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A Critical Review of the Draft 2005 ICRP Recommendations

Proceedings of a scientific seminar held in Luxembourg on
4 November 2004

**Working Party on Research Implications on Health and Safety
Standards of the Article 31 Group of Experts**

Directorate-General for Energy and Transport
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Unit H.4 — Radiation Protection
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FOREWORD

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Under the terms of the Treaty establishing the European Atomic Energy Community, the Community, amongst other things, establishes uniform safety standards to protect the health of workers and of the general public against the dangers arising from ionizing radiation. The standards are approved by the Council, on a proposal from the Commission, established taking into account the opinion of the Group of Experts referred to in Article 31 of the Treaty. The most recent version of such standards is contained in Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.

The European Commission organises every year, in cooperation with the Group of Experts referred to in Article 31 of the Euratom Treaty, a Scientific Seminar on emerging issues in Radiation Protection – generally addressing new research findings with potential policy and/or regulatory implications. Leading scientists are invited to present the status of scientific knowledge in the selected topic. Based on the outcome of the Scientific Seminar, the Group of Experts referred to in Article 31 of the Euratom Treaty may recommend research, regulatory or legislative initiatives. The European Commission takes into account the conclusions of the Experts when setting up its radiation protection programme. The Experts' conclusions are valuable input to the process of reviewing and potentially revising European radiation protection legislation.

In 2004, the International Commission on Radiological Protection (ICRP) offered for public consultation a second Draft of its future Recommendations (Draft 2005 ICRP Recommendations). The European Commission organised, with the help of Working Party on Research Implications on Health and Safety Standards (WP RIHSS) a Scientific Seminar to critically review the 2005 Draft ICRP Recommendations. The Scientific Seminar was held in Luxembourg on 4 November 2004.

The intention of this scientific seminar was to present the line of thinking within ICRP regarding the topics *biological foundations of radiation effects, dosimetric aspects, dose limitation, exclusion, and ethical and legal issues*. Each of these topics was introduced by a representative of the respective ICRP Committee followed by a critical review presented by a challenging speaker. These proceedings contain the critical reviews by the challenging speakers together with a brief summary of the highlights. This document does not cover the ICRP drafts as ICRP Recommendation 103 has been published since.

The Group of Experts discussed this information and drew conclusions that were relevant for consideration by ICRP and by the European Commission. Based on these conclusions, the Commission prepared comments which were sent to the International Commission on Radiological Protection (ICRP) for consideration.

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Head of Radiation Protection Unit

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1 BIOLOGICAL FOUNDATIONS OF RADIATION EFFECTS ON HUMAN REPRODUCTION

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The ICRP report on the risk of hereditary disease is well done. However, there is a major flaw concerning the pathologies which may be a consequence of recessive mutations.

Data on DNA lesions induced by either cell life metabolism or exposure to radiations must be carefully considered.

- Normal metabolism induces about 50,000 DNA lesions per cell and per day.
- These lesions are of various natures (base lesions, single strand breaks etc...) but Double Strand Breaks (DSB_s) are very rare among them.
- Indeed, the very large majority of these lesions are correctly repaired.
- The additional lesions induced by exposure to 1 Gy of low let radiations correspond to those occurring during 1 H cell life, with the exception of DSB_s.
- Exposure to 1 Gy is assumed to induce about 40 DSB_s.

DSB_s are particular lesions because their repair is error prone. Typically, their repair leads to DNA deletions.

Deletions most frequently lead to allele inactivations.

Allele inactivations frequently correspond to recessive mutations, at contrast with gene activations which are rather of dominant expression.

Thus, looking for hereditary effects of ionizing radiations should lead to look for an increase of recessive pathology.

Human genetics has made very important progress recently. Most recognized hereditary diseases were unknown a few decades ago, and almost all genes presently known have been identified since the nineties. However, it would be very hazardous to claim that our present knowledge is fully representative of the question.

A short analysis of present data reveals serious uncertainties:

- number of genes : 30,000;
- number of dominant diseases : < 8000;
- number of recessive diseases : < 2000;
- number of X-linked diseases : # 500, among which 80-90% are recessive;
- relative size of the X chromosome : 5%;
- relative gene density of the X chromosome, compared to average autosomes : about 0,8;
- probability of counterselection during evolution of genes inducing recessive diseases higher for the X chromosome (expression in males) than autosomes (expression in homozygotes);
- probability of identification much higher for X chromosome than autosomes (X-linked traits).

Thus, even if X chromosome and autosomes had similar gene density, one should expect about 20 fold more autosomal than X-linked recessive diseases, i.e. about 10,000 instead of 2,000 autosomal recessive disorders.

This probable strong underestimate of autosomal recessive diseases is related to their diagnostic difficulty. Their recessive condition prevents familial recurrence, especially in medically developed countries with small sibships. All are rare diseases and their rarity prevents paediatricians to repeatedly observe the same disease during their life. Many of them belong to congenital malformation syndromes (about 6% of births) which remain without diagnosis.

Beside congenital malformations, these recent years have focused attention on multifactorial diseases, in which genetic contribution appears of prime importance. They correspond to pathologies of late onset, which affect about 60% of the human population. The genetic mechanisms involved are multiple, including genome instability, allelic expansions, microdeletions.

The highest prevalences are predispositions to cancer, whose genetic origin is dominant for the predisposing trait and recessive for the pathology initiation. For instance, about 1 per 1000 of the population is predisposed to each colorectal and breast cancers. This was totally unknown in the mid eighties! Neurodegenerative diseases, which affect senescent persons principally, also have a strong genetic determinant.

Today, risk estimates are principally based on three sets of data: animal models (principally ancient experiments), descendants of Hiroshima and Nagasaki survivors, epidemiological studies of patients having been medically exposed. None of them shows a clear increase of hereditary pathology following radiation exposure.

However, the complexity of diagnosis and the frequent late onset of multifactorial diseases make animal experimentation quite irrelevant. Data on atomic bombing survivors and patient progeny have a major flaw: several generations are necessary for the passage to homozygote of induced recessive mutations. There is not a sufficient delay to observe their expression today.

In conclusion, we only know that there is no detectable increase of dominant mutations and chromosome aberrations in the populations analysed. New approaches are being developed, allowing whole genome analysis in one step. They will give good opportunities to look for mutagenesis without "a priori" considerations.

For these reasons, it would be a lack of caution to change risk estimates today.

Such estimates may change in the next future, but this should be the consequence of knowledge improvement, in particular about recessive mutations and pathologies.

2 A CRITIQUE OF THE DRAFT 2005 ICRP RECOMMENDATIONS: DOSIMETRY ASPECTS

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The author was invited to participate as a Challenging Speaker at the European Conference on the Draft 2005 ICRP Recommendations, held by the European Commission, in Luxembourg, on 4 November 2004. This text follows closely the format of the presentation made under the 2nd Theme of the Conference, "Dosimetric Aspects", but is an extension of the presentation and also to some extent takes account of comments and suggestions made at the meeting.

The presentation took the form of a critique, presented as a series of challenging statements - propositions - intended to highlight what, in the author's view, were the main defects in relation to dosimetry in the ICRP Draft Recommendations. This text adopts a similar approach: each proposition is presented, explained and, hopefully, justified. Although these following comments are presented as "challenges", as that was the author's remit, the intention is, as far as possible, to be constructive.

The ICRP Draft Recommendations² cover 81 pages, and are based on material contained in Foundation Documents³. The main purpose of this contributor's presentation, and of this text, is to challenge some key issues in the Draft Recommendations relating to dosimetry, largely relating to Chapter 3, "Quantities used in Radiological Protection". Reference is also made to the related Foundation Document⁴.

The author is a member of the UK Committee Examining Radiation Risks from Internal Emitters (CERRIE⁵), which considered and reported on a number of relevant issues, and where appropriate the conclusions reached by CERRIE have been quoted. The views expressed in this document are, however, those of the author and do not necessarily represent the views of any other person or organisation.

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² 2005 Recommendations of the ICRP, Draft for Consultation, October, 2005.

³ The draft recommendations are based on a series of Foundation Documents from the various ICRP expert committees. These were unpublished at the date of the Conference, but preliminary versions were made available to the Challenging Speakers.

⁴ ICRP Foundation Document, Committee 2: Basis for Dosimetric Quantities used in Radiological Protection (Dietze et al.), Draft for Discussion, 22 August, 2004 (ICRP/22/42/04).

⁵ CERRIE: Committee Examining Radiation Risks from Internal Emitters, a UK Committee appointed by the Minister for the Environment to "consider risk models for radiation and health that apply to exposure to radiation from internal radionuclides in the light of recent studies and to identify any further research that may be needed." The Committee commenced work in December, 2001, and reported in October, 2004. The Final Report is available by download from the CERRIE website (www.cerrie.org), or by post from the UK National Radiological Protection Board (www.nrpb.org).

2.1 Purpose and Scope of the ICRP Recommendations

The ICRP states the fundamental aim of radiological protection, as set out in 1990 and still representing the Commission's position, as follows⁶:

"The primary aim of radiological protection is to provide an appropriate standard of protection for man without unduly limiting the beneficial actions giving rise to radiation exposure..."

The system of protection set out in the 2005 (draft) recommendations is intended to be seen as a natural evolution, and further clarification, of the 1990 Recommendations and later documents. The first issue relates to whether the 2005 recommendations actually achieve that aim.

Proposition 1. - With respect to dosimetry, the ICRP Draft lacks clarity. The document does not clearly define the purpose, scope and limitations of its new recommendations, and the extent to which previous recommendations (on dose) are to be retained is unclear. The intended scope and restrictions of ICRP dosimetry become apparent only by stages in the Draft Recommendations, and in some cases, confusion is caused by apparently inconsistent statements.

The ICRP Aim and a summary of the way in which the recommendations may be applied are set out in the Summary of Recommendations⁷. Some key statements are quoted below.

"The Commission's recommendations are based on a simple... general system of protection that... will provide a basis for the more formal systems needed by... managements and regulators....."

"The most fundamental level of protection is the source-related restriction on individual dose called a dose constraint....."

The concept of *effective dose* is central to the ICRP's current methodology and draft proposals for radiological protection. Although no change to the definition⁸ of this concept is currently proposed, the use of the word *dose*, particularly in the Summary and in the earlier sections of the main Recommendations, tends to be ambiguous and would preferably be defined at an earlier stage in the document. As it is, the explanation of effective dose and the reasons for its central position in radiation protection are not explained until Chapter 3 of the Draft Recommendations, long after the term *dose* has been used on numerous occasions in the text. The intended areas of application of the concept and, particularly, restrictions on its use are extremely important, and should be defined explicitly and the rationale explained at a specific point in the Recommendations. As it is, the applications and restrictions emerge only gradually throughout the text, which leads to a loss of clarity and potential for misunderstanding.

The following statements taken from the Recommendations demonstrate the problem. The first indication of the intended use of effective dose, and restrictions to its use, comes in Section 3.1 (para. 36):

(36) The Commission's dosimetric quantities and nominal risk coefficients are intended for use in radiological protection, including the assessment of risks in general terms. Specific investigations, such as retrospective assessments of risks of stochastic effects in a known population of identified individuals, are best undertaken using specific data.

⁶ ICRP Publication 60, "1990 Recommendations of the International Commission on Radiological Protection", Annals of the ICRP 21, 1991.

⁷ 2005 ICRP Draft Recommendations, Oct. 2004. Summary, paragraphs S3-S6.

⁸ *Effective dose* was first defined in ICRP publication 60 (1991), replacing *effective dose equivalent* introduced following ICRP publication 26 (1977).

This paragraph appears to exclude the retrospective application of effective dose estimation. However, this exclusion seems unrealistic as in order both to demonstrate compliance with dose constraints and to estimate doses to individuals for record-keeping purposes, it will be necessary to carry out retrospective calculations using real data. However, the point appears to be re-affirmed in Section 3.3.3 (para. 54):

(54) It must be stressed that effective dose is intended for use as a principal protection quantity for establishment of prospective radiation protection guidance. It should not be used to assess risks of stochastic effects in retrospective situations for exposures in identified individuals, nor should it be used in epidemiological evaluations of human exposure, because the Commission has made judgments on radiation risks in the derivation of 'detriment' for the purpose of defining tissue weighting factors. Its main use is to enable external and internal irradiation to be added as a means to demonstrate compliance with the Commission's quantitative restrictions on dose, which are expressed in effective dose. In this sense effective dose is used for regulatory purposes worldwide.

The combined effect of these two quoted paragraphs is surely to leave the reader with the firm impression that retrospective calculation of effective dose for the purpose of compiling dose records for individuals, or for demonstrating compliance with restrictions, is not an acceptable application of the methodology, although in practice such calculations are (and must be) commonly made. The point is addressed again in Section 3.5.1, Control of Stochastic Effects (para.88), which appears to confuse the issue still further:

(88) Although dose records are for individuals the dose coefficients on which they are based are derived for reference individuals. If doses approach or exceed the dose constraints, then investigations may need to be undertaken to address workplace and individual specific characteristics in the dose assessment. The committed effective dose coefficients from the intake of a radionuclide are also used for prospective dose estimates of individual members of the public. In these cases a commitment period of 50 years is used for the adult and the effective dose to age 70 years for infants and children.

Thus, it is now explained that the reason retrospective calculations are not valid for specified individuals is because the dose coefficients on which calculation of effective dose depends are generic. In specific cases it will be necessary to include "individual specific characteristics in the dose assessment", although it seems that the dose so calculated should not apparently be regarded (at least formally), as an effective dose. In the author's view, the combined effect of all these explanations is confusing.

The position is stated more clearly in the final section of the Foundation Document⁹ and summarised as follows:

It should be noted that the dosimetric models, conversion coefficients and other parameters recommended by the Commission have been developed principally for planning and assessing normal occupational exposures, planning for discharges into the environment and for generic assessments of doses. These are circumstances in which doses are low. The dose coefficients are not intended and should not be used for detailed retrospective dose assessments, for example following high occupational exposures or for epidemiological studies, when more specific information on the individual and the exposure conditions are needed. In such situations all sources of uncertainty should be taken into consideration. Information to take into account can include individual anatomical and physiological data, specific information on radionuclide source-term and biokinetics and the direction of radiation fields in relation to external exposure. For radiological protection, the extent to which individual dose assessments are needed will depend upon the radiation dose received. If doses are low then the use of default parameters may well be sufficient. If, however, exposures approach or even exceed dose limits then individual specific dose assessments may well be needed.

⁹ Foundation Document, ICRP Committee 2: Basis for Dosimetric Quantities used in Radiological Protection (Dietze et al.), Draft for Discussion, 22 August, 2004 (ICRP/22/42/04). Chapter 6 Uncertainties and Judgements in Radiological Protection, p.36, fourth paragraph.

