

Radiation Protection

The Way Forward in Radiological Protection

An Expert Group Report

NUCLEAR ENERGY AGENCY
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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FOREWORD

In April 2000, the NEA Committee on Radiation Protection and Public Health (CRPPH) held extensive discussions with the active participation of Professor Roger Clarke, the ICRP Chairman, on the evolution of the system of radiation protection, and in particular the concept of controllable dose. On this basis, a CRPPH Working Party on Controllable Dose and the Use of Collective Dose prepared a report entitled *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* (NEA, 2000). In addition, the Committee agreed that a new Expert Group on the Evolution of the System of Radiation Protection (EGRP) should be formed to continue these discussions. Such follow-up needed to wait, however, for additional input from various professional radiological protection societies to be presented in a session on controllable dose during the IRPA-10 conference, which took place in Hiroshima in May 2000.

The CRPPH felt strongly that the development of a new, more broadly understood and accepted system of radiological protection should be the result of a combination of evolutionary thinking (starting from the present system) and new thinking (such as that provided by Professor Clarke). These two independent paths should eventually merge into a single approach. It was further felt that any new ideas or approaches should be thoroughly "road-tested" to ensure their relevance and usefulness.

Based on these considerations, the CRPPH provided the new Expert Group with the following Terms of Reference:

1. To identify the areas of the current system of radiological protection that are, in the Group's opinion, most in need of further elaboration. The starting point for this work should be the CRPPH report, *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*. A prioritised list of areas should be developed.

2. To develop more detailed discussions of the top four priority issues, and prepare a report for the CRPPH with suggestions as to what changes should be made, or in which *direction discussions should be pursued*.
3. To engage with Professor Clarke and others to participate at meetings and fora, on behalf of the CRPPH, that discuss and further activities to address and advance this dialogue.
4. To use a case-study approach to “road test” its proposed changes, to assure that the changes move the system of radiological protection towards a more understandable, easy-to-apply, and acceptable system.
5. To report on its progress during the March 2001 meeting of the CRPPH, and submit a summary report of its recommendations to the CRPPH for review and approval at the latest during the 2002 meeting of the CRPPH. The report should include recommendations as to where further work could be usefully pursued by the CRPPH.
6. The resulting CRPPH issues paper should be submitted to the international community, and particularly to the ICRP, as a contribution to the debate to advance the future evolution of the system of radiological protection.

The following report is the result of the work of the Expert Group on the Evolution of the System of Radiation Protection, and is intended to contribute to ongoing international discussions aimed at developing a modern system of radiological protection. Annex 1 lists the members of the Expert Group who took part in all or some of the Group’s discussions. Annex 2 lists the authors of this report, whose views are reflected therein.

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1. INTRODUCTION: MOTIVATION FOR CHANGE

Since the early part of the 20th century when the harmful effects of ionising radiation were first observed, the primary aim of radiological protection has been to provide an appropriate standard of protection for the public and workers without unduly limiting the beneficial practices giving rise to radiation exposure (ICRP, Publication 60). Over the past few decades, many studies concerning the effects of ionising radiation have been conducted, ranging from those that examine the effects of radiation on individual cells, to epidemiological studies that examine the effects on large populations exposed to different radiation sources. Using information gained from these studies to estimate the consequences of radiation exposure, together with the necessary social and economic judgements, the International Commission on Radiological Protection (ICRP) has put forward a series of recommendations as to the structure of an appropriate system for radiological protection.

The ICRP system of radiological protection that has evolved over the years now covers many diverse radiological protection issues. Emerging issues have been dealt with more or less on an individual basis resulting in an overall system, which while very comprehensive, is also complex. With such a complex system it is not surprising that some perceived inconsistencies or incoherence may lead to concerns that radiation protection issues are not being adequately addressed. Different interested parties in decisions involving radiological protection aspects tend to focus on different elements of this incoherence.

For example, the decommissioning of nuclear facilities, old reactors and weapons fabrication facilities has, in many instances, been an issue of some public concern. These liabilities require the expenditure of considerable amounts of money. When such public concerns are raised, it is important, from the public's point of view, that sufficient resources are allocated to these activities to achieve low levels of residual contamination. From the governments' point of view, however, it is also important that residual contamination is low, but not to the extent that scarce resources are used up in reducing radiological risks which are already low, at the expense of ignoring other ionising radiation hazards, or, for example, other hazardous agents. In this

context, governments are increasingly concerned with finding an “appropriate” balance with regard to the allocation of resources for the protection of public health, and with a coherent approach to the management of all health risks.

Various sectors of the public have, in many instances, also been concerned with other activities that result in exposure, including the disposal of radioactive waste, the authorising of discharges from nuclear facilities, and the transportation of radioactive materials. These activities routinely lead, presently or in the future, to some increase in exposure of members of the public, and that need to be fully quantified to allow for an informed decision-making process. More difficult to quantify, but equally important in the eyes of the public, is the possibility of accidents and the consequent potential exposures associated with these activities.

In general, the public and other interested parties are increasingly interested in participating in decision making, particularly with regard to issues that affect public health or the state of the environment. With respect to the system of radiological protection, one way in which this desire concretely manifests itself is in an impetus for a clear distinction of roles and responsibilities in decision-making processes. The current system of radiological protection does not sufficiently identify these boundaries, for example between science and social choice, and has thus come under pressure to better address stakeholder needs.

As regards occupational exposure, some employers are concerned dose reduction efforts are becoming unreasonable. Governments are being pressed to address these industrial concerns in their process of regulating radiological activities.

From the viewpoint of radiological protection professionals, the system as it has developed poses other difficulties. In trying to explain the approach to protection from different sources, for example comparing artificial sources and radon, social and economic judgements, technical considerations, as well as a source’s inherent amenability to control are all relevant to the degree to which exposures from a source can be managed. The recommended approaches to protection in different circumstances, for example in a routine work situation or following an accident, have been developed based on technical criteria and value judgement that are not always clearly defined and which may be questioned. The “absolute nature” of some interpretations of collective dose estimates over large space/time ranges, in terms of predicting numbers of cancer deaths, has also caused concern among some radiological protection professionals, as have difficulties over the distinction between practices and intervention for certain situations.

