendations reaffirm this statement. However the text should be clearer, particularly when describing the use of dose constraints in existing situations.

The dose constraint is recommended to be used for radon-222. The proposed levels of activity are 600 $\text{Bq}\cdot\text{m}^{-3}$ for dwellings and 1 500 $\text{Bq}\cdot\text{m}^{-3}$ for workplaces.

These values were seen to be high in general, although some agreed with the ICRP explanation that these were intended to be maximum constraints, and were appropriate in some countries where average concentrations are relatively high, and the measurements and control are complicated and expensive. The ICRP also noted that the results of recent epidemiological studies do not change the nominal risk further supporting these numerical choices.

It was suggested that individual countries should established specific (lower) constraints reflecting their specific situations.

Environment (Tokyo, Washington and Prague fora)

Protection of non-human species engendered few discussions. While there is no international guidance in this area, it appeared that most developed nations include environmental assessments as part of their national environmental protection legislation. It is agreed that impact of ionising radiation on non-human species provided in ICRP Publication 91 is sufficient. However, it is recommended to define a framework focusing on this aspect as soon as possible, since it will be more difficult to harmonise the worldwide environment protection policy in future, particularly if countries develop and adopt in policies their own national approaches.

Medical exposure (Tokyo and Washington fora)

Medical exposures were a particular focus for discussion during the North-America forum. The medical exposure of patients and the use of computer-aided tomography (CT) are major sources of radiation. The number of CT and magnetic resonance imaging (MRI) facilities and examinations are constantly increasing worldwide. The absorbed dose to tissues from medical exposures can often approach or exceed the levels considered as statistically significant to increase the probability of cancer incidence. It is important to recognise that radiation from medical exposures might increase cancer risk especially among children and young patients. Therefore, every effort to reduce dose while maintaining proper image quality should be made in order to ensure that patients receive real benefit from diagnostic examinations.

The work of the ICRP Committee 3 to preserve the patient-doctor relationship was appreciated. The arising message for practitioners is to do the right test at the right time, for the right reason and on the right patient.

Unfortunately it is believed that patients are not provided sufficient information about the dose, risks, and benefits of medical exposures. Emergency department physicians and radiologists in general are unable to provide accurate

estimates of medical exposures doses regardless of their experience level. Because the estimation of dose is a complex subject that is difficult to explain, questions remain as to whether physicians are able to provide sufficient explanation about the risks and benefit of the requested diagnostic procedure.

Rather than independently, the risk of associated induction of cancer from medical exposures should be discussed in relation to other technical and social risks. Due to the lack of comprehensive scientific background related to induction of radiation effects at low doses, the ICRP suggests that risk calculations should be used with care. Participating medical practitioners believe that this important remark will be clearly communicated in order to avoid unnecessary concerns by associated with medical exposures.

It is suggested that new draft recommendations should provide sufficient bridge to the documents of Committee 3, since the RP06 draft itself provides only a little information on this subject.

Physicians should be trained in the area of radiological protection in order to be aware of the risks and benefits of the procedure involved since radiation exposures in medicine are controlled by the physicians only and are not restricted by any regulation.

Constraints of a few mSv may be reasonable for medical exposures but should not be applied generically, as higher values may be appropriate in specific situations, (for example, higher exposures may be acceptable for parents of a sick child treated with radionuclides).

The release of patients after therapy with unsealed radionuclides needs more explicit guidance which should be included in related documentation.

The special case of women

There is no reason to distinguish women from men in the control of occupational exposure except in the case of pregnancy. Once pregnancy is declared, protection of foetus must be considered. Working conditions should make it unlikely that the dose to the foetus will exceed 1 mSv during the period of pregnancy. It is also important to ascertain whether a female patient is pregnant prior to any radiological procedure.

However it is believed the ICRP should not present any numerical value that could be interpreted as the basis for terminating a pregnancy. Such discussions should be held on a case-by-case between competent medical practitioners and their patients. It was proposed that the current discussion on this topic in the RP06 draft should be removed.

Medico-legal exposures

Medico-legal exposures need further clarification. The question remains as to who is qualified to justify the exposure when the primary benefit is not toward the individual receiving the exposure (as an example may serve the potential use of X-rays for screening passengers at airports in the context of anti-terrorism actions).