Thus, it is clearly foreseen that there will be a wide range of circumstances in which dose assessments may be required, ranging from the formal, prospective assessment of a proposed practice for the planning and regulatory purposes, through retrospective assessment of doses resulting from the operation of a given practice (both in order to demonstrate compliance and for the calculation of individual doses for record-keeping purposes), to the determination of doses for epidemiological investigations. Taken together, the various ICRP statements and explanations make it clear that the use of effective dose is certainly *intended* primarily for the first of these purposes, and is certainly *not intended* for the last, whilst the situation is less certain through the spectrum of possibilities between the two extremes. In any given intermediate situation, a competent national body might well be able to decide and implement the appropriate course of action, but this would probably be a consequence of experience rather than of following ICRP recommendations, which are certainly not clear and at times seem to be conflicting.

Recommendation 1 - Greater clarity in the purposes, limitations and scope of application of ICRP's primary radiological control parameter, *effective dose*, needs to be achieved. Both the intended and the unacceptable applications of effective dose should be clearly set out in a definitive section of the Recommendations, and in the case of inappropriate applications, it should be made clearer what alternative procedures should be adopted.

2.2 Effective Dose: a Blunt Instrument

The Commission has introduced a single quantity, the *Effective Dose*¹⁰, as a dosimetric quantity, which is intended to be quantitatively related to the effects of all types of radiation, regardless of whether the radiation originates from outside or inside the body, and regardless of whether the whole, or merely part, of the body is irradiated¹¹. This raises the Key Question:

Is the concept and intended use of the single whole body parameter, Effective Dose, sufficient, in itself, to achieve the stated Aim, taking into account the diverse sources of irradiation, both external and internal, to which individuals may be exposed?

Proposition 2.- The exclusive use of *Effective Dose* as the control parameter in radiological protection is a major and unnecessary limitation, and may give rise to anomalies in the control of specific sources of radiation.

Effective dose is defined as a calculable¹² quantity, applicable to the whole body, which when multiplied by an overall risk factor will lead to a figure for the total detriment from that level of irradiation, irrespective of source type or location. The advantages of a single-parameter quantity for use in radiological protection - simplicity, transparency, universality - are apparent. However, there is an important disadvantage created by the fact that, if internal emitters are to be included, actual irradiation may be so heterogeneous that the main exposure detriments could be limited to a few, or in the extreme case only one, organ or tissue. Thus, whilst an estimated effective dose may be within a particular constraint (say 20 mSv), it is possible for this dose to have arisen in many ways, from at one extreme the external irradiation of the whole body, to the other extreme, in which the whole of the effective dose results from the internal irradiation of a single organ. Thus, whilst in principle the total risk of "detriment" will, of course, be the same in either case, the actual manifestations of the "detriment" would probably differ, and the various detriments might not be regarded as equally "acceptable" by the recipients (particularly, it may be suggested, if the outcome were to be an unusually high incidence of an otherwise uncommon form of cancer). This issue may be made clearer with

¹⁰ See Footnote 8.

¹¹ 2005 ICRP Draft Recommendations, para. 35.

¹² But not *measurable*, either in principle or in practice (Draft Recommendations, para. 55).

specific examples, such as were considered and reported in similar terms by the CERRIE Committee¹³. The relevant paragraphs are quoted in full, below (CERRIE Report, para. 48 & 49):

"48. Committed effective dose can be seen to provide a convenient whole body parameter for use to ensure compliance with dose limits and constraints, which are based on judgements regarding tolerable levels of risk. However, use of effective dose does not reveal any information about the way in which the dose is made up, and indeed can conceal very different contributions to dose and risk from the irradiation of individual organs or tissues, and in the time-course of dose delivery. For example, consider groups of individuals each exposed to a committed effective dose of 20 mSv. The doses to each group may comprise an almost infinite variety of components a group might have received. Possible variations include:

- (a) a uniform whole body dose of 20 mGy from external low LET radiation;
- (b) a committed equivalent dose of around 400 mSv to the thyroid (with very low doses to other tissues) after ingestion of ¹³¹I (thyroid w_T = 0.05);
- (c) committed equivalent doses largely to liver (~140 mSv) and skeletal tissues (bone surface ~670 mSv; red bone marrow ~30 mSv) after ingestion of ²³⁹Pu (absorbed doses of ~7 mGy to liver, 34 mGy to bone surfaces and 2 mGy to red bone marrow); and
- (d) any other equivalent combination.

49. Thus, whilst a dose of 20 mSv implies an associated risk of $0.02 \times 5 = 0.1$ fatal cancers per 100 population, in case (a) these should encompass the whole range of cancer possibilities, case (b) would be expected to be restricted to thyroid cancers, and (c) would be expected as an appropriate mix of leukaemia, liver and bone cancers. Furthermore, whilst both the external dose and the internal dose from ¹³¹I would be delivered within the year following intake, the dose from ²³⁹Pu, because of its long half-life and long retention times in tissues, would be delivered over 50 years, with only about 5 % in the first year. Such differences suggest that circumspection is required in the use of effective dose when applied to different radionuclides singly or in combination, as the interpretation of a single, whole body quantity is bound to be ambiguous."

The application of the effective dose constraint of 20 mSv would (in principle) limit the overall consequence in each case to the same level of detriment (i.e. to an incidence of fatal cancers of approximately 1 per 1000 people), in case (a) the outcomes would (in principle) encompass a wide range of types of cancer, in case (b) the outcome to be expected would be entirely as cancer of the thyroid, and in case (c), an appropriate mix of liver, leukaemia and bone cancers. In cases (b) and (c), the incidence of these diseases amongst those so irradiated would probably run at a very significantly enhanced levels, and such outcomes would hardly be regarded as acceptable, particularly by the affected groups. That most responsible regulators, under such circumstances, would apply further restrictions specifically to reduce thyroid (or other specific organ) dose seems highly likely. However, the ICRP do not make this a formal requirement, and this fact appears to leave an unnecessary loophole in the recommendations.

The proposition that exclusive use of effective dose may give insufficient protection is based on this type of argument. It is now suggested that keeping within a specified (effective) dose constraint should be regarded as a *necessary* but not in itself a *sufficient* condition for the operation of a practice, and that secondary and more specific constraints should be applied in addition. There are undoubtedly many ways in which this might be achieved and which the Commission might consider. One possibility would be to impose additional constraints related to organ doses, either specifically or in general. For example, this might be done by the introduction of the constraint that no individual organ/tissue components of effective dose

¹³ Report of the UK Committee Examining Radiation Risks from Internal Emitters (CERRIE), October, 2004, Section 2.6, para. 48 & 49 (available from the UK National Radiological Protection Board).

should exceed a certain fraction (say 10%) of the total. Alternatively, constraints could be applied to the *equivalent* doses to specified organs or tissues. None of these needs in practice impose much additional assessment workload on regulators or industrial operators, because in order to calculate effective dose, the required organ-specific equivalent doses would necessarily have been calculated already.

In a wider context, the introduction of additional constraints to that of effective dose may be seen as an application of the principle of "optimisation", although not perhaps in the way envisaged in the Recommendations. For example, under Section 5.2, "The Principles of Protection", the Draft Recommendations state (para. 138):

(138) The radiological principles which ensure the required levels of protection may be characterized by the use of quantitative primary dose constraints for all situations within the scope of the recommendations and, in normal situations only, the use of the dose limits. These are a necessary but not sufficient criterion for protection and therefore have to be complemented by the requirement to optimize protection to enhance the level of protection achieved.

It is suggested that it is entirely within the spirit of this statement, of the need to enhance the level of protection afforded by the use of primary dose constraints, that ICRP introduce a subsidiary dose constraint mechanism along the lines suggested¹⁴.

Recommendation 2 - Constraint of Effective Dose alone is inadequate to meet the ICRP Aims for radiological protection. Whilst retaining constraints to effective dose as a necessary condition in radiological protection, consideration should be given to defining additional secondary constraints to limit radiation doses to organs, either generally or specifically.

2.3 Uncertainty in Dose Estimates: an unevaluated limitation

The ICRP Recommendations consider uncertainty largely in the context of the estimation of risk¹⁵, and hardly, if at all, in the context of uncertainty in the estimation of dose. However, the need to consider uncertainty quantitatively is apparent from a number of statements, such as that following, from Section 3.5, "Practical application in radiological protection" (para. 88):

(88) Although dose records are for individuals the dose coefficients on which they are based are derived for reference individuals. If doses approach or exceed the dose constraints, then investigations may need to be undertaken to address workplace and individual specific characteristics in the dose assessment...

This statement apparently begs the question of how close such an approach will need to be in order to trigger the specific action. Whether an estimated dose to an individual "approaches" a constraint can only be judged in terms of possible uncertainties in making the estimate, on which ICRP give no guidance.

Proposition 3. - The omission of consideration of, or allowance for, uncertainties in dose estimation seriously undermines confidence in the ICRP's ability to demonstrate

¹⁴ Note added following the Luxembourg Conference: In his final summing up at the end of the Luxembourg Conference, Dr Roger Clarke, clearly not impressed by this suggestion, referred to my proposal as one of "abandoning effective dose". This was, and is, an incorrect interpretation of the proposal, which is for the retention of the constraint of effective dose as a necessary primary condition, but to supplement this by an additional constraint or constraints to limit organ doses, which might otherwise reach undesirable levels. – JPD.

¹⁵ 2005 ICRP Draft Recommendations, Section A.3.1: *Uncertainty and sensitivity analysis*, para A18.

achievement of its primary aim of providing an appropriate standard of radiological protection.

The CERRIE Committee considered uncertainties in dose estimates (both radiation-weighted and effective dose) at considerable length¹⁶, reaching the conclusion that assessment of uncertainties in dose and risk estimates should be an important component of the dose estimation process.¹⁷ Only in cases where prospective calculations suggested that doses were "well below" regulatory dose constraints (or limits) would omission of specific consideration of uncertainties be justified¹⁸. The Committee concluded that non-trivial uncertainties arise at all stages in the dose assessment process, and that overall uncertainty in estimates of effective dose would almost always cover a wide range, encompassed by a multiplying factor of 2-3 both above and below the estimated central value of dose¹⁹. In some cases, this factor might be up to or exceed an order of magnitude, again in either direction.

Such considerations might help in the interpretation of otherwise vague statements in the ICRP documents. For example²⁰:

"The Commission considers that the effective dose can be used retrospectively for demonstrating compliance with dose limits provided that exposures are small in comparison to the limits. If exposures are higher and above dose limits more specific circumstances of exposure and information on the individual may be needed."

The use of the word "small" can surely only imply "taking likely limits of error and uncertainty into account"? In which case, given the wide range of possible uncertainty often involved, the use of specific data and quantitative estimation of uncertainties may be necessary even in cases where the initial estimations of exposure are less than 10% of the relevant constraints.

CERRIE also noted²¹ that ICRP had, up to that time, chosen not to address the issue of uncertainties directly in its publications, and the CERRIE working group was critical of this attitude.

In the current draft proposals, inclusion of estimates of uncertainty is not made a requirement of the dose assessment process. The Commission rationalises this attitude only at the end of its Dosimetry Foundation Document²², by explaining that it *"takes the position that the dosimetric models as well as the parameter values that the Commission recommends for determining doses from quantitative information about radiation fields in the environment or from intakes of radionuclides are not subject to uncertainty."*²³ This reinforces a statement earlier in the same document where, with reference to radiation weighting factors, it is proposed that *"values of w_R are fixed by convention and by definition they are not associated with any uncertainty."*²⁴

The apparent disparity in attitude, between CERRIE and ICRP, appears to arise, at least in part, because ICRP consider they are discussing only prospective assessments, for "planning

¹⁶ CERRIE Report, section 2.7, Uncertainties: para. 51-65.

¹⁷ CERRIE Report, Chapter 5: Conclusions, para. 8.

¹⁸ As with the ICRP's related statements, the warning is still in essence paradoxical.

¹⁹ In the CERRIE Report, the range limits referred to were the 5th and 95 percentiles of a hypothetical log-normal distribution.

²⁰ ICRP Committee 2: Basis for Dosimetric Quantities used in Radiological Protection (Dietze et al.), section 3.3, last paragraph.

²¹ CERRIE Report, section 2.7, Uncertainties: para. 64.

²² Foundation Document, ICRP Committee 2: Basis for Dosimetric Quantities used in Radiological Protection (Dietze et al.), Draft for Discussion, 22 August, 2004 (ICRP/22/42/04). Chapter 6 "Uncertainties and Judgements in Radiological Protection".

²³ Foundation Document, ICRP Committee 2: p.36, third paragraph.

²⁴ Foundation Document, ICRP Committee 2: last sentence on p.19.

and assessing normal occupational exposures, planning for discharges into the environment and for generic assessment of doses".²⁵ CERRIE, in contrast, was undoubtedly attempting to determine what level of risk attached to real people, and were therefore concerned to include real doses and the associated uncertainties in their evaluation.

By restricting assessment of effective dose entirely to prospective evaluation, using formal models and reference individuals, and by defining values of parameters and weighting factors, ICRP claim to dispose of issues relating to uncertainty.²⁶ However, such an attitude is surely unrealistic, for reasons given below.

Firstly, whilst specific values of parameters and weighting factors for models may ultimately need to be selected, as the models themselves, whether biokinetic or dosimetric, set out to replicate human physiology, the more closely the parameters and factors reflect this the more realistic and effective do the models' applications become. So it cannot be true to suggest that, because a value for a particular model parameter has been *selected* there is no error associated with it.

Secondly, whilst it is possible to define a formal process for *prospective* evaluation, in which no uncertainty exists, the tests of such an evaluation will necessarily be *retrospective*, and based on observational quantities (e.g. biokinetic parameters, environmental concentrations, etc.) and the habits and physiologies of real people. If ICRP is to demonstrate the ability to achieve its stated aim "to provide an appropriate standard of radiological protection for man",²⁷ then the ability to compare the actual outcome of a process with the formal prediction (on which the regulations to control the outcome would have been based) is an obvious necessity.

Thirdly, in practice to limit the ICRP recommended methodology entirely to prospective assessment would appear to defeat many of the objectives of radiological protection. For example, how could dose records for individuals have any credibility unless based on actual data relating to the individual concerned? How could public stakeholders have any confidence in the safety of an industrial operation in the absence of retrospective demonstration of exposures (say to critical groups)?

Given the above, it seems unlikely that ICRP actually mean what they appear to mean (despite stating it so specifically) in relation to the limitations of assessment of effective dose. Whilst it is quite clear that the use of effective dose in any sort of epidemiological study, or to assign specific causes to clinical manifestations, is totally without scientific justification, the use of retrospective assessments to demonstrate the correctness or otherwise of earlier prospective assessments is not only justified, but is necessary confirmatory exercise without which confidence in ICRP methodology cannot be achieved.

Recommendation 3 - That the ICRP adopt the recommendation from the CERRIE Report, that where appropriate, dose and risk estimates should be combined with an appreciation and an explicit statement of the uncertainties involved. This approach would help identify those situations in which a precautionary approach might be appropriate (and is greatly to be preferred over one in which conservative or pessimistic estimates are arbitrarily introduced).

²⁵ Foundation Document, ICRP Committee 2: fourth paragraph.

²⁶ Uncertainties in the defined quantities are held to be non-existent. Whilst it is certainly possible to claim that the definition of a quantity is not subject to error, it does not follow that measurements made using that quantity are free of uncertainty.

²⁷ 2005 ICRP Draft Recommendations: Summary, para. S2 (p.1).

