MEMORANDUM

THE EVOLUTION OF THE SYSTEM OF RADIOLOGICAL PROTECTION:

THE JUSTIFICATION FOR NEW ICRP RECOMMENDATIONS

The International Commission on Radiological Protection*

ABSTRACT

ICRP has been encouraging discussion, during the past few years, on the best way of expressing radiological protection philosophy in its next Recommendations, which it plans to publish in 2005. The present recommendations were initiated by Publication 60 in 1990 and have been complemented by additional publications over the last twelve years. It is now clear that there is a need for the Commission to summarise the totality of the number of numerical values that it has recommended in some ten reports. This has been done in this paper and from these, a way forward is indicated to produce a simplified and more coherent statement of protection philosophy for the start of the 21st century. A radical revision is not envisaged, rather a coherent statement of current policy and a simplification in its application.

INTRODUCTION

1. The 1990 system of protection, set out in Publication 60, was developed over some 30 years. During this period, the system became increasingly complex as the Commission sought to reflect the many situations to which the system applied. This complexity involved the justification of a practice, the optimization of protection, including the use of dose constraints, and the use of individual dose limits. It has also been necessary to deal separately with endeavours prospectively involving radiation exposure, *'practices'*, for which unrestricted planning was feasible for reducing the expected increase in doses, and existing situations for which the only feasible protection action was some kind of *'intervention'* to reduce the doses. The Commission also considered it necessary to apply the recommendations in different ways to occupational, medical, and public exposures. This complexity is logical, but it has not always been easy to explain the variations between different applications.

2. The Commission now strives to make its system more coherent and comprehensible, while recognising the need for stability in international and national regulations, many of which have relatively recently implemented the 1990 Recommendations. However, new scientific data have been produced since 1990 and there are developments in societal expectations, both of which will inevitably lead to some changes in the formulation of the Recommendations.

3. The previous 1977 Recommendations were made in Publication 26, which established the three principles of the system of dose limitation as Justification, Optimization and Limitation. Assessments of the effectiveness of protection can be related to the source that gives rise to the individual doses (source-related) or related to the individual dose received by a person from all the sources under control (individual-related). Optimization of protection is a source-related procedure, while the individual-related dose limits provide the required degree of protection from all the controlled sources.

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4. Optimization of protection was to be applied to a source in order to determine that doses are 'as low as reasonably achievable, social and economical considerations being taken into account', and decision-aiding techniques were proposed. In particular, the Commission recommended cost-benefit analysis as a procedure to address the question, 'How much does it cost and how many lives are saved?' The Commission recommended that the quantity Collective Dose should be used in applying those optimization techniques to take account of the radiation detriment attributable to the source in question. This quantity was unable to take account of the distribution of the individual doses attributable to the source. Attempts were made to address this problem in Publications 37 and 55, by suggesting a costing of unit collective dose that increased with individual dose received, the procedure was essentially never adopted internationally.

5. The issue was partially resolved in the 1990 Recommendations: while it was still stated, as in 1977, that in relation to any particular source within a practice, the doses should be as low as reasonably achievable, social and economic factors being taken into account, it then continued:

   '*This procedure should be constrained by restrictions on the doses to individuals* ***(dose constraints)****, or the risks to individuals in the case of potential exposures (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgements*' (Paragraph 112).

   The concept of the constraint has not been clearly explained by the Main Commission in its subsequent publications. It has not been understood and, although it has been the subject of debate by international bodies, it has not been sufficiently utilised nor has it been implemented widely. The Commission now aims to clarify the meaning and use of the constraint.

6. The dose constraint was introduced because of the need to restrict the inequity of any collective process for offsetting costs and benefits when this balancing is not the same for all the individuals affected by a source. Before 1990, the dose limit provided this restriction, but in Publication 60 the definition of a dose limit was changed to mean the boundary above which the consequential risk would be deemed unacceptable. This was then considered to be inadequate as the restriction on optimization of protection and lower value constraints were required to achieve this.