Another important area of concern to experts is the relationship between dose and risk. Although the effects of exposure to high levels of radiation can be predicted with considerable confidence, there is no firm scientific evidence on the potential health effects due to very low doses of ionising radiation. In view of this uncertainty, the ICRP has adopted the linear no-threshold (LNT) hypothesis, as an appropriate default option, in developing its recommendations. The assumptions of this hypothesis are that all exposure to radiation, even at low levels, carries some risk, and that the risk is proportional to the exposure. The first assumption, i.e. no-threshold, is in line with the general application of a precautionary principle in the management of radiological risks.

As the results of studies on the effects of exposure to low levels of radiation have emerged, a controversy surrounding the applicability of the LNT hypothesis as a model for making radiation protection decisions has developed. Conflicting or inconclusive epidemiological studies, and the relevance of *in-vitro* observations to *in-vivo* cancer development mechanisms, have led to divergent views on the possibility of a threshold. At the extremes, one side believes in the existence of scientific proofs for a dose threshold or even radiation hormesis, while the other extreme considers that the LNT hypothesis underestimates risks. The development of a system of radiological protection from these different starting points leads to diverging opinions concerning dose limits for the public and other more specific issues such as the degree of effort justified in cleaning up contaminated sites. This controversy within the scientific community has led to some loss of confidence, by decision makers and by the public, in radiological protection.

An area related to the discussion of LNT is that of Effective dose (E), the indicator used by the ICRP to predict the risk of cancer in connection with exposures to ionisation radiation. The value of E is calculated using the absorbed dose, expressed in Gray, weighted by parameters representing susceptibility of the exposed tissue, w_T , and the relative effectiveness of the type of radiation causing the dose, w_R . This concept assumes a linear, non-threshold relationship between E and the predicted risk for cancer induction, without consideration of dose rate or age of the exposed individual. The extent to which this concept is applicable to accidental exposures to high doses and high dose rates involving young children needs to be further considered and clarified.

Other important issues are also the subjects of current discussions among radiological protection professionals, particularly the radiological protection of the environment. One of these is the assumption, as stated in ICRP 60, “that the standard of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk”. The current

system of protection recommended by ICRP is intended to deal with protection of biota at the level of the whole species and balance between species, but does not necessarily protect individual members of non-human species. Some would argue that this approach is inadequate for a number of reasons. For example, the ICRP approach might not be applicable to situations where man is not present in the radiation field or where there are no pathways to man. Those in favour of an ecological approach to environmental protection are also concerned that the approach to the regulation of radiation exposure of man and biota be broadly in line with those adopted for other non-radioactive pollutants. International initiatives to develop consensus on environmental protection standards and supporting guidance for their implementation are ongoing.

In 1999, in an attempt to address the concerns that had developed and to bring the system of radiological protection in line with modern societal needs, Professor Roger Clarke, the chairman of the ICRP, made proposals for a different, less complex, approach to protection. Since that time, there has been widespread discussion of Professor Clarke's proposals within the radiological protection community and he has developed his initial ideas to provide a framework that can be used as a basis for the development of the first draft of the new recommendations.

While all those involved in radiological protection have welcomed Professor Clarke's invitation to discuss the current system of radiological protection and to input into the new ICRP recommendations, many have raised concerns as to the need for a change. In the past, ICRP has undertaken reviews of its current advice only when significant new data on the risks of radiation exposure have become available. This is not the case at present. Another concern, particularly among the many NEA Member countries that have recently modified national regulations to implement ICRP 60, is the need for stability. Implementation of any changes to the system of radiological protection will entail costs that need to be taken into consideration. There are strong views that any change must be assured, a priori, to enhance/improve the current system of radiological protection. Although one of the drivers for change is undoubtedly the need for a more transparent, more coherent system, many feel that the public will be suspicious of a system that, while simpler, may be seen in any way as a relaxation of the radiological protection standards inherent in the existing system.

In its early discussion of Professor Clarke's proposals, the NEA Committee on Radiation Protection and Public Health (CRPPH) identified a number of aspects of the current system of radiological protection that could be improved. This report, which represents the views of its authors as presented to the CRPPH, prioritises the areas previously identified, and elaborates how the system of radiological protection could evolve in the priority areas to better serve the needs of radiation protection regulators, practitioners and other interested parties.

2. SCOPE AND STRUCTURE OF THE SYSTEM OF RADIOLOGICAL PROTECTION

The current system of radiological protection as recommended in ICRP Publication 60 is comprehensive. In discussing how this system could evolve, the EGRP felt that an “ideal” system of radiological protection should provide guidance on virtually all types of exposure. Initially, all known radiation sources and exposures would be considered to be included within the system of radiological protection. This would give the positive message that the regulatory control flowing from an internationally agreed-upon system of radiological protection considers all sources, and then regulates them in a logical fashion. From this starting point, some exposures could then be excluded, based on the fact that they are not amenable/possible to control, control would not improve the situation, or based on some other clearly explained rationale. Some sources could be authorised for release from some or all regulatory control, through a process of constrained optimisation based on clearly explained and, where appropriate, internationally agreed-upon criteria. All remaining exposures and sources would be subject to regulatory control.

In addition, a modern system of radiological protection should fit within a common policy framework with the management of other carcinogenic risks, for example, for chemicals. Although this is not meant to imply that all problems require identical treatment, approaches to the reduction of radiation and chemical risks should assure that the ultimate goal of public health protection is met in a fashion that addresses the need to balance the use of public funds. To achieve this, beginning with the current system, some adjustments, to better respond to modern regulatory and applicational needs are necessary.

The system of radiological protection should be based on state-of-the-art of science, as expressed by scientific bodies such as UNSCEAR and BEIR. Because of the advancing nature of science, some built-in flexibility is necessary to respond appropriately to new developments and consensus. Areas considered should include the biological effects of radiation exposure, scientific approaches to the modelling of exposure that are consistent with the needs of estimating biological effects, and a rationale for the units and techniques used to

physically measure radiation exposure. The statistical study of biological effects, in the form of epidemiology, is also an essential part of the scientific framework of the system of radiological protection. Broadly, these elements already form the basis of the current system, but this basis should continue to evolve as biological sciences advance.