2.4 Radiation weighting factors

Proposition 4. - The present set of radiation weighting factors is insufficient to represent the wide range of biological effectiveness of electrons of low to high energy.

Calculation of *equivalent doses*²⁸ to individual organs and tissues requires the use of *radiation weighting factors*, w_R , to allow summation of absorbed dose from ionising radiations of various types. For such radiations, defined values of w_R for each type of radiation have been selected by the ICRP, based on consideration of the available evidence of the radiations' *relative biological effectiveness* (RBEs). It is recognised that the selection of appropriate w_R values is by nature a compromise, between the need for simplicity in the regulatory process on the one hand, and the actuality of biological complexity on the other. The CERRIE Committee considered these procedures at considerable length, and with reference to the ICRP methodology for selection of generic radiation weighting factors (w_R), stated as follows²⁹:

“It is clear that this is a broad-brush simplification for radiological protection purposes. In a rigorous scientific sense, this procedure would not be regarded as acceptable. However, as a procedure in radiological protection, this approach can be defended on the grounds of simplicity, practicality and transparency – provided, of course, that the outcome can be shown not to have been unduly affected by the simplification.”

In relation to w_R for low energy electrons, this author now suggests that the ICRP have taken an oversimplified view, and that the universal adoption of $w_R = 1$ for all such emissions (high/low energy beta decay, Auger emissions) will lead to a systematic underestimate (albeit usually small) in estimates of effective dose. This may be especially important for the low energy beta emissions from the tritium nuclide (³H).

Experimentally, for internal beta emitters, RBEs around 1 are observed for particle energies greater than around 50 keV up to several MeV, but for lower beta energies the RBEs observed may be higher. Beta emission from tritium (mean beta energy 5.7 keV) has been particularly extensively studied, and RBEs range from 1 - 3.5 from exposure to tritiated water (HTO) or organically bound tritium³⁰ (OBT). Assignment of a value for the tritium radiation weighting factor (w_R) in the region of 2 - 3 would, therefore, appear to be more in line with the evidence than the proposed single value ($w_R = 1$), and likewise for other similar low-energy beta emitters³¹.

In the Draft Recommendations, the ICRP argues³² that use of a single w_R value for all photons and electrons is a justified simplification in the determination of radiation weighted organ doses because other parts of the calculation are more imprecise; that is, calculation of the distribution of radionuclides in the various tissues and organs of the body, and the corresponding organ doses, is accompanied by large uncertainties, chiefly arising from uncertainties in the parameters used in the models. However, whilst the uncertainties described can undoubtedly lead to uncertainties in organ doses of factors considerably greater than two, such deviations are likely to vary randomly in either direction - i.e. to give rise to uncertainty in dose estimates both above and below the hypothetical "central value". In contrast, the uncertainty introduced by systematically using a radiation weighting factor for low

²⁸ Recommended terminology now *radiation weighted dose*.

²⁹ CERRIE Report, section 2.2, para. 21.

³⁰ That is, OBT in general - RBE values for some specific tritiated organic compounds, which act as precursors for DNA synthesis and result in tritium bound to DNA, may be considerably higher.

³¹ The CERRIE Committee as a whole were divided this issue, about half taking the view expressed here, the other half considering that $w_R = 1$ for all electrons was a justifiable approximation (*CERRIE Report, Annex 2B, para. 13 on p.37*).

³² Draft Recommendations, section 3.4.1, Radiation Weighting Factors, para. 64.

energy electrons which is unrealistically low must always lead to a lower estimate of dose. Even though this systematic error is probably smaller than the afore-mentioned random errors, this fact in itself is not a good argument for unnecessarily using an inappropriate value for the radiation weighting factor. In this context, the position adopted by the ICRP in relation to electrons contrasts with the treatment accorded to neutrons, for which a continuum of values, ranging from ~3 to ~20 dependent on neutron energy, are now proposed through application of a formula³³.

The RBEs on which the selected values for radiation weighting factors are determined are experimental quantities, although usually not determined for human end-points. However, the rationale for an enhanced biological effectiveness for low energy electrons (relative to higher energy electrons or for gamma-energy photons) is now well supported by microdosimetry considerations, as acknowledged by the ICRP³⁴:

(100) The accumulation of cellular and animal data relevant to radiation tumorigenesis have, since 1990, greatly strengthened the view that DNA damage response processes in cells are of critical importance to the post-irradiation development of cancer. These mechanistic data on cellular response and animal tumorigenesis together with rapid advances in knowledge of the cancer process in general, give increased confidence that detailed information on DNA damage response/repair and the induction of gene/chromosomal mutations can contribute significantly to judgments on cancer risk at doses between a few mSv and a few tens of mSv; also to associated judgments on RBE/radiation weighting and dose rate effects. Of particular importance are the advances in understanding of the induction by radiation of complex forms of DNA double strand breaks, the problems experienced by cells in correctly repairing these complex forms of DNA damage and the consequent appearance of cancer-related gene/chromosomal mutations. Advances in the microdosimetric aspects of radiation-induced DNA damage have also contributed significantly to this understanding.

In general, the lower the electron energy, the greater the mean density of ionisation along the track: for example, the mean energies and LET values for beta particles emitted by ¹³⁷Cs (taken as a typical medium energy electron) and ³H nuclei are 170 keV and 0.52 keV/μm (¹³⁷Cs), and 5.69 keV and 12.1 keV/μm (³H). Thus, for a tritium beta particle absorbed in water/tissue, the mean separation between ion-pairs will be around 3-4 nm, whilst for the higher energy ¹³⁷Cs, around 70-80 nm. The likelihood of producing a *double-strand* break in DNA is consequently greater, on average, for a tritium beta particle traversing a DNA molecule (double helix diameter around 2 nm) than for a caesium-137 beta particle³⁵. Whilst the ICRP appear to have accepted that the mechanistic understanding derived from such considerations "can contribute significantly to judgements on cancer risks....also to associated judgements on RBE/radiation weighting...", it is suggested that the Commission have not taken these factors sufficiently into account when defining $w_R = 1$ for all electrons.

The ICRP summarise their position as follows³⁶:

(67) While there are good arguments for continuing to keep w_R for low-LET radiations equal to 1, it is important to state that this simplification is sufficient only for the intended applications of the quantity effective dose, e.g. for dose limitation, assessment, and controlling of doses, but not for the retrospective assessment of individual risks of

³³ Draft Recommendations, section 3.4.1, Radiation Weighting Factors, para. 68 *et seq.* and formula 8 (para. 74); see also Table 8.

³⁴ Draft Recommendations, section 4.2.1, Risk of Cancer, para. 100.

³⁵ The assertion is qualitatively true, but the mechanism is actually more complex than the averages suggest. Both the production of secondary electrons ("delta rays"), and the energy reduction of the original electron, lead to a significant proportion of higher-than-average LET regions, and for ¹³⁷Cs beta particle it is estimated that around 30% of the biological damage is generated in the higher-LET regions (so-called "track ends").

³⁶ Draft Recommendations, section 3.4.1, Radiation weighting factors; para. 67.

stochastic effects from radiation exposures or for use in epidemiological evaluations. In those cases, more detailed information on appropriate RBE values should be considered.

In my view, the arguments presented are not good ones, and are likely to lead to avoidable systematic error. There is now sufficient evidence for the ICRP to change its view, and recommend a higher value of w_R for low energy electrons.

Note added following the Luxembourg Conference: An additional issue is involved when considering the biological effectiveness of low energy electrons if these are emitted from nuclei located close to sensitive sites. This arises from the relatively short range of such electrons in relation to cellular or even cell nuclear, dimensions. The consequence is likely to be a marked increase in biological effectiveness if the nuclide concerned is preferentially located within a cell nucleus, or even bound to DNA. Thus, for tritium, other low energy beta emitters, and Auger emitters, the nuclide location is likely to be a very important factor in determining biological effect. These phenomena are described in the ICRP Foundation Document³⁷, and are further acknowledged in the Draft Recommendations³⁸. For example:

From the Foundation Document:

Extreme cases of dose distribution in homogeneity result from the deposition of tritium or ¹²⁵I labelled DNA precursors (thymidine, desoxycytidine) after incorporation into DNA in cell nuclei. Due to specific location of the emitter and very short range of tritium beta radiation and ¹²⁵I Auger electrons, cell nuclei can be exposed to a dose which is much higher than the average dose in the cell and all the more so in the organ or tissue. Therefore tritiated DNA precursors are much more radiotoxic than tritiated compounds which are not specifically located in the cell nucleus like tritiated water (Streffer et al. 1977). Whereas aggregates of the proliferating cells' nuclei should be considered in this rare case of internal exposure as cell-targets and appropriate average dose in nuclei as the average organ or tissue dose, a concept considering these dose heterogeneities still has to be developed. Another approach to quantification of the health effects of predominantly intranuclear exposure and its application for radiological protection purposes, is directly based on comparisons of relevant biological effects in mammals with ones of external or homogeneous internal (tritium oxide) irradiation like that done with regard to radon and its daughters (ICRP 1994c).

From the Draft Recommendations:

(50) For radiations emitted by radionuclides residing within the organ or tissue, so-called internal emitters, the absorbed dose distribution in the organ depends on the penetration and range of the radiations and the homogeneity of the activity distribution within the organs or tissues. The absorbed dose distribution for radionuclides emitting alpha particles, soft beta particles, low-energy photons, and Auger electrons may be highly heterogeneous. This heterogeneity is especially significant if radionuclides emitting low -range radiation are deposited in particular parts of organs or tissues, e.g. plutonium on bone surface or radon daughters in bronchial mucosa and epithelia. In such situations the organ-averaged absorbed dose may not be a good dose quantity for estimating the stochastic damage. The applicability of the concept of average organ dose and effective dose may, therefore, need to be examined critically in such cases and sometimes empirical and pragmatic procedures must be applied. ICRP has developed dosimetric models for the lungs, the gastrointestinal tract and the skeleton that take account of the distribution of radionuclides and the location of sensitive cells in the calculation of average absorbed dose to these tissues.

Although the principles are acknowledged, and special procedures are recommended for alpha emitters in the lung, bone surfaces and gastrointestinal tract, there appear to be no special recommendations for dealing with low energy beta emitters in critical locations and it is

³⁷ Foundation Document, ICRP Committee 2: Basis for Dosimetric Quantities used in Radiological Protection (Dietze et al.), Draft for Discussion, 22 August, 2004 (ICRP/22/42/04), p.11.

³⁸ Draft Recommendations, section 3.3.2, Averaging of dose; para. 50.

suggested that clearer and more specific recommendations are made to deal with such situations.

Recommendation 4 - Radiation weighting factors should be introduced specifically for electron emissions from tritium and other similar low energy nuclides, and for Auger emitters. Consideration should be given to setting w_R around 2-3 for tritium and similar low energy beta emitters in general, and possibly higher for Auger emitters. Situations where such emitters are likely to be bound to DNA or localised in the cell nucleus should receive special attention.

2.5 Conclusions

The declared aim of the ICRP is to make recommendations which will achieve "an appropriate standard of radiological protection for man". In line with improving the achievement of this aspiration, it is suggested that the ICRP should examine the following proposals:

- **Recommendation 1.** Greater clarity in the purposes, limitations and scope of application of ICRP's primary radiological control parameter, *effective dose*, needs to be achieved. Both the intended and the unacceptable applications of effective dose should be clearly set out in a definitive section of the Recommendations, and in the case of inappropriate applications, it should be made clearer what alternative procedures should be adopted.
- **Recommendation 2.** Constraint of Effective Dose alone is inadequate to meet the ICRP Aims for radiological protection. Whilst retaining constraints to effective dose as a *necessary* condition in radiological protection, consideration should be given to defining additional secondary constraints to limit radiation doses to organs, either generally or specifically.
- **Recommendation 3.** That the ICRP adopt the recommendation from the CERRIE Report, that where appropriate, dose and risk estimates should be combined with an appreciation and an explicit statement of the uncertainties involved. This approach would help identify those situations in which a precautionary approach might be appropriate (and is greatly to be preferred over one in which conservative or pessimistic estimates are arbitrarily introduced).
- **Recommendation 4.** Radiation weighting factors should be introduced specifically for electron emissions from tritium and other similar low energy nuclides, and for Auger emitters. Consideration should be given to setting w_R around 2-3 for tritium and similar low energy beta emitters in general, and possibly higher for Auger emitters. Situations where such emitters are likely to be bound to DNA or localised in the cell nucleus should receive special attention.

3 CRITICAL REVIEW OF THE NEW SYSTEM OF DOSE LIMITATION IN THE DRAFT 2005 ICRP RECOMMENDATIONS (INCLUDING DOSE CONSTRAINTS AND USE OF COLLECTIVE DOSE)

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3.1 The scope

The International Commission on Radiological Protection opened a new draft version of its basic recommendations on the protection against the hazards of ionising radiation for comments. Since such recommendations used to have a tremendous impact on the worldwide legislation and on the European one in particular, and since the group of experts foreseen in the framework of Article 31 of the Euratom treaty has to advise the Commission on the concerned issues, it is obvious that the group accepted the opportunity to give some feedback to this first open draft. Several challengers tried to summarise their personal comments on some chapters of the document in order to trigger a general discussion by the group of experts and some additional invited experts. This exercise has been co-ordinated by the internal Art. 31 working group on "Research Implications on Health and Safety Standards (RIHSS)".

This particular contribution relates to:

- The general system of protection;
- The Commission's required levels of protection for individuals;
- The optimisation of protection.

The contribution is exclusively based on personal reflexions on the "Draft for Consultation" as published on the ICRP website (July 2004). The so-called foundation documents, that were made available some days before the Luxembourg meeting, without a clear status, were not considered.

3.2 Some general remarks

Previous recommendations were appreciated as real handbooks on the basic philosophy and rationale of radiation protection. The understanding of the current 2005 version requires an insight in the existing system. This is due to several references to previous publications and to the high preference that is given to the "stability" of the regulatory system. Many statements can be summarised as "Because there is no urgent need to change we confirm the existing position", without reiterating on the logics behind previous recommendations.

ICRP seems to duly consider the practical impact of her recommendations. This leads to an immediate encapsulation of science by pragmatism that might confuse some of the readers. In this way, ICRP has put herself in a much more vulnerable position. Expertise is much easier to accept at the scientific level than on the field of implementation.

At the defence of ICRP, it may be recalled that the lack of pragmatism, proposing revolution instead of evolution, has been the main criticism on some individual try-outs, in particular by the chairman of ICRP, during recent years.

However, we should avoid that a refusal of some implementation-related issues might endanger the open discussion on the scientific consensus, as it was in the past. At the end of the day, it is crucial that the worldwide radiation protection community continues to use a single terminology. Historically this terminology has been defined for a great deal by the ICRP recommendations.

3.3 The genesis of a protection system: the role of ICRP

As summarised on the figure below, the genesis of a protection system is based on several steps, requiring an independent experts' review.