7. This introduction of the constraint recognised the importance of restricting the optimization process with a requirement to provide a basic minimum standard of protection for the individual.

8. The principles for intervention set out in Publication 60 are expressed in terms of a level of dose or exposure where intervention is almost certainty warranted (i.e., justified), which is followed by a requirement to maximise the benefit of the intervention (i.e., the protection level should be optimized). This is effectively an optimization process and therefore it may be seen in exactly the same terms as for practices, i.e. there is a restriction on the maximum individual dose and then the application of the optimization process that is itself expected to lead to lower doses to individuals.

9. It can be seen then that all of the Commission Recommendations since 1990, both for practices and for interventions, have been made in terms of an initial restriction on the maximum individual dose in the situation being considered, followed by a

requirement to optimize protection. This underlines the shift in emphasis to include the recognition of the need for individual protection from a source.

10. The new recommendations should be seen, therefore, as extending the recommendations in Publication 60 and those published subsequently, to give a single unified set that can be simply and coherently expressed. The opportunity is also being taken to include a coherent philosophy for natural radiation exposures and to introduce a clear policy for radiological protection of the environment.

THE PRESENT SITUATION

11. Since the 1990 recommendations there have been nine publications, listed in Table 1, that have provided additional recommendations for what are effectively to be regarded as 'constraints' in the control of exposures from radiation sources. When ICRP 60 is included, there exist nearly 30 different numerical values for 'Constraints', which are set out in Table 2, in the ten reports that define current ICRP recommendations. Further, the numerical values are justified in some six different ways, which include,

    a. Individual annual fatal risk,
    b. Upper end of an existing range of naturally occurring values,
    c. Multiples or fractions of natural background,
    d. Formal cost-benefit analysis,
    e. Qualitative, non-quantitative, reasons, and
    f. Avoidance of deterministic effects

    The rationale for the constraints in Table 2 is indicated using these letters a-f.

Table 1. ICRP RECOMMENDATIONS MADE SINCE PUBLICATION 60.

Publication 62	Radiological Protection in Biomedical Research
Publication 63	Principles for intervention for Protection of the Public in a Radiological Emergency
Publication 64	Protection from Potential Exposure: A Conceptual Framework
Publication 65	Protection against Radon-222 at Home and at Work
Publication 75	General Principles for Radiation Protection of Workers
Publication 76	Protection from Potential Exposures: Application to Selected Radiation Sources
Publication 77	Radiological Protection Policy for the disposal of Radioactive Waste
Publication 81	Radiation protection Recommendations as Applied to the Disposal of Long-lived Solid Radioactive Waste
Publication 82	Protection of the Public in Situations of Prolonged Radiation Exposure

TABLE 2. COMPILATION OF THE EXISTING ICRP 'CONSTRAINTS' TO OPTIMIZATION

SITUATION TO WHICH IT APPLIES			
Effective Dose*	**Basis+**		**Publication**
NORMAL OPERATION OF A PRACTICE			
~0.01 mSv/a	a, c	Exemption level, protection optimized	64, 76
0.1 mSv/a	e	Constraint for long-lived nuclides	82
0.3 mSv/a	e	Maximum public constraint	77
20 mSv/a	a	Maximum worker constraint	60, 68
10 mSv/a ($1500\ Bq\ m^{-3}$)	b	Worker Constraint for Rn-222 -Optimized level between 500-1500 $Bq\ m^{-3}$	65
2 mSv	e	Surface of the abdomen of pregnant worker	60
1 mSv	a, c	Foetal dose over remaining term of pregnancy	75
1 mSv/a	a, c	Dose limit for the public	60
PROLONGED EXPOSURE			
~10 mSv/a	c	Below this intervention is optional, but not likely to be justifiable	82
~100 mSv/a	c, f	Intervention almost always warranted	82
10 mSv/a ($600\ Bq\ m^{-3}$)	b	Constraint for Rn-222 at home -Optimized level 200-600 $Bq\ m^{-3}$	65
~1 mSv/a	c	Intervention Exemption Level, protection optimized	82
10^{-5}/a	a	Risk constraint	81
BIOMEDIAL RESEARCH			
0.1 mSv	a	Minor level of societal benefit	62
1.0 mSv	a	Intermediate level of societal benefit	62
10.0 mSv	a	Moderate level of societal benefit	62
> 10.0 mSv	a	Substantial level of societal benefit	62
SINGLE EVENTS AND ACCIDENTS			
Effective Dose* Averted			
50 mSv	e, c	Sheltering warranted – optimized 5-50 mSv	63
500 mSv 5000 mSv skin	e, c	Evacuation warranted– optimized 50-500 mSv	63
5000 Gy thyroid	e, c	Issue stable iodine – optimized 50-500 mSv	63
1000 mSv	d, a	Arrange relocation (-10s mSv per month)	63, 82
1000 mSv 5000 mSv skin	f	Constraint for planned emergency work	63
10 mSv 100 Bq/g (α), 10000 Bq/g (β/γ)	c, d	Optimized value for foodstuffs 10-100 Bq/g (α), 1000-10000 Bq/g (β/γ)	63