Cost (Washington and Prague fora)

There were issues raised about the potential cost associated with implementing the new recommendations, and whether such costs could be justified in light of benefits that might be gained in terms of health and safety.

One aspect of concern was illustrated with the case of possible shielding upgrades that would be required in the United States for medical x-ray and accelerator facilities should a public dose constraint of 0.3 mSv/year be implemented. In that American medical therapy facilities have been designed to meet a 1 mSv/year public dose limit for those exposed outside of the facility by radiation penetrating the facility walls, decreasing the dose criteria to 0.3 mSv/year would require a significant amount of extra shielding to be installed, at an estimated cost of on the order of 1 billion US dollars.

Another aspect of this concern, although less cost-specific, was the cost of modifying national regulations, as well as international standards, particularly in the areas of what ICRP Publication 60 refers to as intervention situations. Changing the terms and the philosophy of existing national regulations to rather address existing and emergency situations was seen as being a time-consuming process, and thus an expensive process, for regulatory authorities and licensees alike. Although no figures were put to the possible costs of such work, the benefits of such a change were not seen as significant in terms of public, worker and environmental health and safety.

In conclusion, there were still some concerns that the benefits of the new recommendations may not outweigh the costs for changing regulatory and operations programmes and the costs associated with educating stakeholders. However, it was suggested that the cost of proposed changes should be clearly evaluated, and it was noted that this topic would be taken up, as any other change, by national governments when new regulations were considered.

Safety culture (Washington and Prague fora)

The new recommendations clearly describe the system application to exposure situations, and the ICRP continues to draw a connection between

optimisation of protection and the concept of safety culture. However, these are two separate concepts, and the confusion between is not resolved in the draft text.

Optimisation of radiation protection activities alone will not create a safety culture; the concept of safety culture is broader. While the underlying fundamentals of safety culture are also key components in the ongoing process of optimisation, safety culture involves other aspects. Beyond the nuclear industry, where safety culture has existed for some time, some regulatory agencies have been astonished by the lack of safety culture they discovered, particularly at hospitals. Although radiation safety culture is likely to improve radiation protection practices, the relationship between optimisation of protection and the concept of safety culture should be more clearly stated.

Moreover, the draft recommendations do not provide clear definition of or guidance for implementation of safety culture, and thus this important concept may be too difficult to understand, particularly for users of small sources of radiation.

ICRP response on dose constraints

In response to these concerns, over the course of the three meetings the presentation of dose constraints by the ICRP evolved considerably. In general, meeting participants appreciated the ICRP presentations and the responses given by the ICRP Chair to questions. There was broad support for striving to make the final ICRP text as clear as the Chair's presentations. Overall, the ICRP Chair's position on dose constraints as a result of meeting discussions can be characterised as follows:

For all exposure situations (planned, emergency, existing):

- Dose constraints apply to any exposure situation (i.e. planned, emergency or existing).
- Dose constraints are used in conjunction with optimisation of protection to assure that all exposures are kept ALARA.
- Dose constraints are a value above which one plans not to go, and below which one strives to reduce all actual doses.
- All exposures, above or below the constraint, are subject to optimized protection.

In a prospective sense:

- To determine which protection option is the most appropriate, the dose distribution resulting from each considered protection strategy is compared to the pre-selected constraint.

- Those distributions which are below the constraint would be considered as acceptable, and from these the optimum strategy, which yields the highest net benefit, can be selected.

In a retrospective sense:

- Once the exposure has occurred, doses can be measured or assessed in an identifiable population.
- The dose constraint is used as a benchmark against which the effectiveness of protection options can be judged.
- Actual dose distributions, after the application of protection strategies, may include exposures above the dose constraint.
- Efforts should be aimed at reducing exposures that are above the constraint to a level that is below the constraint, if possible.
- All doses, above or below the dose constraint, should be subject to optimised protection strategies.

The evolution of optimised protection

- Protection is optimised in reference to a specific situation.
- Should exposure conditions evolve with time, e.g., in the case of an emergency situation, or repetitive planned activities, or of existing situations that are being progressively addressed, the dose constraints should be periodically revisited to see whether their selected values continue to address protection needs.