In developing radiological protection guidance, a modern system of radiological protection should clearly recognise the boundaries between the scientific aspects of risk assessment, the social aspects of risk evaluation and management, and the regulatory aspects of risk management. One of the most tangible results of making such distinctions will be a clear rationale with regard to where, in the system of radiological protection, international agreement is needed, and where, on the contrary, flexibility is necessary.

While all exposures should be considered within a system of radiological protection, not all exposures need to provoke recommendations for protective actions. Within the current social context, it is important to stress that all risks are addressed and, where possible, quantified based on the current level of state-of-the-art science. This being said, it is also clear that some exposures, such as to cosmic radiation at ground level, while quantifiable, can not be controlled by reasonable radiological protection actions. These exposures should thus not be subject to radiological protective actions. However, a modern system of radiological protection should provide international consensus guidance regarding how to decide whether a particular type of exposure should or should not require protective actions. The rationale for the exclusion of exposures from, and the release of sources within the system of radiological protection from some or all regulatory control should form part of this guidance. Other aspects requiring such harmonisation could include any necessary numerical criteria, as well as the internationally accepted rationale for selecting for example, worker and public dose limits, using latest scientific information.

Some areas of the system of radiological protection, however, should be kept somewhat flexible in nature, and should also be clearly identified. For these, guidance should be provided regarding how numerical values, if any, could be developed at a more regional, national or even local level. Aspects such as the release of contaminated sites from some or all regulatory control could be examples of where such flexibility is necessary. Guidance for these areas should include considerations of the decision-making process or processes that could be used to arrive at accepted decisions, as well as the various scientific aspects that could be taken into account in arriving at a decision. This guidance should be flexible enough to allow for its application under various national regulatory schemes.

To assist in the development of guidance with regard to the appropriate protective actions to take, exposures could be characterised in terms of their receptor/source and various aspects of the exposure. These could include:

Types of exposure (guidance would need to be provided as to how exposures should be classified, for example, what factors should be considered when deciding whether the exposure of non-uranium miners to radon daughters is occupational exposure or not?)

- Public and occupational exposure to man-made sources.
 - Ongoing practices.
 - Past practices.
 - Medical.
 - Accidents.
 - Naturally Occurring Radioactive Material (NORM).
- Public and occupational exposure to natural sources.
 - Cosmic.
 - Radon.
 - Other terrestrial.
- Exposure of the environment to man-made sources.

Various aspects of exposure (guidance should be provided as to how, when and by whom these various aspects of exposures should be taken into account when selecting radiological protection options)

- Factors affecting the exposure.
 - Is the exposure feasible to control?
 - How long is control necessary / feasible?
 - Is the exposure modifiable by individual actions?

- Aspects of exposure “acceptability”.
 - Who gets benefit? Who takes risk?
 - Informed consent.
 - Voluntary versus involuntary exposure.
 - Number of people exposed.
 - “critical group” characteristics.
- Dose and dose rate considerations.
 - Very low total dose (triviality, exemption).
 - Very high total dose and dose rate(deterministic effects).
 - Dose partitioning aspects.

Two areas that should not be forgotten in defining the scope of a modern system of radiological protection are risk transfers and potential exposures.

Risk transfer situations include transfers from the public to workers (in the case of reducing emissions by the concentration and storage of radionuclides, for example), or from current generation to future generations (as in decisions regarding radioactive waste management, for example). Achieving an appropriate balance has been difficult to judge in practice, and examples of the types of considerations that need to be taken into account in the decision-making process should be discussed. In this context, the validity of transferring population-specific risk factors to other groups or populations should also be discussed within the system of radiological protection.

The practical difficulty in assessing potential exposure situations stems from the uncertain nature of both the occurrence and the detrimental consequence. The current system does not provide adequate guidance with regard to making protection choices in cases of potential exposure. This is particularly true when situations of low-consequence / high-probability must be judged against cases of high-consequence / low-probability. Some practical guidance would be helpful; for example, for considering how radiological protection could be integrated with other safety goals.

In summary, the EGRP feels that the system of radiological protection should:

- Be based on state-of-the-art of science, as expressed by scientific bodies such as UNSCEAR and BEIR.
- Logically address all sources of exposure and all exposures within the system, bearing in mind the national need to develop corresponding regulatory approaches for each.
- Include the concept of Authorisation of the exclusion of some exposures from all radiological protection regulatory control, based on internationally agreed-upon and clearly documented rationale.
- Provide guidance on making decisions regarding exclusion for any new exposures that might be identified in the future.
- Include the concept of Authorisation of the release of some sources from some or all radiological protection regulatory control based on internationally agreed-upon and clearly documented rationale.
- Provide guidance on making decisions regarding authorisation of release of sources from all or some regulatory control.
- Clearly situate all its recommendations within the context of the scientific aspects of risk assessment, the social aspects of risk evaluation and management, and the regulatory aspects of risk management.
- Clearly state that international consensus is an important support for any numerical guidance, which is the product of social consent, provided (e.g. dose limits, dose constraints).
- Characterise exposures to facilitate the identification of and social acceptance of possible radiological protection actions.
- Provide guidance regarding the balancing of risk transfers in the development of radiological protection actions.
- Provide guidance regarding the assessment of potential exposure situations.
- Bear in mind the need to balance hazards for the efficient and appropriate protection of the public and workers, and the efficient and appropriate use of public funds.

3. PRIORITY AREAS FOR DISCUSSION

In its critical review of the system of radiological protection (NEA 2000), the Committee on Radiation Protection and Public Health identified eight broad areas where clarity and coherence could be improved in order to facilitate the task of regulators and implementers of radiological protection. In this reflection, no particular attempt was made to prioritise these areas, or to delve deeply into new approaches. Discussions of these issues have continued and intensified since this publication, and the Committee now feels that it is in a position to elaborate new directions.

A key point, on which there seems to be broad agreement, is that the application of the system of radiological protection, as recommended in ICRP Publication 60, has not resulted in members of the public or workers being under-protected. For many circumstances, the current system works very effectively. However, there is also broad agreement that the system is in need of modernisation, not only to make it easier to communicate and explain, but also to fundamentally improve its coherence. The eight areas that the CRPPH initially found to be the most in need of such improvement are as follows:

- Clarity and Coherence.
- Justification.
- Optimisation.
- Collective Dose.
- Dose Limits.
- Triviality.
- Public Protection.
- Protection of the Environment.