*Unless otherwise stated

+**a**. individual annual fatal risk, **b**. upper end of an existing range of naturally occurring values, **c**. multiples or fractions of natural background, **d**. formal cost-benefit analysis, **e**. qualitative, non-quantitative, reasons, and **f**. avoidance of deterministic effects

12. The Commission had previously suggested the term 'Protective Action Level' (PAL) be used in the specification of the restriction of individual doses from single sources. The term appeared to cause concern and was not well understood. The Commission has considered the issue and now feels that the already established term 'constraint' correctly reflects the concept it wishes to promote.

13. The question to be addressed is whether, for the future, fewer constraints may be recommended that are sufficient to encompass the needs of radiological protection, and whether they can be established on a more uniform and consistent basis.

MAJOR CHANGES FROM THE 1990 RECOMMENDATIONS

14. The primary aim of the Commission continues to be contributing to the establishment and application of an appropriate standard of protection for human beings and now explicitly for other species. This is to be achieved without unduly limiting those desirable human actions and lifestyles that give rise to, or increase, radiation exposures.

15. This aim cannot be achieved solely on the basis of scientific data, such as those concerning health risks, but must include consideration of the social sciences. Ethical and economic aspects have also to be considered. All those concerned with radiological protection have to make value judgements about the relative importance of different kinds of risk and about the balancing of risks and benefits. In this, they are no different from those working in other fields concerned with the control of hazards. The restated recommendations will need to recognise this explicitly.

16. Where exposures can be avoided, or controlled by human action, there is a requirement to provide an appropriate minimum, or basic, standard of protection both for the exposed individuals and for society as a whole. There is a further duty, even from small radiation exposures with small risk, to take steps to provide higher levels of protection when these steps are effective and reasonably practicable. Thus, while the primary emphasis is now on protection of individuals from single sources, it is then followed by the requirement to optimize protection to achieve the best level of protection available under the prevailing circumstances.

17. In order to achieve this, it is proposed that the existing concept of a constraint be extended to embrace a range of situations to give the levels that bound the optimization process for a single source. The optimization of protection from the source may involve either, or both, the design of the source or modification of the pathways leading from the source to the doses in individuals. They would replace a range of terms that include intervention levels and action levels since there would be no need to distinguish intervention situations separately, constraints, clearance levels and exemption levels as well as the dose limits for workers and the public.

18. There will be a revision to the radiation and tissue weighting factors in the definition of Effective dose. A coherent philosophy for natural radiation exposures will be included and a clear policy for radiological protection of the environment will be introduced.

THE 2005 SYSTEM OF PROTECTION

19. The Commission now recognises that there is a distribution of responsibilities for introducing a new source leading to exposures, which lies primarily with society at large, but is enforced by the appropriate authorities. This requires application of the

principle of **JUSTIFICATION**, so as to ensure an overall net benefit from the source. Decisions are made for reasons that are based on economic, strategic, medical, and defence, as well as scientific, considerations. Radiological protection input, while present, is not always the determining feature of the decision and in some cases plays only a minor role. The Commission now intends to apply the system of protection to practices only when they have been declared justified, and to natural sources that are controllable.