In terms of the application of dose constraints to specific situations:

- The ICRP stated that in the planned situations, constraints represent an ambition level of protection based on experience. For nuclear energy production it is clearly stated that the system will not practically change since optimisation based on ALARA continues to be extremely effective at managing of occupational exposures. However, the ICRP insists that while ALARA is well implemented in the nuclear energy field, it is not well established in other sectors of radiation activities.
- In emergency or in existing controllable exposure situations, constraints represent a level of dose or risk where action to reduce that dose or risk is almost always warranted. In this sense, the ICRP wishes to define a unified system for all exposure situations, and this is one of the main motivations behind the new draft recommendations. The ICRP recognised that this aim is not well presented, and that more clarification is needed on this point in the final document.

- In no situations should the dose constraints be regarded as a legal boundary. Exceeding the dose constraint should not be considered as a regulatory infringement.

As far as the potential costs are concerned, the Commission responded suggesting that constraints on public doses from regulated activities, still referred to as practices, had been called for in Publication 60, such that national regulations that are in compliance with Publication 60 need not change. In terms of the broader question of the overall benefit of the change not being sufficiently large to justify the efforts necessary to change regulations, the Commission suggested that this modification was really based on experience since the issuance of Publication 60. The proposed system, focusing on optimisation and using dose constraints as a planning tool and a retrospective benchmark, better reflects what governments actually do now than what was recommended in Publication 60. As such, again there should not be any great need to significantly modify national regulations to appropriately implement the new recommendations.

GENERAL COMMENTS FROM TOKYO TO PRAGUE

The evolution of the system of radiation protection is driven by scientific developments, social evolution, experience, lessons learnt and by new exposure situations. The important role of the ICRP in this process comes from the fact that regulations need to be based on well-accepted standards, and it is best if these standards exist on the international level.

In general, the draft recommendations are well viewed, however additional clarification is needed in some areas as described in the previous paragraphs. As mentioned in all three fora, it is welcomed that the ICRP maintains as much stability in its recommendations as is consistent with the new scientific information.

Among the most significant conclusions of all three fora was the fact that further clarification of the constraint concept and its use within the ICRP radiation protection framework is needed.

The new classification of exposure situations (planned, existing and emergency) was welcome. It was found easy to understand and implement in the current regulations.

General consensus on the use of collective dose as main instrument for optimisation was achieved between ICRP and stakeholders. Collective dose should not be used for the epidemiological risk assessments and risk estimates.

Along with scientific evolution, anticipated challenges raised in a previous report of the CRPPH⁵ were confirmed. Despite the epidemiological methods are more accurate there is still a statistical uncertainty at dose levels in practices. In addition, new radiobiological effects have been confirmed:

- Bystander effect, which is now well described in cells, but the extrapolation to tissue and individual remains unknown.

5. *Developments in Radiation Health Science and their Impact on Radiation Protection*, NEA, 1998.

- Individual susceptibility is now confirmed at high doses, but could be a problem for medical practices (radiotherapy), and is not observed at low doses.
- Non-cancer effects are also observed at high and not observed at low doses.

The main challenge today is how to include new scientific phenomena in the practice, which was primarily based on the cancer incidence and hereditary effects in the past.

However, experience and practical lessons learnt from the implementation of ICRP Publication 60 have shown that the distinction between practices and interventions is difficult to explain to populations living in contaminated areas. This phenomenon was described in the collective opinion of the CRPPH in 1994.⁶ The need for the extension of the current system becomes more and more obvious in the context of societal evolution. Even if it is not clearly written in the new draft recommendations, it is perhaps the main justification for the evolution of the system. Moreover, the good results obtained by optimisation (ALARA implementation) in the realm of nuclear power production (with NEA/IAEA ISOE system confirming success of this procedure), has to be extended to other applications and to all source-related exposures. On the other hand, it needs to be clearly shown that the improvements in emergency and in existing situations present enough advantage to warrant change.

Participants of all three fora appreciated the open consultation launched by the ICRP. The ICRP should be acknowledged for its valuable contributions to the current radiation protection system. Despite the high quality of new recommendations, regulators and international agencies have an opinion that the change of current radiation protection regulations, which have proven their efficiency, is not among their top priorities.