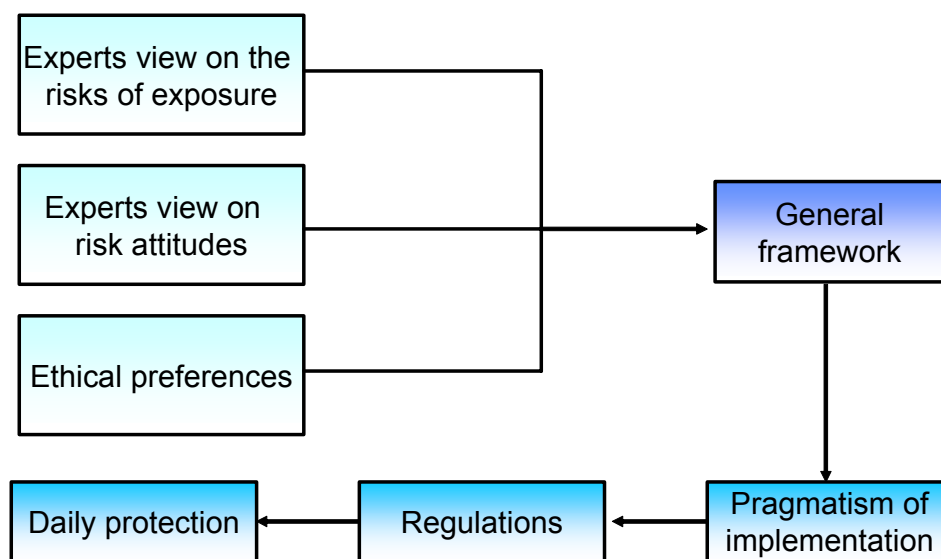


Figure 1
The genesis of a protection system: ICRP is penetrating to the endpoint.

It is not obvious that the competence on each step can be requested by ICRP, although as an independent body she has the right to claim each competence. Regulatory bodies and groups as the one foreseen in the framework of the Article 31 Group of Experts is however not enforced to follow each recommendation. A divergence between the ICRP recommendations and the practical implementation of the protection system would however lead to confusion and might harm the credibility of all those concerned. In this way, ICRP is invited to consider how far they want to go into the practical points of regulatory responsibilities.

The position of ICRP on biological effects and on ethical choices is discussed by other contributions to this conference. The protection system implies also a view on the attitude of all stakeholders versus risks and the balance between risks and benefits. The current draft supposes implicitly that this attitude did not change over a few decades. Although this item is very difficult to quantify, some reflexions need to be better documented, if useful in a separate scientific foundation paper.

By penetrating to the implementation concerns of the general framework of protection, ICRP implicitly and explicitly implies some priorities on pragmatism. The keywords are "stability" and

"simplification". This trend is generally welcomed, as far it is not confusing the scientific rationale of the recommendations.

The recommendations do not mention the objective to harmonise the protection standards worldwide. This is however the main objective of the Euratom treaty. ICRP is invited to examine how their recommendations make harmonisation easier or more difficult. The emphasis on the role of national regulatory authorities, in particular for emergency and existing situations, seems to me a potential threat to harmonisation.

3.4 The principles of protection

"The source-related restrictions on individual dose give the most fundamental level of protection". This translates the current practice of daily life, but the single (main) – source – most exposed individual analysis is not a principle in se, but a powerful tool. The instrument should be put in a global protection context.

I recommend that the basic principles of justification, optimisation and limitation will be reconfirmed as fundamental. The practical implementation of those principles depends obviously on the controllability of sources and on the limitations of the power to control. This discussion and its practical conclusions are however secondary. "Justification" and "limitation" should remain a part of the general radiation protection culture of each stakeholder. Although it is obvious that not all stakeholders, including safety regulators and operators, dispose of the comprehensive information and competence to conclude on justification and limitation, it should be useful to attribute to them a role as "responsible watch dog", ensuring that those who have the authority to decide obtain the complete and correct information and take the decisions considering all the relevant aspects.

The application of the optimisation principle within the restrictions of the dose constraints for the maximal exposed individual for each single source is put forward by ICRP as the most powerful tool to obtain an adequate level of protection. Optimisation is not the monopoly of the legislation but requires a daily conditional response by safety authorities and operators.

The 2005 recommendations seem to put more emphasis on the formal role of the safety authorities. This implies the risk to paralyse the optimisation practice by administrative rules and a lack of daily feedback.

As responsible for a nuclear research centre, in my status as nuclear operator, I prefer the system as summarised in the figure below.

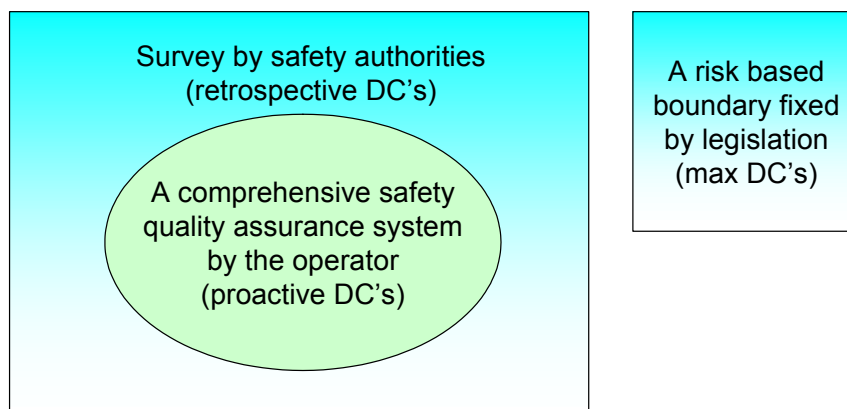


Figure 2
An operator's view on the optimisation system.

This system is based on a strict boundary, based on a transparent risk analysis, fixed by legislation and worldwide harmonised. The system of maximum constraints as recommended by ICRP plays this role. Within the framework, operators are enforced to introduce a comprehensive safety quality assurance system. This system might use secondary dose constraints, of a proactive nature, as it is formally the case in the currently existing system. The safety authorities have to survey the appliance of the quality assurance system. They can use retrospective yardsticks that have the nature but not necessarily the status of dose constraints.

As a member of the group of experts in the context of Article 31 of the Euratom treaty, with a more global responsibility on radiation protection, I recommend to present optimisation of protection as a defence-in-depth-approach, with three barriers: the operator, the safety authority and the regulation, as indicated by the figure below.

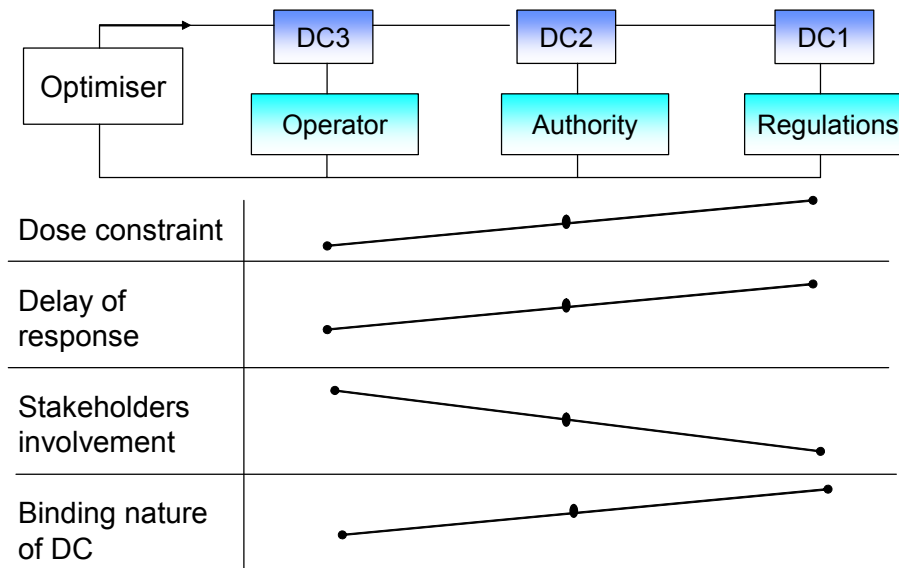


Figure 3
Optimisation as a defence-in-depth approach.

Each barrier can impose different dose constraints within the other boundaries. In normal situations, the feedback loop of the operator with the lowest dose constraint and the shortest delay of response will stabilise the system within acceptable boundaries. The involvement of stakeholders can also be organised in the most direct way, close to the source. This interplay between several levels is only possible, as far as the regulatory power of the operator is not too much restricted by crisp rules.

3.5 Individual versus collective protection

The concern for the individual and for the collectivity depends on the absolute risk of the individuals involved. It is obvious that in case of a traffic accident, nobody cares about the 1000 kg of scrap that is spread on the public road. The attention is put on the mitigation of severe consequences for the most affected individuals. But this gives no excuse to spread empty cola-cans along the roadway, although the individual risk for the most exposed individual can be considered as insignificant.

In this way, it is not ensured that the exposure of a very high number of persons or of the environment can be kept acceptable by restricting the dose to the maximum exposed individual. This problem may be resolved by reviewing the chapter on the protection of the

environment. Instead of using the dose to some typical animals as an indicator, it may be better to regulate the contamination of air, water and soil.

3.6 The proposed needs for action

The reference to the natural background to define a need for action looks very simple and straightforward. It is obvious that this rationale can easily be applied to exposures far below background and even up to a few times background, considering the observed heterogeneity of the background. The approach becomes however more questionable at levels to ten or hundred times background. A reviewed discussion on the tolerability of risk to justify actions or the lack of actions seems to be unavoidable.

3.7 A single scale for normal, emergency and existing situations

The simplification of the recommendations by introducing general warning and action levels for as much as possible controllable situations is welcomed. It is obvious that the current recommendation has been contaminated by the search for stability, at least for normal situations. There is some need to better explain the continuity of protection philosophy between the current approach and the recommended one, in particular for emergency and existing situations. These are situations where not the entire source can be considered as controllable. It is suggested to include a reflexion on the meaning of controllable dose for each situation.

The simplification process leads to some ranges of dose constraints that might be considered as too high, as compared with the current practice, as e.g.

- High levels of controllable existing exposure: 10 – 100 mSv/a;
- Protection of the thyroid:
 - o Evacuation: 200 – 2000 mSv – thyroid
 - o Prophylaxis: 40 – 400 mSv – thyroid.

Those values may endanger the harmonisation of the applied dose constraints over the European member states.

3.8 The collective dose concept

ICRP identifies some difficulties to apply the collective dose concept. The addition of some higher individual dose rates, close the source, with a lot of very low dose rates, at further distance or after a very long time period, is indeed very difficult to accept, given the implicit different perception of higher and very low dose rates, independently of the hypothesis of the no threshold-linear dose-effect relationship.

ICRP is introducing the concept of the dose-matrix, disaggregating the collective dose considering the distribution of individual doses and the nature of the exposed persons. This procedure allows of course to continue the application of the global collective dose concept, but it is euphemistic to say that the recommendations do not make much publicity to do so. The multi-attribute approach, giving different weights to specific components of the collective dose, is already common practice in the discussions w.r.t. waste disposal sites.

The dose matrix gives the opportunity to introduce a "societal weighting factor". However, the use of the collective dose, integrating dose rates, that are reasonably comparable, remains useful to compare alternatives and to control the hazards of a widespread low level contamination. ICRP is invited to complement the guidance on this matter.

3.9 Public exposure

ICRP reviewed the concepts of critical groups and representative individuals. The discrimination of specific age groups with their specific dose factors and consumption habits seems to be preferred, although the concept of the average individual is still considered. An average individual should be averaged on the basis of risk. This approach might lead to the definition of an artificial, non-existing person. Such a model will be very difficult to explain to the public. In this way, it is recommended to further consider an age-dependent approach.

3.10 Conclusions

The search of ICRP to stability and simplification is welcome. However, ICRP must be aware that statements with regard to practical implementation might be much more vulnerable than scientific ones. The basic principles of radiation protection should remain fundamental and an integral part of the radiation protection culture. The optimisation process may not become too administrative, by focussing on the role of the safety authorities. Low maximum individual exposures do not always justify a wide spread of lower exposures. Basic action levels for the contamination of air, water and soil should be considered.

The reference to natural background, with regard to risk tolerance, is only valid below or up to a few times background. The discussion on the tolerability of risk should be reviewed.

The controllability of sources should be discussed for all situations. Some guidance is needed how the optimisation process can deal with individuals and collectivity.

The assessment of public exposure must remain understandable by the general public. In this context, the model of the average individual seems questionable.

4 CRITICAL REVIEW OF THE POLICY REGARDING EXCLUSION, CLEARANCE AND EXEMPTION IN THE DRAFT 2005 ICRP RECOMMENDATION

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The new ICRP Recommendation deals with the term "exclusion" in three places, and explains the meaning of exclusion.

4.1 Exclusion of radiation sources

At the beginning of the Recommendation in the chapter "Summary of the recommendations" under the section "Exclusion of radiation sources" the following is stated (S 12) :

"There are many sources for which the resulting levels of annual effective dose are very low, or for which the combination of dose and difficulty of applying control are such that the Commission considers that the sources can legitimately be *excluded* from the scope of its Recommendations. Since cosmic rays are ubiquitous and all materials are radioactive to a greater or lesser degree, the concept of exclusion is essential for the successful application of the system of protection. The Commission has concluded that the activity concentration values in Table S2 provide a definition of what is to be considered radioactive for practical radiological protection purposes, and therefore the levels at which materials are to be within the scope of its recommendation. It now recommends the figures in Table S2 as the basis of exclusion from the scope of its recommendations".

Table S2. Recommended Exclusion Levels

Nuclides	Exclusion activity concentration
Artificial α -emitters	0.01 Bq/g
Artificial β/γ -emitters	0.1 Bq/g
Head of chain activity level, U-238, Th-232	1.0 Bq/g
K-40	10 Bq/g

In this paragraph the ICRP deviates significantly from previous definitions of "exclusion", which related to exposure that is very difficult to change, such as potassium-40 in the human body. In the strict sense an exclusion level is not being introduced here, but with the values in Table S2 rather a de-minimis level, especially for artificial radioactivity.

One point of criticism is that the respective nuclides have a very varying biological impact and cannot be adequately covered with four activity concentration values (differences up to 1,000,000).

A further point of criticism is that artificial radioactivity should never be excluded. There are a range of administrative instruments, e.g. the authorisation of radioactive discharges and reference values for emergency situations that make the application of the exclusion principle superfluous.

Proposal: The exclusion of exposure from artificial nuclides is neither advisable nor necessary and should therefore be omitted.

The next point of criticism is the much too high values of activity concentration for the natural nuclides. The IAEA document (RS-G-1.7.) "Application of the Concepts of Exclusion, Exemption and Clearance" also indicates possible difficulties, such as the application of these values to building materials. This reference is, however, missing from the ICRP recommendation.

With 1 Bq/g for U-238, doses of well over 1 mSv/a arise, see RP-112 for building materials, and well over 30 mSv/a for corresponding material in mine waste heaps from uranium mines.

Table S2. Doses estimated for different age groups of residents near a mine waste heap of 10 ha area (200 m x 500 m) and 1 Bq/g activity concentration of the radionuclides of the U-238 decay chain in equilibrium.