20. The justification of patient diagnostic exposures is included, but has to be treated separately in the recommendations, because it involves two stages of decision-making. Firstly, the generic procedure must be justified for use in medicine and, secondly, the referring physician must justify the exposure of the individual patient in terms of the benefit to that patient. It is then followed by a requirement to optimize patient protection and the Commission has advocated the specification of Diagnostic Reference Levels as indicators of good practice (See paras. 48-53).

21. The system of protection being developed by the Commission is based upon the following principles, which are to be seen as a natural evolution of, and as a further clarification of, the principles set out in Publication 60. Once the source is justified by those appropriate authorities, the radiological principles may be expressed as,

For each source, basic standards of protection are applied for the most exposed individuals, which also protect society

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If the individual is sufficiently protected from a source, then society is also protected from that source.

However, there is a further duty to reduce doses, so as to achieve a higher level of protection when feasible and practicable. This leads to authorised levels

- OPTIMIZATION

22. This system of protecting individuals and groups is intended to provide a more coherent basis for protection than the previous one. A necessary basic standard of protection from each relevant source is achieved for individuals by setting constraints that are values of quantities, usually dose, but may be activity concentrations. Constraints are usually annual values, but may be a single value depending on the circumstances.

23. These constraints or basic levels of protection can be recommended by ICRP and accepted internationally. The responsibility for optimization then rests with the operators and the appropriate national authority. The operator is responsible for day-to-day optimization and also for providing input to the optimization that will establish Authorised Levels for the operation of licensed practices. These levels will, of necessity, be site and facility dependent and beyond the scope of ICRP.

FACTORS IN THE CHOICE OF NEW CONSTRAINTS

24. The present system, which is unduly complex and has used at least six different methods to determine the numerical values, has set maximum constraints that are, in general, about ten times the global average natural background. It is at around this level that doses are usually deemed to require some action, whether they are for practices or intervention, workers or the public.

25. The Commission now considers the starting point for selecting the levels at which any revised constraints are set is the concern that can reasonably be felt about the annual dose from natural sources. The existence of natural background radiation provides no justification for additional exposures, but it can be a benchmark for judgement about their relative importance. The worldwide average annual effective dose from all natural sources, including radon, as reported by UNSCEAR is 2.4 mSv.

26. A general scheme for the degree of concern and the level of exposure, as a fraction or multiple of the average annual natural background, is shown in Table 3. The fact that the effective dose from natural background varies by at least a factor of ten around the world, and even more if the highest radon doses are included, supports the view that concern should begin to be raised at the higher end of the natural range.

27. At even higher levels of individual effective dose, i.e. more than 100 mSv in a year, the risk from a source cannot be justified, except in extraordinary circumstances such as life saving measures in accidents, or in manned space flights. Individual doses of the order of 500 mSv, if acute can cause early deterministic effects, or if either acute or delivered over decades, can cause significant probability of increased cancer risk. This then becomes an individual-related restriction on dose and the appropriate authorities must ensure that the individual is not likely to receive significant additional dose from other controllable sources.

28. At the other extreme, additional effective doses far below the natural background effective annual dose should not be of concern to the individual. Provided that the additional sources come from practices that have not been judged to be frivolous, these doses should also be of no concern to society. If the effective dose to the most exposed is, or will be, less than about 0.01 mSv in a year, then the consequent risk is negligible and protection may be assumed to be optimized, thus requiring no further regulatory concern.

29. In the intermediate region, doses between a fraction of a mSv and a few tens of mSv, whether they are received either singly or repeatedly, are legitimate matters for concern, calling for action by regulatory bodies.