Implications for international agencies and national regulators

The new ICRP recommendations should be used for revision of the international BSS, and the new European BSS Directive. While it is understood that there is no urgent need for change, this change will bring certain improvements and should be communicated to the national levels.

6. *Radiation Protection Today and Tomorrow*, A Collective Opinion of the Committee on Radiation Protection and Public Health, NEA, 1994.

The ICRP assumes that the new recommendations will not evoke the need for significant change in the existing international BSS. However, some changes will be necessary. The focus in draft ICRP recommendations has shifted to one of having a single approach to all exposure situations (from the approach of separating practices and interventions). This may require some changes in regulatory focus and terminology. The ICRP is presenting the new recommendations as being based at least in part on “operational” experience since the issuance of Publication 60, and thus it is expected that these new recommendations are build up along current practice. Taking this fact into consideration, the need for changes at the national regulatory level will be neither urgent nor profound. As was already mentioned above, in the optimal case, the new recommendations would be transformed into the next international BSS revision in 2010 and followed by their implementation in 2015.

Participants of all three fora suggested that the ICRP should be as clear as possible in explaining the concepts and philosophy behind the new recommendations. It will also be appreciated if the new recommendations were presented in a form that allows a certain amount of flexibility to national authorities in implementation them into regulatory application. As an example it can be stated, that the requested dose constraints should be fixed at the national level, either by national authorities or by operators, so as to be appropriate for the particular circumstances and situation.

Implications for the CRPPH

The quality of the dialogue and large number of constructive and positive proposals as well criticisms has encouraged the CRPPH to continue the open communication between the ICRP and various stakeholder groups. All speakers greatly appreciated the CRPPH and the ICRP for soliciting such feedback.

The fora highlighted three areas of CRPPH activity: to scrutinise i) scientific advances, ii) social evolution and iii) practical experience, all three of which are intended to identify issues that, in the mid-to-long term future, could have significant influence on radiation protection policy, regulation and application.

Based on these discussions, several areas have emerged where the CRPPH could continue to work, primarily focusing on implementation aspects. These areas include the use and application of dose constraints, the broad concept of regulatory authorisation, particularly in terms of exclusion and exemption, collective dose, potential exposure, emergencies, the consideration of science in decision making, in parallel with a discussion of the ties between scientific research and radiation protection policy and regulation.

It is clear that the CRPPH is a valuable forum for developing guidance for implementation of ICRP recommendations. Within the CRPPH the perspectives of regulators, professionals and operators can merge. Judging from past experience (exercises ISOE and INEX) the CRPPH reinforces the importance of these dialogue fora. We are entering a new era of dialogue and co-operation to respond the forthcoming challenges. For this, it will be essential to maintain and further develop links among relevant stakeholders participating in new processes of evolution of the system of radiological protection, and more broadly in radiological protection decision making. These links will span from fundamental research to practical radiation protection application, and will help to ensure the effective protection of the public, workers and the environment.



A Stakeholder Dialogue on the Implications of the ICRP Recommendations

Since its inception the NEA Committee on Radiation Protection and Public Health (CRPPH) has been involved in the assessment and implementation of the recommendations of the International Commission on Radiological Protection (ICRP). The development of new general ICRP recommendations, to replace those of the 1990 ICRP Publication 60, was thus of great interest to the NEA and its member countries. As a result, the NEA initiated a process of interaction and dialogue with the ICRP to ensure that the views and concerns of NEA member countries could be voiced and appropriately addressed in the new ICRP recommendations. The new ICRP recommendations were approved by the ICRP Main Commission in March 2007, by which point the NEA had sponsored 7 international conferences and produced 13 publications on the subject.

This report is the summary of the three international dialogue conferences (held in Tokyo, 5-6 July 2006, Washington, DC, 28-29 August 2006, and Prague, 24-25 October 2006) that were organised to provide the ICRP with feedback regarding the June 2006 draft of its new recommendations. It includes a presentation of the key points of the draft recommendations, a summary of the suggestions made during the three conferences, and an assessment of the significant evolution that has been seen in the ICRP's presentation of its draft recommendations over the course of the conference series.

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