In its further deliberations, the CRPPH has identified, within these eight areas, four broad subjects of highest priority. These subjects, which will be addressed individually, are as follows:

- Numerical Guidance: Dose Limits and Intervention Levels.
- The Concepts of Regulatory Control, Exemption and Triviality.
- Justification and Optimisation.
- Decision making versus Decision Aiding.

Numerical guidance: dose limits and intervention levels

Previous discussions have highlighted the need to develop international consensus regarding which are the aspects of the system of radiological protection that need to be internationally harmonised, and those for which guidance is necessary but harmonisation is not. Dose limits, dose constraints, intervention levels, and other numerical radiological protection criteria are key examples of where international consensus on this distinction is necessary.

Some have questioned the role of an “Expert Organisation” such as the ICRP in making recommendations in areas that are clearly dominated by social judgement aspects. The Commission states in its Publication 60:

It is the Commission’s intention to choose the values of dose limits so that any continued exposure just above the dose limits would result in additional risks from the defined practices that could reasonably be described as “unacceptable” in normal circumstances. (ICRP 60, paragraph 123)

In this framework, a dose limit represents a selected boundary in the region between “unacceptable” and “tolerable” for the situation to which the dose limit is to apply, i.e. for the control of practices. (ICRP 60, paragraph 150)

Words like “unacceptable” and “tolerable” are strongly linked to social choices. While these choices may be fed, in a decision-aiding fashion, by scientific information, the selection of the boundary between unacceptable and tolerable is not a scientific question. However, it is a historical fact that the ICRP has for many years provided numerical recommendations on dose limits that have been widely implemented directly in national regulations and international standards. In this sense, while the role of the ICRP in making such

recommendations may be questioned, the regulatory usefulness of having internationally harmonised dose limits for occupationally exposed workers and for members of the public is widely accepted. This has, in a *de-facto* sense, given an international approval to the ICRP's recommendations.

In this same context, it is also recognised that source-related dose constraints can be effective tools for the protection of the public. This would suggest that national regulatory authorities would need to consider the effects of multiple sources when fixing source-related dose constraints.

The EGRP acknowledges that ICRP has played a meritorious role in establishing the scientific bases for recommending dose limits, for which a scientific input is a necessity, but that scientific considerations ought also to be corroborated by broader views of what is thought to be socially acceptable. Broad consultation processes, such as that are currently being pursued by the ICRP, are welcome for achieving international consensus.

It should be remembered that ICRP Publication 26 based its selection of numerical dose limits for workers on comparison to "other occupations recognised as having high standards of safety" (ICRP 26, paragraph 96). In selecting a numerical dose limit for members of the public, ICRP Publication 26 again based its reasoning on the comparison of radiation to other socially accepted risks, stating; "It seems reasonable therefore to consider the magnitude of radiation risks in the general public in the light of public acceptance of other risks of everyday life." (ICRP 26, paragraph 117). This type of rationale ties selected dose limits to the acceptance of other risks, implying that as social acceptance of risks change (often by becoming less tolerant of risks) dose limits must also change. While this perhaps presents decision makers and regulators with the challenge of periodic re-assessment of dose limits, there is a much more clear recognition of the social aspects involved in the selection of numerical limits.

However, the ICRP's description of the rationale for the selection of the numerical values of worker and public dose limits leans far more towards scientific issues than towards social judgements and international consensus (see paragraphs 150 to 175 of ICRP Publication 60 for occupational exposure limits, and 188 to 194 for public exposure limits). As previously stated, the system of radiological protection should more explicitly recognise the fundamental differences between scientific facts, assumptions and social judgement. While the scientific rationale is necessary as input to discussions, and should be kept in future ICRP recommendations, the justification of numerical recommendations for dose limits should be solidly expressed in terms of international consensus and social judgement.

Intervention Levels, as defined in ICRP Publication 60 and more thoroughly described in ICRP Publication 63, represent another “class” of numerical recommendations that have been made by the ICRP, but that should be revisited in terms of modern social governance processes.

There is, however, no logical structure in ICRP 63, analogous to that discussed above in ICRP 60, concerning the basis from which numerical values of Generic Intervention Levels for intervention situations are derived. The Commission does state:

The dose limits recommended by the Commission are intended for use in the control of practices. The use of these dose limits, or any other pre-determined dose limits, as the basis for deciding on intervention might involve measures that would be out of all proportion to the benefit obtained and would then be in conflict with the principle of justification. (paragraph 2, Publication 63)

However, this statement is somewhat unclear, and does not address the apparent contradiction that it is “justified” in accident or chronic exposure situations not to intervene even at levels of dose that would be judged “unacceptable” under “normal” situations. In addition, there is no real explanation of the basis from which the numerical values for Generic Intervention Levels for sheltering, evacuation, administration of stable iodine, restrictions on food and water, and relocation were determined. Numerical values are simply stated as though they were obvious. There is a need for guidance that has to be both flexible and convincingly argued, also but not exclusively from a scientific viewpoint as social considerations appear of the essence in the context of intervention levels.

While many national regulations and international standards and guidelines use the ICRP’s philosophy and numerical values as planning tools for interventions, this has not always been the case in practice. Emergency planning zones around such fixed potential sources as nuclear power plants have been established using design-basis accidents, dispersion models and numerical intervention levels. However it is widely recognised that, in application, decision makers would implement urgent countermeasures well before any actual exposures were to occur, often even if such exposures were far from certain. In the longer-term situations, remediation actions have often aimed for residual exposure levels (above natural background levels) far below many internationally recommended numerical levels. For example, case studies presented at the two Villigen workshops (NEA1998, NEA2001) suggest that, as a kind of “target”, many remediation actions have used 1 mSv/a, and in many

cases the end point agreed upon by the affected population and their government has been developed on a case-specific basis.

It is thus suggested that the use of rigid, pre-determined intervention levels, and of subjective statements that pre-empt social judgement, such as “intervention is not likely to be justified below a dose of X mSv/a”, should be avoided in a modern system of radiological protection. These should be replaced by a more flexible approach that does not, *de-facto*, institutionalise different pre-determined levels of protection before and after an accident or emerging exposure situation.