Exposure Pathway	Effective Dose (mSv/a)			
	0-1 a	1-2 a	2-7 a	adults
Inhalation of dust	0.022	0.035	0.039	0.054
Ingestion of dust	0.000	0.000	0.119	0.003
External exposure	0.053	0.046	0.138	0.071
Radon exposure	0.329	0.329	0.337	0.332
Garden and agricultural products (cont. dust)	0.567	0.478	0.496	0.238
Groundwater pathway	30.230	10.269	11.760	5.683
Total dose	31.200	11.156	12.889	6.382

Proposal: No general value should be given for an exclusion of natural radioactivity and the exposure it causes. Instead exclusion should be restricted to certain situations that are not amenable to control in the presence of natural radioactivity.

4.2 Chapter 2.3 Exclusion and Authorisation

Chapter 2.3 "Exclusion and Authorisation of Exposure" (paras. 24 – 28) outlines once again the concept of exclusion as viewed by the ICRP in its new draft. All exposure above the exclusion level is subject to the radiological protection system. However, this exposure is only subject to control and authorisation above the exemption level. Thus the fundamental concept of exemption is described as an "important regulatory instrument" and reference is made to existing national and international regulatory provisions. Radioactive wastes are also referred to, but the concept of clearance is not separately listed and is instead integrated into the concept of exemption.

Proposal: The terms "exclusion", "exemption" and "clearance" should be explained such as by the IAEA Publ. 115:

Exclusion: deliberate exclusion of a particular category of exposure from the scope of an instrument of regulatory control on the grounds that it is not considered amenable to control through the regulatory instrument

Exemption: determination by a regulatory body that a source or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure is too small to warrant the application of those aspects

Clearance: removal of radioactive materials or radioactive objects within authorized practices from any further regulatory control.

4.3 Chapter 8 Exclusion of sources from the scope of the recommendation

Chapter 8 "Exclusion of sources from the scope of the recommendation" describes once again in paras. 204-212 the concept of exclusion with regard to artificial (Chapter 8.1) and natural (Chapter 8.2) radionuclides and with regard to exposure from cosmic rays (Chapter 8.3).

The principle of exclusion applies to a dose value of 0.01 mSv/a in para. 205, while in para. 206 the "exclusion from the scope of the recommendation" applies to 0.1 or 0.01 Bq/g.

Criticism: Depending on the nuclide this leads to differences of up to one million. There is no consistency between both criteria.

Proposal: The principle of exclusion should not be applied at all to artificial exposure since this is always controllable and is amenable to control.

Paras. 207 and 208 describe several situations of exposure from natural radioactivity that are typically scarcely amenable to control, such as exposure from K-40 in the body, and which should therefore be excluded. Para. 209 outlines the derivation of the exclusion values in Tables S2 and 10 from the naturally occurring observed highest values (see UNSCEAR report) and claims that these values do not lead to more than approx. 0.2 mSv/a. Para. 210 refers to the IAEA publication DS 161.

Criticism: The proposed values in Tables S2/10 of 1.0 and 10 Bq/g for natural radioactivity can lead to significantly higher dose values than 0.2 mSv/a. For this reason DS 161 refers expressly to this problem.

Proposal: The principle of exclusion should only apply to natural nuclides with regard to certain scenarios.

Para. 211 refers to exposure from cosmic rays, which is not amenable to control at ground level and should therefore be excluded. While this exposure at high altitudes of pilots and couriers should be considered as occupational exposure, it should be excluded for passengers in airplanes (para. 212).

Proposal: These provisions should be followed.

4.4 Summary - Concept of Exclusion

The new ICRP draft attempts to redefine the system of exclusion, exemption and clearance via dose and activity concentration values. This comes up against a range of difficulties in practice. The following proposals are therefore made:

Application of the concept of exclusion, exemption and clearance

4.4.1 Exclusion of natural exposure

Proposal: Exposure of natural radioactivity in special situations, whose magnitude or likelihood is essentially not amenable to control, for example K-40 in the body, cosmic radiation at the surface, and of passengers in airplanes or exposure from the unmodified undisturbed concentration of natural radionuclides should be excluded.

4.4.2 Exclusion of artificial exposure

Proposal: The exclusion of the exposure of artificial nuclides should strongly be excluded.

4.4.3 Consequence of proposal of 1. and 2.

Proposal: As a consequence of 1. and 2. and to avoid an inconsistency in the application of a model which is a radioactivity concentration model and a dosimetric model of de-minimis constraints the concentration values in Table S2 should be deleted.

4.4.4 Exemption and clearance

Proposal: The dose criterion of 0.01 mSv/a for artificial nuclides and 0.3 mSv/a for natural nuclides for exemption and clearance should be used. The values of clearance should be applied as a starting point for consideration of radiation protection.

5 CRITICAL REVIEW OF ETHICAL AND LEGAL ISSUES IN THE DRAFT 2005 ICRP RECOMMENDATIONS

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The following article represents a collective critical analysis of the 2005 ICRP⁴⁴ draft recommendations concerning Basic Safety Standards on demand of the EC. It was set up and presented in order to stimulate discussions within the Art. 31 Expert Group, charged with a high level consultative mission.

The group was asked to challenge ICRP in an interactive way by deliberately provocative questions on ethical and legal issues coming up with the current draft..

5.1 Historical Introduction

The very important international network ICRP, composed of high level experts, is shaping nuclear activities in the globalised world. Its authority is outstanding and based on old traditions of scientific risk assessment with remarkable conceptual work on risk management.

Major breakthroughs were historically made by quantification of risk through definition of quantities, units, the set up of measurement capacities and epidemiological data bases. Quantification was developed by the X-Ray Units Committee founded by the International Congress of Radiology in 1925, transformed later into ICRU⁴⁵. Their first recommendation defined the roentgen (R) as unit for exposure.

Risk quantification allowed the start of the International X-Ray and Radium Protection Committee (IXRPC), which was created in 1928 by the International Congress of Radiology (IX00).

The early recommendations of IXRPC were concerned by avoiding threshold (deterministic) effects.

5.1.1 The shadow of war and secrecy

In the twenties radium had caused professional diseases through internal exposure (outside the medical profession). The critical organ concept was developed in the thirties.

Coming Second World War created secrecy in nuclear activities and complicated regulatory developments. Nazi's intervened on a Jewish member of ICRP in 1934 (Lindell 1996) and concern was given to institutionalise independency.

The Manhattan project, the military development of radiation technology during World War II used the concept of the body burden which was taken up by ICRP in 1955.

³⁹ Programme of Integration of Social Aspects in SCK.CEN, Nuclear Research Centre, Mol, Foundation of Public Utility.

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⁴² Université Catholique de Louvain, Louvain-La-Neuve.

⁴³ Belgian Federal Agency of Nuclear Control.

⁴⁴ International Commission on Radiological Protection.

⁴⁵ International Commission on Radiation Units and Measurement.

Extensive research on effects continued at UK and US universities during the war. Later, ethical concern was expressed on numerous experiments, such as gonad exposure on prisoners in the USA, declassified from 1970 on and summarised bibliographically (Samei, 1995). Epidemiological evidence on risk, in particular for leukaemia, became clear in the early fifties when Hiroshima-Nagasaki data were analysed.

The name of ICRP was formally taken up in London in 1950.

In 1952 a joint meeting took place with the international committee on Radiobiology. The executive committee of the Congress of Radiology has set up the rules in 1953. After the UN Geneva conference of 1955 where President Eisenhower launched civil nuclear energy "Atoms for Peace", it became evident for ICRP that stricter recommendations were needed considering the challenges of workers and the public confronted with new economic pressures (1956 meeting). ICRP became formally affiliated as NGO to the WHO⁴⁶ and started together with ICRU in 1957 collaboration with UNSCEAR⁴⁷.

Rolf Sievert, an early pioneer of quantification became chairman in 1956 and saw his name later given to the unit of dose. The first formal ICRP recommendation, named publication 1, was agreed on September 9, 1958 (IC01) and signed by Sievert. It gives an overview of the 30y genesis of ICRP.

It was clear that ICRP considered the importance of as well carcinogenic (in particular skin and leukaemia) as genetic effects, which were of dominant concern regarding the public. The gonads were specified first as critical organ by NCRP⁴⁸ at US level, where the publications of the BEAR⁴⁹ (later BEIR) committee of NAS⁵⁰/NRC⁵¹ had their impact on ICRP. The concept of genetically significant dose emerged.

UNSCEAR and BEIR are today still the two legitimated scientific references (peer reviewers) on radiation risk estimation. They are contested the last decennia by interest groups from nuclear industry, nuclear medicine and environmental NGO's.⁵² Differing opinions respectively over- and under-stating radiation risks are referring to controversial science interpretations such as from respectively ECCR⁵³ and the French Academy. It is remarkable that both dissident schools were driven by early pioneer members of ICRP such as Maurice Tubiana (Académie de Médecine, France) and the late Karl Morgan (Oak-Ridge, USA) (Morgan 1977).

From 1956, ICRP extended its concept of *average dose rate* levels (e.g. 0,3 rem/week), derived from skin detriment evidence in radiology to the limiting of accumulated dose, also for the public. It left the assumption that lower exposure rates could not lead to injuries becoming apparent over life time. Previous recommended levels seemed close to the probable threshold for adverse effects, but a statistically significant life shortening had been noticed with radiologists.

The concept of maximum permissible exposure was set up "such as to involve a risk which is small to the other hazards of life". "The aim of protection would be to reduce the incidence of leukaemia to the lowest practical limit... and the degree of effect (such as life shortening) to the lowest practical value" §7 (IC01). ICRP was aware of the uncertainties on radiation risks from the beginning (§22).

Stochastic effects came up where the probability and not the severity of the effect is proportional to dose and the threshold became rejected.

⁴⁶ World Health Organisation, Geneva.

⁴⁷ United Nations Scientific Committee on Biological Effects of Atomic (Ionising) Radiation.

⁴⁸ National Commission Radiological Protection (USA).

⁴⁹ BEAR (BEIR) USA- Committee on Biological Effects of Atomic (Ionising) Radiation.

⁵⁰ National Academy of Sciences (USA).

⁵¹ National Research Council (USA).

⁵² Non Governmental Organization.

⁵³ European Committee on Radiation Risks (NGO).

5.1.2 Stochastic Risk Philosophy

The extrapolation to low doses was already considered in 1958 because exposure at maximum permissible limits “may entail some life shortening...a slight acceleration of the natural ageing process” (§6). ICRP started to recommend to keep exposure “as low as possible” (IC01).

In the period 1958-1962 many scientists expressed concern on the large fall-out of atomic bomb tests, since radioactivity was measurably dispersed over the globe. Nobel Prize winners such as Bertrand Russell and Joseph Rotblat (former editor in chief of Physics in Medicine and Biology) took the lead. This first world wide controversy on nuclear technology (Laes 2004), forced ICRP to pay attention to the effects of global environmental uptake.

ICRP set up task groups to deal with specific problems leading in 1966 to its seventh report on environmental monitoring (IC07).

In its important publication 9, ICRP starts in 1966 to assume a linear non threshold relationship between dose and effect. ICRP stated “...as the existence of a threshold dose is unknown, it has been assumed that even the smallest doses involve a proportionately small risk of induction of malignancies” (§7). It recognises that thresholds can exist for some effects, but is also not excluding that synergistic effects may occur (the concept of risk in IC09). ICRP proposes limits instead of maximum permissible dose (§37) for the public and launches the ALARA⁵⁴ principle (§52).

The cultural background of controversy against military culture in nuclear developments together with the new economic and medical perspectives allowed in the seventies a change towards more coherent radiation standards.

ICRP developed an original stochastic risk philosophy serving later as a model for numerous other risks. Justification and optimisation could be developed, based on the ALARA principle. Without a threshold assumption it was no longer a question of safe or non-safe, but how safe. The former chairman of ICRP, Bo Lindell, insisted on a strict hierarchy of justification of practices, optimisation of protection (the ALARA principle) and limits (and levels). Since even low doses can cause detriment in principle, justification ought to present a mandatory balancing of benefits and risks as cornerstone of the system.

The ALARA concept and the quantification of risk for external and internal exposure was driven by the later ICRP president Dan Beninson and by committee 2 president Karl Morgan, highly conscious professionals with remarkable ethics. Morgan was teacher of generations of health physicists. He created IRPA, but finally opposed the utilitarianism⁵⁵ of ICRP regarding low dose effects (in Dubrovnik Summer School 1977), referring to the later Nobel Prize for Peace Joseph Rotblat and together with Oxford epidemiologist Alice Stewart, later founder of ECCR (EC03). After his retirement Karl Morgan started to defend victims of earlier radiation experiments.

The epidemiological evidence from Hiroshima-Nagasaki data, indications of higher sensitivity of developing organisms for radiation in the Oxford children survey, hard reactions from the nuclear establishment and early information about human radiation experiments on soldiers and prisoners have driven those scientists towards a more polarised attitude. Some dubious ethics during the cold war remained long time without discussion but transparency was created by open publication in Health Physics (Sa04). In this context ICRP published in 1993 its report 62 (IC93) proposing informed consent on risk in biomedical experiments on humans. This was implemented in the EC basic safety standards.

⁵⁴ As Low As Reasonably Achievable.

⁵⁵ A theory of ethics based on quantitative maximization of a form of good for society or humanity (greatest happiness for the greatest number). It is a form of consequentialism and can be reduced to a balance of costs and advantages. (from Latin *utilis*, useful).

Publication number 26 (IC26), where ICRP recommended in 1976 its stochastic risk philosophy, is still of high relevance for the international discussion today. ICRP warned for the underlying value judgements (§71) and made explicit ethical choices in its risk concept, such as for the thyroid where radio sensitivity is recognised to be higher than for red bone marrow leukaemia induction. But as treatment and slow progress of thyroid cancer give more favourable prospects, risk weighting factors took mortality into account, so the representation of thyroid risk remained very low, leading to relative high tolerance in limits and risk assessment. This was changed in ICRP publication 60 (IC60) in 1990. Incidence of cancer was given a certain importance, as perception does. The Chernobyl indications of increased cancer risk in children has meanwhile illustrated the sense of this reduction. The stochastic limit for exclusive thyroid exposure for the public decreased from 166 mGy in 1986 to 20 mGy now and for the workers from 500 mGy to 400 mGy.

5.1.3 Early role of stakeholders and optimisation

IRPA, the professional organisation of radiation protection experts, created by Karl Morgan in 1964, has shaped the interaction in the field as well as with UN institutions as IAEA, ILO & WHO through performant networking. IRPA is organising world meetings of all involved experts each four years. It became the major stakeholder forum of ICRP.

At European and UN level stakeholders became also more and more involved in these new options for basic safety standards. The IAEA⁵⁶ started a collaborative process with ICRP, NEA⁵⁷, EC⁵⁸, ILO⁵⁹ and WHO experts in Vienna in 1982 to develop a more operational version of ICRP 26 (IC26) in a regulatory way. This resulted in the basic safety standards of IAEA (IA84). It helped to create an informal as well as a structured dialogue on radiation protection mainly in Europe, through efforts of the EC. This process helped to make operational the triple dose limitation system and clarified even European Directives (Eggermont 1983).