TABLE 3. LEVELS OF CONCERN AND INDIVIDUAL EFFECTIVE DOSE RECEIVED IN A YEAR

GLOBAL AVERAGE ANNUAL NATURAL BACKGROUND EFFECTIVE DOSE FROM ALL SOURCES IS 2.4 mSv (UNSCEAR 2000)

HIGH	More than 100 mSv
RAISED	More than a few 10s mSv
LOW	1 - 10 mSv
VERY LOW	Less than 1 mSv
NONE	Less than 0.01 mSv

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30. The challenge is whether fewer numbers could replace the 20-30 numerical values for constraints currently recommended in Table 2. Further, could they also be more coherently explained in terms of multiples and fractions of natural background.

OPTIMIZATION OF PROTECTION

31. The Commission wishes to retain the phrase 'Optimization of protection' and applies them both to single individuals and to groups. However, it is applied only after meeting the restrictions on individual dose defined by the relevant constraint. It is now used as a short description of the process of obtaining the best level of protection from a single source, taking account of all the prevailing circumstances.

32. The Commission stated in Publication 77 that the previous procedure had become too closely linked to formal cost-benefit analysis. The product of the mean dose and the number of individuals in a group, the collective dose, is a legitimate arithmetic quantity, but is of limited utility since it aggregates information excessively. For making decisions, the necessary information should be presented in the form of a matrix, specifying the numbers of individuals exposed to a given level of dose and when it is received. This matrix should be seen as a 'decision-aiding' technique that allows different weightings of their importance to be assigned to individual elements of the matrix. The Commission intends that this will avoid the misinterpretation of collective dose that has led to seriously misleading predictions of deaths.

33. The concept of collective dose was also previously used as a means of restricting the uncontrolled build-up of exposure to long-lived radionuclides in the environment at a time when it was envisaged that there would be a global expansion of nuclear power reactors and associated reprocessing plants. Restriction of the collective dose per unit of practice can set a maximum future global *per caput* annual effective dose from all sources under control. If, at some point in the future, a major expansion of nuclear power were to occur, then some re-introduction of a procedure may have to be considered to restrict a global build-up of *per-caput* dose.

34. The process of Optimization may now be expressed in a more qualitative manner. On a day-to-day basis, the operator is responsible for ensuring the optimum level of protection and this can be achieved by all those involved, workers and professionals, always challenging themselves as to whether protection can be improved. Optimization is a frame of mind, always questioning whether the best has been done in the prevailing circumstances. For the more formal authorisations, which are decided by the regulator in conjunction with the operator, they may in future best be carried out by involving all the bodies most directly concerned, including representatives of those exposed, in determining, or in negotiating, the best level of protection in the circumstances. It is to be decided how the Commission's recommendations will deal with this degree of societal process. However, the result of this process will lead to the authorised levels applied by the Regulator to the source under review.

EXCLUSION OF SOURCES AND EXPOSURES

35. The Commission intends its system of protection to apply to the deliberate introduction of a new controllable source or the continued operation of a controllable source that has deliberately been introduced, i.e. a practice, and to controllable natural sources. Its Recommendations can then be applied to reduce doses, when either the source or the pathways from the source to the exposed individuals can be

controlled by some reasonable means. Sources that do not fall within this definition of controllable are excluded from regulatory control. There are sources for which the resulting levels of annual effective dose are very low, or for which the difficulty of applying controls is so great and expensive, that protection is already optimized and the sources are therefore excluded.

36. In its restated policy the Commission defines what sources and exposures are to be excluded from the system of protection and will not use the term 'exemption'. Exemption or clearance is seen as a regulatory decision that is applied to non-excluded sources by the appropriate regulatory body. That body has the responsibility for deciding when radioactive material is to be released from its control, which is in effect an 'Authorised Release' no different from that specified for effluent discharges after application of the optimization process.

37. Apart from these exclusions, the Commission has aimed to make its recommendations applicable as widely and as consistently as is possible, irrespective of the origin of the sources. The Commission's recommendations thus will now cover exposures to both natural and artificial sources, so far as they are controllable.

NATURAL SOURCES

38. The Commission intends to include explicit recommendations for protection from natural radiation sources. It is clear that it is the controllability of the exposure that determines whether the exposures are excluded from, or included in, the system of protection. In particular, the control of radon-222 is a special case because of its ubiquitous nature.