The utility of distinguishing between practices and interventions should be revisited. It is not clear that, under a system that stresses the social aspects of *de-facto* exposure situations, and which treats many such situations on a case-by-case basis, the distinction between practices and interventions would serve any purpose. The elimination of the distinction between practices and interventions could also have the advantage of simplifying the system of radiological protection, and eliminating what has often been seen as relatively confusing terminology.

At the very least, some further international reflection should be initiated regarding intervention levels, and as a result, if such terminology is kept, their basis should be clarified, as should their relationship with the basis for dose limits. For consistency, dose limits, dose constraints, and intervention levels should all fit into a single transparent logical structure, although this does not necessarily mean numerical consistency.

To assist in these international discussions of dose limits, intervention levels, etc., several useful conclusions seem to be approaching consensus:

- There is a broad consensus that regulators need “numbers” as benchmarks for regulation. These can be limits, action levels, reference levels, etc. In view of the previously discussed differences between the social aspects of risk acceptance, and the regulatory aspects of risk management, the selection of numerical regulatory criteria should be supported by scientific assessment of risks, but should be clearly presented as regulatory tools and not as “scientific facts”.
- Points of reference, or benchmarks, are useful in the justification of numerical values. For example, doses from natural sources of exposure, and variations in levels of natural exposure have been

cited as easy to understand. At the same time, the need to socially justify any “additional” dose should not be forgotten.

- In this same line of reasoning, experience and approaches from other industries, such as the chemical industry could be studied. Approaches taken for other risks could also be investigated. Concepts such as “relevant good practice”, and “best available technology” should also be considered. ICRP Publication 60 abandoned the approach previously taken in Publication 26 of basing radiation dose limits on “acceptable” risk levels taken from other “safe” industries. The rationale behind this shift was, in part, to avoid tying dose limits to the “moving target” of safety levels in other industries. Perhaps, in view of the importance of the social justification of numerical criteria, it is more desirable to use such “societal norms” as “safe industries” as benchmarks, even if they tend to change with time.

In summary, the EGRP feels that the system of radiological protection should:

- Include “dose limits”, which are socially well accepted, and “source-related dose constraints” which are widely viewed as very useful tools from the regulatory perspective.
- Clearly recognise the importance of the social judgement aspects of setting numerical criteria, such as dose limits, for radiological protection purposes.
- Tie the rationale for numerical radiological protection criteria to international agreement and social judgement, and consider tying this rationale to a broader public acceptance of other risks.
- Propose guidance for addressing *de-facto* exposure situations (post accident, long-term exposures, etc.) that is flexible, and perhaps based on a case-by-case approach.
- Clearly show and explain the relationship between the use of numerical radiological protection criteria for ongoing activities, and the flexible approach taken for *de-facto* situations.
- Avoid making social judgements such as, “Below X mSv/a, in *de-facto* exposure situations, radiological protection actions are not likely to be justified”.

The concepts of regulatory control, exemption and triviality

The concept of triviality has received much recent attention from several different aspects. Particularly, noting current social trends, it seems clear that the social judgement aspect that is inherent in the concept of triviality has taken on far more importance, in the public's estimation, than have the scientific risk assessment aspects that are stressed in existing guidance from the ICRP. This has led to a general rethinking of the concept of triviality, and of its place in the broader context of the system of radiological protection.

Initially, triviality was intended to designate exposures that were so low as to not require regulatory actions to assure public or worker protection. Exposures that were declared "trivial" were thus no longer considered in a radiological protection sense. It was noted, however, that activities "upstream" of this declaration might well require regulation. An example of such a situation would be the production of smoke detectors using small radioactive sources. The USE of the smoke detector containing small radioactive sources has been viewed as justified, and assessed in some cases to result in trivial doses, thus as a source these detectors and their owners are not individually subject to regulatory actions. However, the PRODUCTION of these detectors involves larger quantities of radioactive material, and this practice would be subject to radiological protection regulations.

For certain situations, this use of the concept of trivial has worked effectively. However, this has not been the case in other situations. For example, the release of slightly contaminated materials from decommissioning activities has been analysed using an approach similar to that used for the exemption of smoke detectors from regulatory requirements based on the concept of triviality. The fact that resulting doses have been below the pre-defined, internationally-accepted level of triviality (10 $\mu\text{Sv/a}$ individual dose, 1 manSv/a collective dose) has not lead in many instances to this practice being publicly accepted.

It seems, therefore, that the generic use of a pre-defined, internationally-accepted level defining trivial dose is, at this time, not universally accepted for all cases in the context of modern society. In fact, the selection of a universally applicable numerical dose level defined as trivial seems to present more problems, in terms of social justification, than it solves. Given this situation, and taking into account the previous discussion concerning the need to agree on those aspects of a system of radiological protection that need international consensus and those that should be more locally decided, triviality can perhaps be seen as part of the broader question of authorised release. Seen in this way, the concept of triviality is no longer needed. A caveat to this, as will be

discussed further on, is the development of universally agreed-upon levels below which international trade of commodities and food can take place free of radiological protection regulation.

Part of the motivation to modernise the current system of radiological protection arises from its relative incoherence with respect to the regulatory control of radioactivity and its authorised release from some or all regulatory controls. For example, the release of a contaminated site is often regulated through the use of optimisation below a predetermined dose constraint. Many countries are currently using a value on the order of 300 $\mu\text{Sv/a}$ individual dose to the average member of the critical group, and different approaches to the optimisation process. A similar approach is used to the release of gaseous and liquid effluents from industrial facilities, that is, optimisation below a predetermined constraint, also often on the order of 300 $\mu\text{Sv/a}$. At the same time, the release of materials that are slightly contaminated is regulated based on the concept of triviality, that calls for annual individual exposures to be less than 10 μSv , and annual collective dose to be less than 1 manSv . Another case, that of Naturally Occurring Radioactive Material (NORM) is regulated in yet another fashion. Not all NORM industries are currently under regulatory control by radiological protection authorities, but it has been suggested in ICRP publication 82 (paragraph 126) that commodities that contain radioactive substances should be controlled at a level of around 1 mSv/a individual exposure.