In different countries involvement for safety at work was organised by law already at different levels in the seventies and eighties. Unions and employer organisations expressed opinions on new regulations. Only recently in this draft 2005(IC05), ICRP took the principle option to involve also other stakeholders and to extend its optimisation approach to safety culture.

The development and early implementation of optimisation originated in the USA in order to manage high dose problems in nuclear power plants (NPP) (Baum 1994). Optimisation was directed afterwards to manage low doses and collective risks. A broad set of tools was developed to improve the radiation protection level in an interactive way.

The economic approach of cost-benefit analysis was based on human life value quantification. It created ethical problems and was opposed by involved unions in EC and ILO (Zerbib 1993).

In the eighties the scope of optimisation was enlarged to safety culture. Optimisation was finally organised in the nineties in a structured way mainly in Europe. This has led to the creation of the European ALARA network (EAN⁶⁰) under CEPN⁶¹ impulse. Operational optimisation using the collective dose concept had remarkable successes in NPP's. Operators were confronted with media pressure for high dose problems of external workers during steam generator replacements. Optimisation allowed to realise win-win situations of dose reduction and improved economy in situations of complex work organisation. Optimisation was less successful in the medical sector where numerous professionals did not accept the stochastic risk philosophy at low doses. Justification and optimisation were first based on cost benefit

⁵⁶ International Atomic Energy Agency, Vienna.

⁵⁷ Nuclear Energy Agency (OECD), Paris.

⁵⁸ European Commission.

⁵⁹ International Labour Organisation (UN, Geneva).

⁶⁰ European ALARA Network; www.ean.cepn.asso.fr.

⁶¹ Centre d'Etude sur l'Evaluation de la Protection dans le domaine Nucléaire.

analysis and introduced utilitarian concepts in radiation protection which were also difficult to accept for law specialists arguing against increasing soft law⁶². Optimisation brought more flexibility in risk management, but in INLA⁶³, the international nuclear law association warnings are heard more and more for problems created by increasing soft law content in regulatory implementation (Veuchelen, 2004), which is more difficult to enforce and also requires law innovative development work. At IAEA soft law is considered as effective as hard law, but it depends on implementation measures at national level.

The third element of the dose limitation system, the limits, has to guarantee protection and equity of the individual in this utilitarian protection approach directed by efficiency. They add egalitarian⁶⁴ ethics to the dose limitation system.

5.1.4 Medical problems rediscovered

As limits are not applicable for patient exposure, justification and optimisation are even more crucial for protection in medicine. But due to the culture of medical professionals the implementation of both building blocks of protection progressed very slowly in medicine. Medical professionals are confronted daily with life and death, which makes them not very receptive for low dose risk considerations.

European studies of RP practices, particularly in radiology, showed a large variability in protection related to diagnostic quality. It needed the development of reference levels, a process of QA and a structured role for medical physicists. This was laid down in the EC medical directive clarifying justification and optimisation. It has contributed to put RP in radiology again on the priority list of ICRP. A lot of transdisciplinary work is being done since, in particular on interventional radiology, vascular brachytherapy, CT and nuclear hospital waste management.

The growing application of radio nuclides in nuclear medicine is also creating problems for RP, such as related to contamination caused by ambulant patients at home which could be noticed in waste streams. Some uncertainties on risk persist, mainly related tot the effect of Auger electrons.

The LNT⁶⁵ hypothesis of radiation risk, still the best fit of empiric data following epidemiological peer review and UNSCEAR, was contested again mainly by professionals in nuclear medicine. A certain lobbying was noticed in the IRPA11 conference in Madrid where high level peer review of epidemiology was not taken serious by these professionals (IR04). Group think mechanisms, such as cognitive dissonance, and perception, are considered recently in a scientific way in order to explain such positions (Bombaerts 2004) (Hardeman 2003).

ICRP was structured very independently, but should formally still report to the International Congress of Radiology, the historical professional stakeholder in one aspect of exposure, X-rays. ICRP has the mandate to advance science of RP for public benefit, to consider principles and providing recommendations with guidance for measures (Constitution ICRP 1987). It broadened activities to many other fields. Representative leaders of international organisations were also nominated as members. During a meeting of the EC Conference on Stakeholder involvement in RP, the need was expressed for a kind of peer review broader than the Congress of radiology.

⁶² Rules of conduct that are laid down in instruments which have not been attributed legally binding force as such, but nevertheless may have certain (indirect) legal effects, and may produce practical effects" Senden, 2004.

⁶³ International Nuclear Law Association.

⁶⁴ Doctrine to treat people the same, as equals in value or status (different types of equality), characterised by belief in equal political, economic, social and or civil rights for all people.

⁶⁵ Linear non threshold hypothesis for dose effect relation.

Meanwhile public perception for nuclear activities remains negative, except for medical and natural exposure. Both sectors yield the major collective dose contributions in radiation protection. They were not given the priority they deserve for a long time, as well by ICRP as the field experts.

Perception studies such as the risk barometer of PISA in collaboration with IRSN⁶⁶ illustrate, contrary to the common belief, that no general public fear for radiation exists (Eggermont 2003).

5.1.5 Social controversy on ICRP

ICRP became a very important network operating in the globalised world driven by free trade, where national authorities loose impact on the shaping of society and where lobbies or interest groups interact with media and politics in order to influence regulatory processes. ICRP tries to forward recommendations while being confronted with diverging worldviews e.g. Anglo-Saxon, European or the Developing World with their different cultural framings.

During the IRPA-10 Conference in Hiroshima in 2000 first public protests were noticed against the shift in principles within ICRP. The concern on individual rights of potential victims of the Tokaimura accident seemed a catalyst in Japan. The change in risk rationale in ICRP created a fear for decreased distributive justice when neglecting low dose effects (Hi00).

An alternative critical network, ECRR⁶⁷, was set up, structuring scientific reaction with clear policy objectives in ICRP style (EC03). It published a political document addressing mainly nuclear energy developments using a rather weak scientific base but with some ethical, political and social questions of relevance for the globalised role and legitimacy of ICRP in particular within the EU social, legal and democratic system.

The draft ICRP 2005 had in this context of evolution of interests and worldviews a difficult genesis. Moreover it was prepared in a fast changing period where many nuclear experts became confronted with civil society. The mentioned group think mechanisms do not yet facilitate a cultural change towards more openness and integration of safety, health and environment. While the climate issue on the contrary is announcing some change in social attitude.

Over the last years ICRP made considerable efforts to bridge gaps between science, socio-economic and political interests and culture. Communication initiatives were structured with website involvement of all professional organisations. The development of new principles caused however a lot of controversy. Interests also from non-nuclear actors such as NORM⁶⁸ industry were very active in international institutions as IAEA and joined economic concern for waste costs in large (military) remediation activities.

Conflicts of interest complicated judgements while clarification, coherence, consistency and stability were asked for. Ethical theoretical framing could allow clarifying this discussion.

5.1.6 Different implementations in USA and Europe

ICRP is confronted with the nuclear isolation from other policy fields.

Nuclear activities still remain poorly integrated with non nuclear developments in regulatory work, in particular in Europe where at constitutive level nuclear activities receive a separate treatment based on the EURATOM treaty. ICRP is practically not considering other

⁶⁶ Institut de Radioprotection et de Sûreté Nucléaire.

⁶⁷ European Committee on Radiation Risks (NGO).

⁶⁸ Naturally Occurring Radioactive Materials.

approaches such as sustainable development which contains precaution for risk management of health and the environment (in the Rio UN declaration).

The creation of EURATOM (Treaty of 1957), with its very progressive concepts of technology regulation had brought a dual development in the institutionalisation of radiation protection with a different approach in old and new continent. It has created a more favourable context for implementation of ICRP recommendations in Europe.

The EC had a considerable mandate to harmonise national regulations and could clearly structure RP regulation in Europe. The EC must consult politically the European Parliament and the Economic and Social Committee of the European Union on standard setting but has to leave implementation to national authorities. The Committee is composed by employers and trade union organisations. In both institutions the industrial and NGO lobbying has increased its influence over time. The *Article 31 Group* of high level experts is advising the EU and its competent authorities for radiation protection on a scientific base.

In the USA, different organisations are involved, the NAS BEIR committee reviews effects, NCRP recommends regulatory implementation while different agencies (the former AEC⁶⁹, EPA⁷⁰, DOE⁷¹ & NRC⁷²) act with different missions at federal level. A more direct democratic control, in particular more access to documents existed in the US compared to Europe, but openness became overshadowed by military developments, secrecy, legacies and recently terrorism. ICRU and ICRP concept implementation was delayed in the USA over the last decennia, also due to opposing agency views.

During the last ten years ICRP Chairman Roger Clarke has tried to bridge this gap.

5.2 Methodology

SCK•CEN, the Belgian nuclear research centre in Mol, has taken 6 years ago the initiative to integrate social aspects into nuclear research (PISA). Particular aspects were studied such as transgenerational ethics, culture of experts, perception of experts and public, safety culture, sustainable development and precaution in nuclear activities.

Periodic reflection groups were set up to discuss with universities, authorities and industry, problems such as ethical choices in radiation protection.

The PISA programme was asked by the EC to make a critical analysis of ethical and legal views in the ICRP 2005 draft.

Discussions were organised with radiation protection staff of SCK•CEN, the Belgian regulator FANC/AFCN, science philosophers of UCL associated in CITES, law researchers of PISA and with the working group of the Belgian Association of radiation protection (BVS/ABR).

In the present article all inputs of these discussions have been used as a contribution, while the Peking foundation papers of ICRP could no more be integrated.

Two of the authors have a long experience in EU and ICRP analysis and consultancy. They are also involved in medical and environmental policy advisory work in the Belgian Health Council. Two others are human scientists observing and studying nuclear ethics and regulation from a certain distance.

CITES and PISA have prepared an international conference on the follow-up of this subject in 2005 in UCL Louvain-la-Neuve.

⁶⁹ US Atomic Energy Commission.

⁷⁰ US Environmental Protection Agency.

⁷¹ US Department of Energy.

⁷² US Nuclear Regulatory Commission.

5.3 Ethical Issues

In this section we are looking at the present risk base of ICRP, with particular attention to uncertainties on hereditary effect, pre-implant embryonic sensitivity and genetic susceptibility and how precaution is applied. ICRP seems to shift its risk reference from a scientific health rationale towards a more communicative background rationale which is ethically questionable, while precaution is a missing perspective at least explicitly. Moreover a paradigm change occurs due to another hierarchy in the dose limitation system. Justification starts to fade away, having consequences on responsibility at all levels. Optimisation becomes vague and the shift from anthropocentric to a more eco-centric approach lacks an ecosystem view. Exclusion finally creates equity problems for some exposure conditions.

The accompanying shifts in ethics seem not characterised by a move away from utilitarianism to more attention for the individual but by a decreased attention for the common good and for individual rights.

5.3.1 Risk Uncertainties and Ethics

ICRP is still referring but seems no longer basing its dose limitation system on a scientific health risk rationale. This is particularly the case when we consider the first level of protection, the dose constraint at the source.

So ICRP pays less attention to hereditary effects while ignoring major health uncertainties, limiting its risk estimate to only two generations.

ICRP is also less concerned about pregnant woman and the protection of the foetus. The ICRP 2005 draft neglects the uncertainty on foetus sensitivity for individuals who are genetically more vulnerable and is decreasing protection of pregnant woman in particular in medical exposure.

Finally recent evolutions in genetic susceptibility for cancer could become a major ethical challenge in future and are hardly taken into account.

5.3.1.1 Hereditary effects

In the estimation of genetic risk only two generations are considered in the ICRP draft (§A17). The equilibrium value of ICRP 60 is now judged to be of questionable scientific value because of the unsupported assumptions on selection coefficients, mutation components and population changes over hundreds of years.

As a result, the genetic risk associated with dose is estimated to be around 20 cases per 10.000 people/Sv, rather than around 100 cases in the former ICRP 60. §109 states: "On current knowledge, those repeat sequence mutations (mini-satellites) are only rarely associated with heritable disease. For this reason...not considered relevant..."

However, when we compare the UNSCEAR 2001 Report (UN01) with the UNSCEAR 1993 Report (UN 93), we arrive at comparable or higher risk factors for the hereditary effects.

The total genetic risk up to the second generation is 0,7-1,1%/Sv (UN01) compared to 0,5%/Sv (UN 93). This risk estimation includes dominant and X-linked diseases (0,2-0,4%/Sv compared to 0,4); chronic multi-factorial diseases (0,05-0,2%/Sv not estimated in 1993) and congenital abnormalities (0,4-0,5%/Sv compared to 0,03; the latter value corresponding in fact to chromosomal diseases).

The total genetic risk at equilibrium is then 1,6-6,5%/Sv based on UNSCEAR 2001, compared to 1,2%/Sv in UNSCEAR 1993, where chronic multifactorial diseases and congenital abnormalities were not taken into account.

On comparable bases, it can therefore be concluded that the genetic risk has in fact not diminished. The sharp decrease of the genetic risk coefficient recommended by ICRP in its new draft is based only on its *choice* to take now the effect on the generations over the second

as being zero. ICRP justifies this decision by the radiobiological data suggesting that the major contribution to the genetic risk comes from large deletions expressing themselves essentially in the first generations and by the numerous uncertainties involved in the estimation of the long term genetic risk. Doing this, ICRP recognizes on the one side that considerable uncertainties still exist in this field but, on the other side, it paradoxically claims that enough is known as regards the mechanisms of radiation induction of genetic effects to allow ignoring the possibility of significant long term risks.

In reality, the uncertainties include also the question of the mechanisms. This is in fact shown implicitly by the wide range of values of the UNSCEAR 2001 risk coefficients for different kinds of long term hereditary effects, some of which being associated with more subtle mutations than large chromosomal multi-deletions.

On scientific grounds, it is plausible that the genetic risk coefficient could be higher than the new ICRP estimation and even higher than its old estimate. One can doubt whether the risk evaluation in the ICRP draft recommendation can be considered as a balanced position according to the present scientific knowledge.

5.3.1.2 *Uncertainties on embryonic/foetal risk*

The draft ICRP mentions “true dose-thresholds” of around 100 mGy (§116) for the induction of malformations during organogenesis and judges that risk of malformation after in utero exposure to doses up to a few tens of mGy may be discounted. Considering the pre-implantation period, ICRP judges that lethal effects “at doses of a few tens of mGy will be very infrequent” (§115) and sees no reason to believe” that there will be significant risk to health expressing after birth.

ICRP judges also that any effects on IQ following in utero doses of a few tens of mGy (during the sensitive period) would be “undetectable and therefore of no practical significance”. (§117).

In this context, ICRP’s evaluations or judgments are disputable, as they are often very “definite”, not specifying uncertainties and not taking into account uncertain but plausible detrimental effects. Judging undetectable effects on IQ of no practical significance can also be challenged as a particularly unwise position where consent of future mothers is not evident.

Recent animal studies of P. Jacquet (2004) and Japanese researchers have been discussed at the Article 31 Group (2001 Scientific Seminar on Effects of in-utero exposure to ionising radiation during the early phases of pregnancy (RP 131, 2001).