39. The ICRP Recommendations for radon-222 in Publication 65 have been widely accepted and the Commission proposes they should continue. These suggested a maximum level of dose (the constraint) that was translated into an activity concentration, then followed by an activity concentration range within which an optimized 'action level' would be found (Table 2). As now, the recommendation would be that for exposures above this level, the system of protection is applied. Exposures below the designated level are then excluded from the system of protection. The Commission now refers to this designated level as the **Exclusion Level**.

40. The Commission is now considering an approach analogous to that for radon-222 for protection from the other controllable natural sources. The principal sources of both internal and external exposure in environmental materials are potassium-40 and the decay series of uranium-238 and thorium-232. The Commission is considering recommending a maximum constraint for these, on the grounds that it is impractical to control all natural sources. The constraint, as with radon, would not be expressed in dosimetric quantities but rather as an activity concentration, since that is more appropriate and with a value at the upper end of the existing natural range. The appropriate authority would apply generic optimization, or broad experience on practicability, to find an **Exclusion Level** that is lower than the constraint.

41. The only protective actions are relocation of populations and, if the sources are mainly in building materials, extensive rebuilding. These actions are disruptive and require considerable resources. Thus the Exclusion Level, while lower than the constraint, but probably not by more than a factor of a few, will be somewhere in the naturally existing range, corresponding probably to dose of about a fraction of a mSv annually.

42. Cosmic rays at ground level and the resultant exposures are not controllable. They are therefore excluded from the scope of the Recommendations. Limiting the time spent by passengers and crew at high altitudes is the only action that could control exposure to cosmic rays in aircraft. The average annual effective doses to some aircrew are about 3 mSv, while the exposure of some specialist aircrew and a few professional couriers may be twice as high. The Commission has recommended in Publication 60 that the exposures of aircrew in the operation of jet aircraft should be treated as occupational exposure in its system of protection. The Commission considers that there is no justification for controlling doses to members of the public from flying and these exposures should be excluded.

DOSIMETRIC QUANTITIES

43. There have been some persistent difficulties with, and misunderstandings of, the definitions of the Commission's dosimetric quantities. The Commission will remove these by clarifying its definitions and specifying their application.

44. The Commission uses the **weighted averaged absorbed** dose in an organ or tissue. It no longer uses the term 'equivalent dose' in order to avoid confusion with 'dose equivalent' in translation to other languages. The implicit averaging is valid only if the range of doses is such that the proportional dose-effect relationship applies. There is no proposal to move away from the use of effective dose as currently defined,

$$E = \sum_T w_T \sum_R w_R D_{T,R}$$

45. There is, however, a need to reconsider the basis used to derive the numerical values for both the tissue and radiation weighting factors. There is evidence from a recent report by a Task Group of ICRP Committee 1 that the w_R values for protons and neutrons may need revision (ICRP 2003a). The 2001 UNSCEAR Report gives reduced estimates of the risk of hereditary defects and another Task Group of Committee 1 is developing proposals to simplify the way in which cancer risks are used to establish w_T values.

46. It should be emphasised that effective dose is intended for use as a protection quantity and therefore should not be used for epidemiological evaluations, nor should it be used for any specific investigation of human exposure. Rather, absorbed dose should be used with the most appropriate biokinetic, biological effectiveness, and risk factor data.

47. Those health effects that exhibit a dose threshold result from the loss of function of a significant number of cells in a tissue. The dosimetric situation causing this loss of function is complex. If the dose is approximately uniform over the tissue, the mean absorbed dose is a good starting point. If the dose is far from uniform, the localised damage may not reduce the performance of the tissue, but the localised damage may be severe. All these situations depend heavily on the distributions of delivered dose in position and time. This complexity cannot be reflected in the dosimetric quantities. The only approach is to make qualitative judgements based on the distribution of absorbed dose in location and time. In many cases, there is no need to introduce any weighting based on RBE, because its value will rarely exceed two.