These cases all seem to involve the authorisation, by national radiological protection authorities, to release radioactive materials into the environment based on a locally optimised approach below some pre-determined dose constraint. These situations have been called exemption (in the case of NORM materials that are not regulated), clearance (in the case of release of materials), authorised release (in the case of sites), authorised effluent release (in the case of gaseous and liquid effluents), and intervention exemption levels (in the case of commodities). These situations can all be considered “equal” from the standpoint of physics and health effects, in that a dose is a dose, no matter what the source. However, from the same technical assessment of a dose/risk, individual situations may result in different accepted end points. For example, doses resulting from discharges from an NPP versus discharges from a hospital are viewed differently by interested parties. This is the nature of the process of optimisation below constraint, social and economic considerations being considered.

Based on actual experiences in various countries, at best one can say that the acceptance of releasing materials from some or all radiological protection regulatory control, has been mixed. This is particularly true for the clearance of

materials. Given this situation, it is suggested that the release of radioactive materials should be more subject to an authorisation, optimisation “process” rather than a pre-defined “triviality” level below which no further actions are necessary. By declaring the system of radiological protection to provide regulatory consideration of all exposures and sources, the Authorisation of release from some or all regulatory control becomes a deliberate regulatory act based on an optimisation process, and which may include provisions in generic national legislation. Such an Authorisation process can be viewed as an overarching approach to all releases, which inherently “harmonises” the somewhat incoherent approaches described in the previous paragraphs. Such a uniform guiding principle makes the regulatory process more transparent, and easier to express and explain. It also sends the social message that government recognises that all radiological risks should be recognised and addressed in an appropriate, deliberate and controlled fashion.

In terms of the hierarchy of “concepts”, as previously stated, all sources and exposures would be subject to regulatory consideration. Within this envelope, some sources could then be authorised (not excluded from regulatory control) on clearly explained grounds, for example, that they are inherently not amenable/possible to control. International consensus would need to be reached with regard to which sources and exposures to authorise (exclude from regulatory control) on these grounds. Guidance would also be needed to judge whether sources or exposures identified in the future should be authorised (excluded from regulatory control). Those sources and exposures not authorised (excluded from regulatory control) would be subject to some form of regulatory control as identified by national competent authorities. These sources and exposures could be released from some or all radiological protection regulations through the process of authorisation, based on optimisation below a pre-determined constraint. Thus, authorisation would encompass and replace the concepts of exclusion and exemption. International consensus would need to be developed with regard to any internationally harmonised numerical criteria felt to be necessary

Under this approach, other currently used concepts could also be eliminated. For example, triviality is more socially divisive than it is useful. The above-described process of regulatory control and authorisation of release from some or all regulatory requirements, is more simple, coherent and logical. In particular, the terminology used is easily understood common language, and is easy to translate. The word “trivial”, for example, is translated in many languages into the word “negligible”. In that the ICRP seems to be considering using, in its new concepts, both “trivial” and “negligible”, each with a different meaning, the Expert Group feels that a modern system should be more simple rather than more complex. In this same sense, the Expert Group feels that the

concept of clearance, which has also been the source of much discussion, would no longer be necessary under a system of authorisation. Clearance is simply a type of authorisation. Thus, on the grounds that the system of radiological protection is “somewhat overly and needlessly complicated”, international discussions should take place as to whether terms like exclusion, exemption, clearance and triviality are still needed. It should be noted that the social message sent by expressing exclusion, exemption, clearance and triviality all as “authorisation” is that government maintains sources of exposure actively within its control, but can use the dynamic process of authorisation for some specific cases.

It should be recognised, however, that in some situations, generic, internationally agreed-upon numerical criteria may not be applicable. This could be the case, for example, when national regulatory authorities agree, with local interested parties, on release criteria for land that has been contaminated with radioactive materials. To assist national authorities under for such situations, the system should provide guidance as to how more local and/or case-specific numerical criteria should be set so as to be consistent with broader, generic guidance.

To assist in the application of such authorisation processes, however, practical guidance is necessary. Examples of the types of considerations to include, and of stakeholder processes to use would be very useful. Given that the social judgement aspects of such questions are clearly keys to arriving at solutions that are accepted, the following considerations should be appropriately taken into account during authorisation:

- It should be clearly stated from the beginning of any process that the “free release” of radioactive materials implies governmental consent for any further use of materials. In general, these releases will be irreversible, although releases can always be halted or discontinued should new elements bring the original authorisation study into question.
- In order to judge the acceptability of residual exposures resulting from the release of materials, the absolute value of dose must be considered, as well as how easy it is to lower this dose (optimisation).
- Those that are “worried” should be involved in the decision-making process.
- Discussions with interested parties during justification, authorisation and optimisation processes should include consideration of benefits as well as risks (individual, local, regional, national, international).

One area where a flexible, locally focused “process approach” will not work is that of international trade. Because of the ubiquitous presence of radioactivity in nature, there is a need for an internationally agreed-upon level below which the international trade of commodities (such as metals, woods, plaster, gypsum and brick building materials, foods, milk products, meat, grains, etc.), is not subject to radiological protection regulation. A set of operationally measurable quantities, e.g. specific activity, should be developed and internationally agreed upon. These values could be derived from dose criteria using appropriate models. In a complementary fashion, these could also be based on the existing ranges of radionuclide concentrations found in various classes of commodities. Again, because of the social judgement that is inherent in such a set of numbers, a broad discussion is necessary in order to arrive at a workable consensus.

In the case of commodities coming from areas affected by large-scale radiological accidents, commodities would in many cases not be below the “naturally occurring” range of radionuclide-specific concentrations, particularly for artificially-produced radionuclides. Although it is likely that market forces would reject such products even without internationally-agreed trade restrictions, regulatory consideration of the “waste disposal” aspects would be necessary for such commodities deemed “unfit” for trade. In the case of food and feedstuff, flexibility would also be necessary for such cases where “uncontaminated” replacements were not immediately available.

In summary, the EGRP feels that the system of radiological protection should:

- define an overarching approach based on the consideration of all exposures and sources for radiological protection purposes;
- include the use of a process of constrained optimisation for the authorisation of;
- the release of sources from some or all regulatory control;
- exposures to occur without the need to comply with some or all regulatory controls;
- include an umbrella concept of authorisation to simplify the system of radiological protection, superseding the concepts of exclusion, exemption, clearance and triviality;
- provide guidance for the optimisation process used for the authorisation of release;

- specify the types of dose constraints, if any, should be internationally harmonised, and identify internationally agreed upon numerical values for these dose constraints;
- provide guidance for the development of “locally applicable” numerical values for dose constraints;
- include internationally agreed upon radiological criteria below which the international trade of commodities would be free of radiological protection restrictions.