After irradiation during the pre-implantation period and during the early post-implantation period, *non lethal* congenital malformations have been induced in animals, particularly those with a *genetic predisposition* to specific congenital malformations or with *genetic disorders* in the pathways of apoptosis or DNA-repair. Both periods have been generally considered safe as regards risks to live births from irradiation.

During the zygote-stage (about 1 day), no threshold dose for this radiation-induction of congenital malformations has been observed in those genetically predisposed animal strains.

After irradiation during the organogenesis, *more* congenital malformations have been induced in animals with genetic disorders. There are similarities with the effects of chemical agents.

In these cases, the cause of the congenital malformation may not be an increased loss of cells (classic deterministic effect) but rather the persistence of un-repaired or mis-repaired DNA-damaged cells.

In humans, the same susceptibilities probably exist: there are indeed families showing *clusters* of spontaneous congenital malformation.

There are also in humans many genes implicated in the DNA-damage response and involved in the genetic susceptibility to cancer induction by irradiation; if the mechanisms are similar (persistence of mis-repaired DNA-damaged cells), it is plausible that human genotypes

leading to cancer-proneness are also associated with a genetic susceptibility to the radiation-induction of congenital abnormalities (or more subtle tissue dysfunctions). The use of generally applicable threshold doses (like the 100 mSv figure for the radiation induction of malformations after exposure during organogenesis) could then be an unjustified simplification.

It is interesting to note here that, according to UNSCEAR 2001 (UN01), 50% of the human congenital abnormalities have some genetic *component* (even if not evidenced by the existence of a visible cluster).

Due to genetic susceptibilities, there could then be for some individuals a higher risk of radiation-induced malformations or lower thresholds and this risk could also exist during the "safe" periods of pre- and early post-implantation. Although frequently assumed to be low, the frequency of these individuals is not known.

Clearly ICRP has chosen to ignore the individuals with possible genetic susceptibilities. It recommends no precaution measures for them, even in the section regarding medical exposures, although the above mentioned observations have clear potential implications for the high dose medical examinations performed in women not aware of being pregnant.

5.3.1.3 Genetic susceptibility in cancer processes

The recent evolution in molecular biology has clearly shown the existence of genetic susceptibility in cancer processes as already demonstrated in radiotherapy where a small fraction of patients have heritable mutations in single genes (de St. Georges 2004, RP123). Selection could become in future a major ethical challenge in particular at work, while offering therapeutic opportunities at clinical level.

More than 30 familial cancer genes are identified such as retinoblastoma. There is evidence from human and mouse studies that cancer prone individuals are also susceptible to IR induced cancer (e.g. early breast cancers).

As indicated in the proceedings of the EC scientific seminar on Genetic Susceptibility and New Evolutions on Genetic Risk, held in Luxembourg in 1999 (RP 123), large uncertainties still remain as regards the collective impact of low penetrance mutations, i.e. the weakly expressing ones.

In occupational medicine, there is at present no routinely applicable method to identify workers who could be especially susceptible to radiation induced cancer, except for the rare and obvious diseases, which are immediately detected by clinical examination or family history of cancer. It is the responsibility of the occupational physician to exclude such persons from any work involving significant exposure to ionizing radiation. This also concerns the members of emergency intervention teams. The possible future availability of screening tests for some genes related to cancer susceptibility will raise legal and ethical questions concerning their use.

The main implication of these genetic susceptibilities is certainly related to protection of patients undergoing high level radiation exposures during radiotherapy, interventional radiology or some high-dose diagnostic procedures. One of the conclusions of the 1999 above-mentioned seminar was that it would be useful to elaborate a guide for the practitioners whose practices may potentially lead to high risk of exposure to radiation.

ICRP should take these complex risk questions into account in its future recommendations.

5.3.2 No precaution discourse on the consideration of uncertainties

"Ethical considerations will have to be part of the reasoning and may include an assessment of the societal principle of the day (e.g. the precaution principle)" (Letourneau, NEA conference Public confidence in Management of Nuclear Waste)

Precaution is a political as well as a risk management principle, driven by a new social discourse, searching for approaches to assess and manage risks in uncertainty or even ignorance.

The principle (PP) is part of agenda 21 of the UN Rio declaration on sustainability of 1992 (principle 15) where it is listed as general right of national authorities and as an obligation. Precaution has not yet been explicitly integrated in ICRP concepts and recommendations. It is even not yet part of the discourse, while being an implicit ICRP cornerstone since almost 40 years, as illustrated in the historical introduction above.

In the EU an overarching framework now exists on precaution. It became part of the EU treaty in 1992 (art.174). The PP has been implemented in EC environmental instruments in particular regarding climate change, biodiversity and GMO's⁷³.

It should be applied for environmental protection when threats for serious and irreversible damage exist. Lack of full scientific certainty shall not be used as a reason for postponing measures.

An innovative new rationale for action is being set up essentially in the non-nuclear field. The EC has developed the principle in a communication in 2000 (EC00). Precaution now interconnects all Commission policy fields, even the nuclear as a new element in governance. The European Environmental Agency (EEA) analysed in 2002 numerous examples of historical lack of precaution, such as with asbestos and ionising radiation. The document "Late lessons from early warnings" (EE02) establishes responsibilities for neglected initiatives in the past also in the nuclear field and gives interesting recommendations for regulatory work such as ICRP is doing.

Meanwhile Court judgements have also created in Europe considerable references (jurisprudentia) on precaution. (von Schomberg 2004).

In the nuclear sector precaution is less referred than the climate issue which however is focussed for reasons of precaution.

In health policy, similar approaches already existed and become elaborated such as in the EU regulation EC 178/2002 on food law. In health policy it is even stated that public health should undoubtedly be given greater weight than economic considerations. New policy developments in health and environment are referring to this principle (PP), while proactive initiatives regarding precaution are lacking in nuclear recommendations.

It is up to now a neglected opportunity that ICRP is not positioning its draft recommendations within these new trends in international law.

It could be explained by the differences still existing between Europe and the US on political objectives on precaution, but the principle has an UN backing. It could also be explained by a scientific expert culture opposing the extension of scientific methodology to social proof (Latour 2000). It is the more surprising when we notice that ICRP opens perspectives to involvement and safety culture, which are implicit steps towards more precaution.

Uncertainties are omnipresent in risk and technology assessments such as ICRP is considering. They have already been illustrated and argued above in this article for in utero exposure during the various phases of the pregnancy. They illustrate real opportunities for applying precaution in the nuclear field, at least in Europe. A number of uncertainties concerning the effects on health and environment were not highlighted by ICRP, as scientific method requires, and considerable gaps of knowledge still exist (Auger electrons, foetal sensitivity, low level long term radiotoxic exposure, multi-factorial exposure conditions, etc...).

The evaluation of the genetic risk by ICRP for instance is ethically questionable. By giving an authoritative message that the genetic risk is lower (and therefore of lower concern), while

⁷³ Genetically Modified Organism.

ignoring deliberately possible long term victims (including the “rare heritable diseases” possibly associated to mutations in mini-satellites) ICRP adopts an ethically disputable attitude. Here ICRP takes a position exactly opposite to the application of the principle of precaution (understood here as recommending measures of precaution or prevention to avoid plausible but uncertain serious detrimental effects). The opinion of ICRP could even discourage medical practitioners from making efforts to limit or avoid gonad exposure. With its scientific authority, ICRP could influence societal and regulatory actors that have to decide on the necessity to apply or not precaution measures.

ICRP has a risk rationale and developed a coherent triple system of dose limitation that could be presented as a model of precaution, since it is already bridging gaps between structured prevention and precaution.

The ALARA principle was *precaution avant la lettre*. It has been situated historically as an implicit invocation. Optimisation has developed original precautionary tools which could even be exemplary for other fields. Optimisation is a very interesting precursor of dealing with uncertainties at low dose, whereas may-be not enough developed in some fields, such as the medical.

Nuclear safety practice has acknowledged as well risk based as uncertainty based approaches. Human and social factors have been integrated in risk assessment in order to be able to manage risk lessons learned in reactor accidents. The reactor safety PSA⁷⁴ of MIT⁷⁵ had to integrate after the Harrisburg and Chernobyl accidents, human and management reliability in its engineering concept of prospecting of accident consequences and probabilities. This was before unnoticed (ignorance or limited disciplinary system view) and not stated as major uncertainty. It illustrates how the French philosopher B. Latour sees precaution: a good governance common sense approach, applying a kind of collective experimental science to practise “élargir scientific proof à l'épreuve sociale” (2000).

Why is ICRP not broadening its scope and its recommendations to precaution as done in other fields? How is ICRP going to handle uncertainties in the precaution context?

Why is ICRP not offering its tools and strengths to non-nuclear sectors, while developing risk analysis and management.

Why not learning lessons from reactor safety by structuring precaution approaches related to involvement and safety culture?

Is ICRP aiming more social robustness for its RP experts involved in social interaction?

A more proactive assessment of uncertain multifactorial risks for health and environment could be a precautionary challenge for ICRP as already put forward by its pioneers in 1958 (IC09). The reconsideration of radiotoxicity in chronic mixed exposure with heavy metals and organics could be a challenge of relevance as well for waste disposal as for protection in remediation activities.

The lack of precaution could increase legal and liability problems. When scientific uncertainties are not clearly stated with present scientific indications such as in medicine, problems could multiply such as discussed by Lierman in 2004.

A basic question is *how much* scientific evidence is needed before a scientific community feels it is necessary to apply the precautionary principle.

As an example: Are the new observations concerning the risks of irradiation during pregnancy and their potential implications not sufficient to warrant action? In other words, can they not be considered as “early warnings” asking for precaution measures?

⁷⁴ Probabilistic safety assessment.

⁷⁵ Massachusetts Institute of Technology.

5.3.3 Paradigm change in the dose limitation system

Most striking and having an enormous impact on system implementation and effectiveness of protection is the reversal of the hierarchy of the system and of the dose concepts by the draft ICRP 2005.

The primary level of the basic safety standards system, justification, is considered in a very restrictive way as a political task outside the scope of radiation protection (§18). *The responsibility for judging the justification of a practise falls on governments...*) or is left even for generic justification in medicine mainly to medical practioners (§19). It is discussed in chapter 5.3.4.

The dose constraint, originally a simple aiding tool for the second level of protection, optimisation, becomes in this ICRP 2005 draft a primary protection level. Moreover it refers to natural background and no longer to a scientific risk rationale.

The involvement of relevant actors and safety culture as a new way of thinking is only mentioned as an apparent new development in optimisation (ch 7.1), while the collective dimension of optimisation also fades away, as discussed in chapter 3.5.

The change of paradigm for justification and optimisation is particularly crucial in the context of medical exposures and exposure of the public to radon representing together more than 90% of public exposure. Indeed the third level, the limits, have no protective capacity in these cases, while they should add equity in the utilitarian system.

We have considered the statement of ICRP that its utilitarian approach (of justification and optimisation) decreases for more concern for the individual (§6), but we notice that the new ICRP 2005 draft is only considering average individuals and groups but not the most vulnerable ones. This represents an ethico-legal concern already discussed in chapter 3.1.

Per Wikman from the Royal Institute of Technology, Stockholm develops a PhD on the coherence of assumptions of ICRP introducing e.g. the disaggregation principle⁷⁶ (2004). For him the reference to natural sources may not be used as the new legitimation because of the uncertainties on background dose effects, called the natural dose fallacy by Shrader. *We always have to make value judgement of the fact.* The ethical code of IRPA ("sound scientific base of all statements") and of the Article 31 Group ("avoid confusion scientific and value judgement") is offering some guidance. Field experts could lose credibility and be challenged on integrity when the coherence in their scientific risk base is no longer evident. Background is very variable and nature can be harmful as evolution learns.

R. Clarke introduced the concept of controllable dose in 1999, assuming that when an individual dose is trivial, also the sum of numerous trivial doses represents a trivial risk and that if the risk for human health of the most exposed individual is trivial, the total risk is. This controversial idea is no longer taken up in the draft 2005 but still supports the trivial dose concept in the dose constraint.

The risk is not necessary negligible when individual exposures are trivial. There is a difference between negligible dose and acceptable risk. ICRP even warned in the 1997 recommendations not to ignore systematically individual low doses as their sum can amount to important collective dose. Trivial doses are relevant at individual level but can only be justified based on collective risk management.

The concept of dose for the critical group may dilute the risk in a statistical way when it is based on averaging a population.

⁷⁶ *If the risk to the most exposed individual is trivial, than the total risk is trivial.*

The disaggregation is not self evident and ethically questionable regarding distributive justice. Moreover the dose concept is only an abstract indicator of risk, questionable for different kind of exposures, particularly for chronic internal exposures.

The methodology to assess doses and to estimate risk in radiation protection refers to a different justification than in a regulatory process.

The justification of exposures at low doses reintroduces the existence of a threshold at low level, which is controversial in radiation protection.

5.3.4 Justification is fading away

Justification is not only a judgement for authorities at the end of a process but as well a daily challenge for RP experts as a responsibility for operators

Justification in general had remained rather vague in ICRP progress since 1976, while the challenges for RP experts increased. Societal interaction changed their role. Technical judgements are no longer sufficient. The ability is required to balance costs and benefits and to make explicit as well value judgements as technical risk considerations and comparisons.

ICRP should not leave justification of practices to authorities (licensing sources and practises) and to the medical profession. Then ICRP no longer considers justification as a major responsibility attitude for each actor in RP, while it is directly related to professional responsibility or commitment to the radiation protection system. Justification should not lose its importance at field level.

Even if justification should be limited to authorisations by authorities, ICRP should give indications how to develop methods of justification within authorisation processes. Silini was already defending in his Sievert lecture in 1992 to develop justification in a structured way.

The idea of justice of the USA Philosopher John Rawls (Rawls, 1971) refers to the idea of managing justice by some institutions, structured with fair principles, asking for procedures of consensus building to achieve some agreements. The ICRP is acting in such a way, asking professional experts to interact in a structured hierarchy of delegated powers in order to debate about the right norms to be applied.

This configuration of a consultation process gives priority to the capacity of this category of expert stakeholders but requires that they act morally within a broader scope than their professional mandate. They should represent care taking for a broader common good⁷⁷, which is not an easy task in a context of confrontation where ICRP is questioned.

ICRP had already stated since 1990 "...not unduly limit beneficial actions..." (S2). Without a justification responsibility based on low dose effect rationale, the illustration of benefits could give priority to economy in health concerns in the growing market approach.

Justification should be an effort in distributive justice, a balancing of advantages and disadvantages, where health, environment and economy, individual and collective interest, are at stake (Feltz, 2003).

When we frame justification in Kantian⁷⁸ (Kant, 1956) philosophy, a spiritual precursor of Rawls, our rationality requires not only procedures in which each stakeholder has to fill in the content of justice but essentially requires common criteria to assess what's fair and right with regard to the right methodology. With Kant, the construction of justification means that the contributors are able to advance the sense of justification, to state what is the common good

⁷⁷ Specific "good" shared by or beneficial for most members of a community (ex. general welfare).