RADIATION EXPOSURE OF PATIENTS

48. The application to the medical uses of radiation for patients requires separate guidance. Limitation of the dose to the individual patient is not recommended as it may, by reducing the effectiveness of the patient's diagnosis or treatment, do more harm than good. The emphasis is then on the justification of the medical procedures.

49. There are three levels of justification of a procedure in medicine. At the first and most general level, the use of radiation in medicine is accepted as doing more good than harm. Its justification is now taken for granted. At the second level, a specified procedure with a specified objective is defined and justified, e.g. chest radiographs for patients showing relevant symptoms. The aim of this generic justification is to judge whether the radiological procedure will usually improve the diagnosis or treatment or will provide necessary information about the exposed individuals. At the third level, the application of the procedure to an individual patient should be justified, i.e. the particular application should be judged to do more good than harm to the individual patient.

50. The subsequent formal Optimization concentrates on the requirement to keep the doses to patients as low as is consistent with the medical objectives. In diagnosis this means reducing unnecessary exposures, while in therapy it requires delivery of the required dose to the volume to be treated, avoiding exposure of healthy tissues.

The generic justification of a defined medical procedure

51. The generic justification of the procedure is a matter for national professional bodies, sometimes in conjunction with national regulatory authorities. The total benefits from a medical procedure include not only the direct health benefits to the patient, but also the benefits to the patient's family and to society. Although the main exposures in medicine are to patients, the exposures to staff and to members of the public who are not connected with the procedures should be considered. The possibility of accidental or unintended exposures (potential exposure) should also be considered. The decisions should be reviewed from time to time, as more information becomes available about the risks and effectiveness of the existing procedure and about new procedures.

The justification of a procedure for an individual patient

52. For complex diagnostic procedures and for therapy, generic justification may not be sufficient. Individual justification by the radiological practitioner and the referring physician is then important and should take account of all the available information. This includes the details of the proposed procedure and of alternative procedures, the characteristics of the individual patient, the expected dose to the patient, and the availability of information on previous or expected examinations or treatment.

Diagnostic Reference Levels

53. These are used in medical diagnosis to indicate that, in routine conditions, the dose to the patient from a specified procedure should not normally exceed the reference level for that procedure as indicated by a measurable quantity such as entry dose in an x-ray examination. These have already been used as Guidance Levels for medical diagnostic procedures in the IAEA Basic Safety Standards and in the Euratom Directive on health protection against ionizing radiation in medical exposure.

RADIOLOGICAL PROTECTION OF THE LIVING ENVIRONMENT

54. The current ICRP position regarding protection of the environment is set out in Publication 60: *"The Commission believes that the standards of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk."* Up until now, the ICRP has not published any recommendations as to how protection of the environment should be carried out. The Commission has recently adopted a report dealing with environmental protection (ICRP, 2003b). This report addresses the role that ICRP could play in this important and developing area, building on the approach that has been developed for human protection and on the specific area of expertise to the Commission, namely radiological protection.

55. The Commission has decided that a systematic approach for radiological assessment of non-human species is needed in order to provide the scientific basis to support the management of radiation effects in the environment. This decision to develop a framework for the assessment of radiation effects in non-human species has not been driven by any particular concern over environmental radiation hazards. It has rather been developed to fill a conceptual gap in radiological protection and to clarify how the proposed framework can contribute to the attainment of society's goals of environmental protection by developing a protection policy based on scientific and ethical-philosophical principles.

56. The proposed system does not intend to set regulatory standards. The Commission rather recommends a framework that can be a practical tool to provide high-level advice and guidance and help regulators and operators demonstrate compliance with existing legislation. The system does not preclude derivation of standards, on the contrary, it provides a basis for such derivation.

57. At present, there are no internationally agreed criteria or policies that explicitly address protection of the environment from ionizing radiation, although many international agreements and statutes call for protection against pollution generally, including radiation. The current system of protection has indirectly provided protection of the human habitat. The lack of a technical basis for assessment, criteria or standards that have been endorsed at an international level, makes it difficult to determine or demonstrate whether or not the environment is adequately protected from potential impacts of radiation under different circumstances. The Commission's decision to develop an explicit assessment framework will support and provide transparency to the decision making process.