Justification and optimisation

As with all risks, actions that expose people and/or the environment to radiological risks must be justified *a priori*. Viewpoints on what is meant by this fundamental principle of the current system of radiological protection have, however, evolved. In the context of an evolving system of radiological protection, interpretation of what is meant by justification, and of how this principle should be included in system, need to be reconsidered. Similarly, the relationship between optimisation and justification should be discussed internationally, within the context of societal expectations, to reach consensus.

The EGRP feels that justification should maintain its place as one of the pillars of the system of radiological protection. It is also felt that the scale of the situation being considered is an important factor in the process of justification. Justification may be expressed as a very broad concept as in ICRP Publication 60 applying to “practices” such as “the general use of x-rays for medical purposes” or “electricity generation by nuclear reactor.” In these cases, the EGRP considers that there is a need to take account not only of health, safety and environmental issues but also economic, social and other factors. In the case of decisions regarding justification, scientific input from radiological protection specialists is an important contributor, but will most likely not form the most significant part of the basis for decision. Justification may also apply to small-scale activities, such as a given radiological medical examination. In such cases, radiological protection is one of the driving factors in the decision on justification.

In some cases it will be clear whether an action is justified or not. For example, it is widely accepted that it is not justified to intentionally put radioactive materials into children’s toys. In other cases more finely balanced factors need to be considered.

When optimisation is applied to activities causing risk to society, selecting options may well be seen as a largely social process. Scientific input on optimisation from radiation protection specialists is again seen as necessary but may not be the most significant part of the basis for a decision. For example, for effluent release from a nuclear installation there may be a need to involve local and regional groups in the decision-making process, and discussions of benefits and risks are tied to optimisation. Such discussions are very closely tied to the demonstration that the most appropriate option is being put forward – i.e., the decision may be to justify the activity, but it will only be widely accepted if it is seen as a good balance between costs of reductions and residual radiological impact, taking into consideration the local social and economic benefits of the installation. The release of slightly contaminated materials is a particular example where, rather than local and regional groups, it is national and international groups who need to be involved because of the implications for international trade.

These aspects of the relationship between justification and optimisation should be thoroughly explored and clearly explained in the evolving system of radiological protection.

Guidance as to the practical application of these concepts should also be developed. This is particularly true of optimisation. While the EGRP feels that optimisation must remain as a fundamental pillar in the system of radiological protection, there is a great need to provide practical guidance as to the types of methods, elements and considerations that should be taken into account, in the technical decision-aiding sense, when performing optimisation analysis.

It must be recognised, though, that the case-specific nature of optimisation in this context will lead to specific optimised results that may well vary from place to place. Considerations taken by decision makers from the social and political arena will include time and space aspects. As such, it should not be surprising if different solutions are selected in different countries, regions, areas, etc

Finally, another area where guidance should be provided within the system of radiological protection concerns what can be loosely termed “backfitting”. Specifically, as scientific knowledge and social norms evolve, how should “old” or “existing” practices or processes or methods or tools be “re-evaluated”? Do such things automatically become “unjustified” if rules change, or should a flexible “grace period” be allowed to affect upgrades, or should a “grandfather clause” be evoked to simply let such actions continue based on historical precedent? Guidance as to how such situations should be considered should be developed.

In summary, the EGRP feels that the system of radiological protection should:

- Continue to include the principles of justification and optimisation as fundamental pillars of the radiological protection philosophy.
- Explore and clarify the relationship between justification and optimisation.
- Recognise that it is important to maintain a distinction between the social and political elements of justification, and the scientific elements and input that support decisions regarding justification.
- Recognise that the case-specific nature of the optimisation process may well result in different solutions from place to place.
- Provide guidance regarding the application of evolving radiological protection rules to old or existing practices, processes, actions, methods, etc.

Decision making versus decision aiding

Discussions within the radiological protection community, which mirror broader discussions of the much more general subject of modern governance, have converged on the idea that a better understanding of the roles of various stakeholders in the decision-making process would very much facilitate finding solutions that can be accepted. The implications of this consensus should be explored thoroughly so that improved decision making and decision aiding processes can be developed.

As part of the understanding of these roles, a clear, theoretical distinction is made between “Decision Making” and “Decision Aiding”. Decision making is intended to mean the process of arriving at a decision that is accepted. This will involve different groups of interested parties depending upon the nature of the situation requiring a decision. Decision aiding is intended to mean the development of elements, (e.g. technical, social, economic) that are necessary to make an informed decision. Although it is often difficult to separate these processes in real situations, the importance of making the distinction lies in the trust that can be gained if this distinction is clearly made. A particularly important aspect of this is the recognition of the different roles involved in the scientific aspects of risk assessment, the social aspects of risk management and acceptance, and the regulatory aspects of risk management.

Specifically, in situations involving radiological protection decisions, when stakeholders beyond the regulators and radiological protection experts are involved, it is important that the “decision maker” not be perceived as being the “Expert/Decision Aider” and the “Decider” all in one. In complex societies, governments (national and perhaps local) and parliaments can be considered in many cases as the ultimate decision makers. The role of radiological protection experts, on the other hand, includes the performance of assessments, the quantification of risks, in an absolute and relative fashion, the definition of alternatives, the provision of advice and recommendations, and the explanation and clarification of the radiological implications of decisions. However, when experts also hold the role of “Regulator” or “Decision Maker”, there can be a mixing, or perceived mixing, of the scientific understanding of risk, and the social justification and acceptance of risk. This can lead to a lack of trust in the decision-making process. If, on the other hand, the distinction of roles is appropriately made, the identification of a socially accepted solution can be greatly facilitated.

It should also be mentioned here that the scientific aspects of decision aiding should not try to account for social preference or other social considerations, but should remain scientific. This being said, the scientific aid that is provided to decision makers must recognise the social context and nature of each decision being made, and provide appropriate scientific input. For example, for site release, important scientific input would be the risks associated with particular residual doses, and uncertainties associated with those risks and with site characterisation. The final decision will take this scientific input into account, along with other social and political aspects, in arriving at accepted cleanup criteria.

To assist decision makers and radiological protection experts with decision-aiding roles, the development and broad distribution of a “code of conduct” would be welcomed.

In most NEA Member countries, a regulatory authority is mandated by its national government to regulate radiological protection to assure public and worker safety. In this context, decisions must be made and regulations must be written and enforced. If, however, the role of decision making is kept conceptually apart from the role of decision aiding, regulation may be more freely accepted, and is more likely to enjoy active stakeholder participation in meeting regulations.

It should be recognised that most regulatory decisions will not be socially contentious, and that the stakeholder process approach to decision making will only be necessary for certain decisions. Clearly, stakeholder consultation is

difficult in the early phases of an emergency situation, but should be undertaken at the emergency planning stage. However, for those cases in which a broad stakeholder consensus is necessary, the “Decision Maker” must be perceived as taking all factors, not just the technical issues, into account in arriving at a decision. The extent to which such a decision-making process involves and/or requires stakeholder involvement will vary from country to country, but the acceptability of the final adopted solution will clearly improve if the “Decision Maker” enjoys the trust of all, or the majority of interested parties.

As numerous case studies have shown, finding an accepted solution to a problem or situation can be greatly facilitated by identifying, in advance, an appropriate process by which to arrive at the solution. As such, mechanisms to identify in advance situations that could best be resolved through stakeholder processes would greatly aid regulators in approaching such situations.

Given this broad assessment of decision making and decision aiding, some concrete considerations that should be taken into account in the evolution of the system of radiological protection towards a more modern system include the following:

- LNT is a dose/risk management tool that is used by the ICRP and by national regulators to make estimates with which radiological protection options can be judged. The presentation of LNT in future ICRP publications should take this view into account.
- Radiological protection should try to fit within a policy framework that is consistent with the assessment and management of other environmental and health risks, such as those from chemicals, for example.
- The “back fitting” of past practices and discovered situations has led to some perceived incoherence within the system of radiological protection. The different levels of protection recommended for “Practices” and “Intervention Situations”, as defined in ICRP Publication 60, are a good example of how technical logic can result in recommendations that may prove to be socially contentious. In the context of decision aiding and decision making as discussed here, ICRP recommendations regarding how such situations should be addressed need to be revisited. Specifically, the need for internationally harmonised “Intervention Levels” should be reviewed, and those areas where a more flexible, case-by-case approach would better serve society should be identified. Guidance should be given with regard to the elements that should be used to

identify such cases, and the elements that should be used to resolve such situations, without the use of prescriptive intervention levels.

As discussed earlier, the “Types” or “Characteristics” of exposure situations might serve as useful guides to identify how to deal with the exposure. Some pertinent examples would be:

- Are the exposures voluntary or involuntary?
- Is there a choice? Can personal action affect the exposure?
- What are the benefits the process or thing producing the exposure? Are these individual, local, regional, national, etc.

Such a set of criteria might be used to both identify exposure situations that could best be addressed through a stakeholder process, and to facilitate discussion of their resolution in a stakeholder setting.

In a technical sense, the need for the development of consensus and guidance in two specific areas of “Decision Aiding” has been identified. These areas are:

- First, what is the goal of radiological protection actions? For example, is the goal to reduce the dose to the maximally exposed individual dose below the “Limit”, to reduce the average dose to the critical group to the optimised level, or both, or something else? Guidance on this fundamental question is necessary.
- Second, in that the evolution of the system of radiological protection seems to be moving towards more emphasis on the individual, how will dilution be considered? Should or should not dilution be encouraged? If individual dose becomes the most important factor in optimisation, then dilution may become an effective “ALARA Tool”. Consistent and well-justified guidance should be provided.

In summary, the EGRP feels that the system of radiological protection should:

- Clearly distinguish between decision making and decision aiding, and should specify in which of these cases each of its recommendations fall.
- Include a “code of conduct” for radiological protection experts, to help assure the clear separation of roles in decision-making processes.
- Offer guidance with regard to identifying, in advance, those radiological protection decision situations that could best be resolved through a stakeholder process.

4. CONCLUSIONS

The NEA Committee on Radiation Protection and Public Health considers that while the system of radiological protection as currently recommended by the ICRP is comprehensive and affords a high level of protection to the public and to workers, it is however fairly complex and incoherent in some aspects. In an effort to make a constructive contribution to the evolution of the existing system so that it meets the needs of decision makers, regulators, practitioners and social stakeholders in general, the EGRP offers its views on a possible way forward for consideration at the national and international level.

The use of the concepts of exclusion, exemption, clearance and triviality has led to difficulties in interpretation and implementation, which undermine confidence in the system of radiological protection. Broadly, the EGRP suggests that a simplified approach, based on a process of authorisation, involving interested parties as appropriate, should be considered. Such an approach would send the very positive message that national authorities appropriately and actively protect the public and workers from all radiation sources. The elimination, or at least de-emphasising, of various terms (exclusion, exemption, clearance, triviality, etc.) would result in a greatly simplified, more coherent and understandable system, while at the same time maintaining flexibility in application.

Recognising that modern processes of decision making in areas addressing public and worker health risks are moving towards increasing transparency and stakeholder participation, the EGRP also suggests that very clear distinctions should be made between the scientific aspects of risk assessment, the social aspects of risk evaluation and management, and the regulatory aspects of risk management. In applying these distinctions within the ICRP recommendations themselves, the EGRP feels that the organisations and individuals implementing the recommendations will more easily be able to define their roles and responsibilities.

To assist in the practical application of any new ICRP recommendations, the EGRP considers that some further guidance should be given. While some

numerical values will be internationally agreed upon and harmonised, such as worker and public dose limits and international trade in commodities, others will be developed and applied at the national level, such as those used to address long-term and post-accidental exposure situations.

Finally, the principles of justification and optimisation are fundamental pillars of the system of radiological protection, which in certain situations may be seen as interrelated and difficult to apply in practice. The relationship between justification and optimisation should be thoroughly explored and clearly explained in the evolving system of radiological protection. Practical application of these concepts should also be developed.

It is hoped that these suggestions by the CRPPH will be useful at the national and international level for the development and application of new general radiological protection recommendations.

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