58. A framework for radiological protection of the environment must be practical and simple. The ICRP framework will be designed so that it is harmonised with its proposed approach for the protection of human beings. To achieve this, an agreed set of quantities and units, a set of reference dose models, reference dose-per-unit-intake data and effects-analysis will be developed. A limited number of reference fauna and flora will be developed by ICRP to aid assessments, and others can then develop more area- and situation-specific approaches to assess and manage risks to non-human species. ICRP has a unique position in relation to human radiological protection, from which it has played a major role in influencing legal frameworks and objectives at international and national levels. In contrast, the subject of protection of other species is more complex and multi-faceted, with many international and national environmental legislative frameworks and objectives already in place.

59. The Commission proposes that the objectives of a common approach to the radiological protection of non-humans organisms are to safeguard the environment by preventing or reducing the frequency of effects likely to cause early mortality or reduced reproductive success in individual fauna and flora to a level where they would have a negligible impact on conservation of species, maintenance of biodiversity, or the health and status of natural habitats or communities.

60. A considerable challenge for ICRP will be that of integrating any approach to protection of the environment with that of the protection of human beings, bearing in mind that the latter is also the subject of a current, in-depth, review. ICRP can, and is prepared, to play the key role with respect to ionizing radiation in the environment, both in advising on a common international approach, and in providing the basic interpretation of existing scientific information. This will include identifying where further research is necessary - in order for such a common approach to be delivered.

SOME OUTSTANDING ISSUES AND PROPOSED TIMESCALES

61. The Main Commission is preparing a number of supporting documents on which the main recommendations will draw. These include summaries of the health effects of radiation at low doses and the review of RBE values, which together will lead to a document on the decision for revised radiation and tissue weighting factors. Other major issues which are under development and need further discussion are;

    - Exploration into the possibility of specifying a fewer number of numerical constraints than presently exist and whether they can be more coherently explained
    - Clarification of the Exclusion concept and further elaboration of the observation that all releases from regulatory control are 'Authorised releases'
    - A review of the 'critical group' concept as used to represent the hypothetical individual. ICRP has not addressed this since well before the 1990 recommendations.
    - Develop methods by which the optimization of protection can realistically be achieved

62. The intention is to have draft recommendations prepared for discussion with the four Committees late in 2003 so that a well-developed draft is available for the IRPA 11 Congress in May 2004. It is planned to produce the final version in 2005. Table 4 shows a brief compilation of some of the major topics where there will be changes from present recommendations to the new proposals.

Table 4. Brief summary of essential changes expected in the new recommendations

TOPIC	PRESENT RECOMMENDATIONS	NEW RECOMMENDATIONS
Linearity	Linear Non-Threshold i.e. Proportionality	Clarify concept and applicable range, i.e. above a few mSv/yr
Effective Dose	Yes	Yes
Radiation weighting factor	Publication 60	Revised values for protons and neutrons
Tissue weighting factor	Publication 60	New values based on revised risk factors and a simplified basis
Nominal risk coefficient	Publication 60	Total Cancer Fatality similar, but individual organs changed Hereditary use UNSCEAR 2001
Limits	Worker and public in Publication 60	Incorporated into revised constraints
Constraints	See Table 2	Number and complexity to be reduced
Collective dose	Publication 60	Disaggregated and replaced by weighted matrix
Justification	Publication 60	Retained, extended for patient exposure
Optimization	Cost-benefit analysis	Stakeholder involvement
Exemption	Publication 60	Replace by Exclusion
Definition of 'individual'	Publication 29	New consideration
Practice	Publication 60	Retain
Intervention	Publication 60	Incorporate into constraints
Environment (non-human)	Assumed protected in Publication 60	Explicitly addressed
Natural radiation sources	Radon-222 only	Comprehensive treatment

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