⁷⁸ Personal duty (moral freedom) is based on universal reason not dependant of cultural context and procedures.

and to refuse bargaining independent of the context (ex. clean atmosphere, drinking water, social security...). In a way experts and stakeholders must agree on the recognition of some principles of justification like the priority for protection of public health or the need to protect the most exposed groups. With Kant, there is no place for the protection of a statistically average individual. Each person deserves his own respect; the protection by eco-centrism doesn't necessary mean the protection of human beings.

The duty of justification is often seen as a paradigm shift by scientists in a risk society but it is already mandatory in different legal tools such as "Environmental Impact Assessment". The requirement in Europe to consider alternatives for technology practises is part of the justification task of radiation protection and safety experts. The comparison of alternative options is an implementation of justification. It becomes self-evident when involvement experiments are set up.

Involvement starting with justification was implemented successfully in nuclear waste disposal. Local partnerships were set up in different countries such as in Mol (MONA 2005) and followed up at NEA level and stimulated in EC research networks such as COWAM (www.cowam.org).

Contrary to its reasoning on the too broad scope of justification for RP experts, ICRP is now defending to include involvement (§196 ...*incorporation of values in decision making, building of shared understanding*) as well as safety culture (§195 ...*another state of thinking*) in the scope of optimisation. This has been studied by the PhD of Fucks in 2004. It requires social and organisational insight and is broadening the scope of an expert. The taking into account of social aspects is a complex challenge for experts as it requires a change of their culture. Involvement of relevant actors will always require justification of practises.

The delegation of justification to regulatory authorities confuses authorisation of a practise with system application and legal follow-up. The preparatory processes through experts and the legal system control set up, applying the ICRP former system, daily requires justification and guidance.

Moreover for medical exposures even generic justification is left by ICRP (§217) to national professional bodies, sometimes in conjunction with regulatory agencies, which could weaken the increasing role radiation protection officers and hospital physicists play in the protection of staff and patients in medicine. In medicine 50% of public dose occurs and optimisation was not as successful as in nuclear industry.

A clear distinction should be made between generic and patient specific justification in medicine. Generic justification of a technological practise can, due to the technical and organisational complexity, no longer been handled by one discipline or professional group. It could even be ethically unacceptable. Generic justification became a multidisciplinary practise of technology assessment, medical care opportunity consideration and procedural quality assurance including protection. Original transdisciplinary work is done now in Europe to master costs of new high tech medical imaging, to justify technological choices or a mix of technologies such as MRI, US and PET-CT. These choices in medical TA are as well directed by individual and collective risks for patients and staff. Other disciplines interact: cardiologists and peditary in justification of IR or CT, hospital physicist in optimisation and process QA. To develop a scientifically complete approach of justification and optimisation a transdisciplinary approach is mandatory. An ethical requirement of scientific method to be as complete as possible stating uncertainties is necessary, more than before. In the complex evolution of technological medicine generic justification can no longer been left to the medical profession.

In its future dimension justification is related to the precautionary responsibility for potential impacts and opportunities. Precaution as well as justification is not only a policy principle but also a challenge for risk management in the field.

5.3.5 Optimisation loses its collective dimension

Justification and optimisation were seen as utilitarian instruments (Shrader, 2001) corrected by egalitarian ethics with the third level of protection, individual limits. Well defined limits should protect individuals and guarantee equity in the former ICRP hierarchy. ICRP now proposes the use of a former optimisation aiding tool, dose constraint, as first level of protection before optimisation. The intent is now to provide a level of protection for the most exposed individual in a class of exposure (§6).

Optimisation focuses now completely on the individual level, while collective public health, as essential component of the common good, loses attention. Considering the definition of the individual in legal terms as a physical person, coverage will be weak. Limits could also lose a part of their legal meaning regarding the introduction of constraints at a higher level, but being related more to sources than to the complexity of multiple individual exposures.

Is the average individual a virtual individual while the regulatory concept requires an individual as legal subject?

We notice at least in ICRP another priority for the common good and less guarantees for individual rights. Philosophically speaking it is not feasible to protect a virtual average individual, respecting individual rights of all.

Some incorrect use of the valuable concept of collective dose⁷⁹ was at the origin of criticism and proposals for change within ICRP. This has been discussed by IRSN in a balanced way in 2002.

Collective dose considerations have led to remarkable RP successes in reactor remediation and allowed us to discover again the most important challenges for public health and RP: radon in dwellings and patient exposure to X-rays.

The cohesion between justification and optimisation is based on the stochastic risk LNT rationale. It decreases when another background rationale is applied or when low doses are no longer taken serious in particular at the level of a population.

We have considered the statement of ICRP that its utilitarian approach decreases for more concern for the individual, to provide a level of protection for the most exposed individual in a class of exposure (§6). But this contradicts an ethical judgement taken by ICRP 26 and confirmed in §80 to consider only one single set of w_T values for both genders and ages. Genetic susceptibility now makes more complex individual vulnerability. We have shown above that for genetic susceptibility the draft ICRP is only considering average individuals and does not consider individual rights as put forward by I. Kant (respect of the individual as such). The Kantian approach considers the need to protect the person for his own good as a valuable goal. In SCK•CEN it could be noticed that from the philosophical point of view most experts seem to adhere to Kantian ethics, a concept that guarantees integrity and untouchable human rights and liberties (Cornelis, 2004).

ICRP wants to add a collective dimension by involvement, but should specify in future its new involvement approaches even with patients. The broader social interaction should be considered as another interesting challenge for the already transdisciplinary job of radiation protection.

⁷⁹ Total dose received by a population, summing up the individual doses.

ICRP is no longer mentioning the structured participation with unions and employer organisations set up in the past at ILO and EC level also with the main commission of ICRP (Zerbib 1992). The handbook on involvement of the European University (UN03) and TA methodologies as analysed in COWAM could improve involvement practises.

In the development of safety culture it was illustrated how the integration of human factors and organisational reliability could improve reactor safety and the probability of core melt.

Moreover in risk management outside the nuclear sector, new QA systems have been developed in which RP could be more integrated.

A broadening of the ICRP dose based approach to safety concepts at the source, taking probabilities into account even at the level of human and management reliability, could help to manage risk in a more effective way.

5.3.6 Enlarged anthropocentric approach without ecosystem view

The extension of the framework of RP to the environment links ethical issues to principles and objectives of environmental policy, management and pollution control.

ICRP is leaving its strict anthropocentric approach and now considers additionally environmental detriment as such as already done in most other environmental policies worldwide.

The aim of the ICRP is to fill a conceptual gap and to develop a more harmonised approach with other pollutants. ICRP remains convinced however that its former dogma "the environment is sufficiently protected if man is" still holds.

This is surprising in the context of major challenges and recent approaches in environmental policy and contradicts nuclear discourses regarding climate change.

The concern for the environment as such and for sustainability remains limited. The new approach rather represents a broadening or projection of the anthropocentric approach of ICRP to 12 other species.

This can be considered as a progress in nuclear culture, but the shift in ICRP policy regarding the environment still seems to project an anthropocentric concept on a limited selected number of species such as rats, grass, pine trees and some fishes but an ecosystem view to protect environmental components such as the atmosphere, the soil, outer space is still missing.

This comment adds to the delay and lack of precaution in the ICRP approach compared to new dynamics in environmental policies in general.

We also notice a lack of coherence in principles with the climate change discourse of the nuclear sector, referring to the carbon dioxide benefits of nuclear energy.

The anthropocentric approach as developed earlier in ICRP has caused in the non nuclear sector the CO₂ problem. CO₂ as not toxic for human health, was allowed to be released without major restrictions in industrial production. It now causes a major long term problem for the planet, due to a lack of vision on the global even high atmosphere as a system.

But ICRP too is not considering protection of the atmosphere. The ICRP concern for human health allows neglecting a small increase in skin cancer risk world wide due to the complete release of noble gasses in nuclear industry and in particular in reprocessing plants. Pollution control efforts were stopped in 1977 when ICRP published its w_T value of 1% for skin.

The end of pipe technology for noble gas storage was available, but not applied. The best available technology was developed earlier in order to limit small collective health risk by skin exposure over the whole world. As a result the atmospheric background of Kr⁸⁵ has increased with a factor 10⁷ since 1945. (Eggermont, 1999).

Few studies are made on atmospheric effects of radiation. Effects have been demonstrated regarding SO₂ by F. Raes et al (1987). Kr⁸⁵ is globally mixed in the atmosphere over 2y and

could play a rather small but still uncertain role. The nuclear discourse on reduction of CO₂ for protection against climate change could be more coherent if similar principles were used for nuclear atmospheric releases of radioactivity.

ICRP should also take care of the ecosystems soil and water for reasons of precaution. ICRP has not yet paid attention to the new priority of long term concern for endocrine disruption in particular related to chemical exposures. Effects of radiation in endocrine disruption should not be excluded a priori and should be studied in particular regarding river systems.

Considering limitations and uncertainties in the abstract dose concept, which was not developed for environmental exposure, ICRP could much more rely on specific activities, total activities and activity concentration of RN in the environment which are measurable and controllable. Other indicators than dose, such as biodiversity, could be looked for. Around Chernobyl, where the micro fauna in the East Ural foot print decreased 97% in an early phase, measurement of diversity of micro fauna was a main indicator for life and healthy soil (Velikhov 2004). It was commented by this president of Kurchatov that "*at the beginning of the nuclear age, no one unfortunately made efforts to formulate rules and norms to protect the environment. Americans and Britains were as irresponsible as Russians were*".

We can only express the hope with Pentreath (2004) that the emerging framework of RP for the environment will link ethical issues to principles (such as sustainable development and precaution) and to objectives of environmental management. When multi factorial exposure will remain or become more and more the real issue, the health and environmental endpoint of combined exposure stress should be considered by reliable and sensitive biomarker developments.

5.3.7 Exclusion not justified within European risk approaches

While ICRP is proposing to delegate justification to national authorities, it does the contrary for the particular problem of exclusion (Ch. 2.3).

ICRP surprised numerous independent experts and institutions such as EC with its exclusion concept which is not really argued referring to health concern and collective hygiene. This innovation in ICRP was prepared within IAEA under impulse of new actors in RP. However IAEA has set important framing conditions surprisingly not taken over by ICRP. It seems to be rather inspired by concerns on expensive military remediation and waste costs for NORM industry. Mining multinationals in particular, have surprised nuclear regulators by their performing lobbying capacity and high level radiation expertise.

The IAEA vision on exclusion, integrated in ICRP 2005, represents no consensus for Europe. ICRP justifies exclusion without really balancing benefits and risks and without arguing its decision. Considerable individual and population exposures are possible due to these exclusion proposals, in particular when large amounts of material just below such values should be applied without optimisation. This could occur for instance due to increased use of phosfogypsum construction blocks.

Exclusion levels could create inequity for different kinds of exposures if other risk criteria are used for exposures with comparable radio toxicity. Exclusion levels proposed for natural radio nuclides are a factor 10 to 100 higher than for artificial radio nuclides in spite of comparable radiotoxicity. This could complicate the application of legal proportionality in Europe which requires environmental measures proportional to risks.

According to RP 112 (EC 99) Vanmarcke calculated exposure in a building with concrete at 1 Bq/g uranium and thorium decay series (BVS/ABR working group on ICRP 2005, Kockerolls et al 2005). Doses from 14 to 18 m Sv/y are possible. The dose index of RP 112 calculated for the exclusion levels is 12 which mean that exclusion levels could be more than an order of magnitude too high.

Anyways in Europe no regulatory need exists for exclusion.

Involvement on exclusion was only considered for some industrial actors, while serious doubts exist on the evolution of perception of the public and of clients of the industry such as car industry using steel with marginal traces of RA in recycled products. Similar difficulties can occur with toys from recycled materials.

The depleted uranium (DU) problem has already shown that a number of uncertainties still exist on mixed exposure which can occur in the use of a lot of recycling products. Such situations could also occur in contaminated regions and near nuclear waste disposal sites.

A. Métivier suggested reconsidering our knowledge of radiotoxicity in case of chronic (mixed) long term exposure by considerable research programs (www.sfrp.asso.fr).

5.4 Legal Issues: a decreased legal enforcement capacity

The (national) authorities define normative issues for ionising radiation, taking into account ICRP recommendations which have a high authority. This de facto legitimisation creates a large responsibility for ICRP. Courts and judges will play an important role too in future. Dialogue with legal professionals in due time could improve the legal enforcement capacity in ICRP recommendations.

As public controversy on ICRP statements is increasing, formal legitimation of ICRP could become necessary. A kind of peer review was asked for during the EC Involvement Conference on RP. It could be useful to set up a procedure to deal with always existing conflicts of interests, in order to be able to judge on eventual mix of interests by third parties. The code of ethics for the EC Article 31 Group was developed in that sense.

ICRP should be an independent guardian of the system, as defined by RISCUM⁸⁰ and should not leave principal elements of its mandate to professional organisations with interests in the field.

The publication of minority positions could increase transparency as driving force behind the options and has a considerable pedagogic importance for field experts and for the interpretation capacity of judges.

ICRP has increased soft law in nuclear regulations in the past, especially through the optimisation approach. These trends are not generally welcomed in the forum of international nuclear law association (INLA), while defended by IAEA.

This led to confusion between the duty of care principle, BATNEEC⁸¹ options and ALARA and could create precaution cases in Courts in particular related to liability in medical applications. ICRP should clarify its (concept) developments in future, taking legal constraints into account as faced by judges confronted with complexity. The optimisation matrix prepared by ICRP will be very difficult to consider in legal terms while courts should be able to consider the effort made by operators to realise an optimised level of protection. Linking the dose constraint in the draft to failure could handicap its legal binding capacity and make sanctioning difficult. This could also create problems within funds for professional diseases in Europe where responsibilities are fixed by technical committees which are referring to ICRP and in particular to its limits.

ICRP is opting implicitly for a legal system in its recommendations. It is characterised by technical scientific descriptive norms, creating an objective of means by specifying conditions but leaving considerable roles to medical staff, operators,....

Moreover ICRP specifies who should implement, how and who is responsible. While doing this ICRP should be aware of the fact that it stimulates here negotiations on regulation. ICRP here

⁸⁰ Risk Communication for transparency (Anderson 1998).

⁸¹ Best available technology not entailing excessive costs.

acts no longer as scientific adviser but intervenes at the State level of regulatory policy making.

When we consider the two major legal orders in law: *common* law and *civil* law, ICRP is more and more positioning itself within the first Anglo-Saxon order.

Common Law is case law essentially shaped by judges. It is the dominant approach in many international networks (no guardian in the global world). In the USA, clear principles are left to the management system. No clear responsibilities are given in advance. More confusion exists in courts between technical principles and legal interpretation.

Civil Law is an abstract regulatory formulation of equal obligations. It is applied in the field and interpreted by judges. The State is the guardian of the common good. Legal obligations are constraining actions to follow rules, evaluating results, stating responsibilities and sanctions.

In Europe the command- and- control regulation has been demonstrated more effective than self regulation. Prescriptive Civil Law directs more the steps of legal obligations indicating the way to arrive at results.

The ICRP 2005 draft will open doors for interpretation. Justification is no longer clearly specified, leaving room for negotiations with regulators and in (pre) court law procedures. For legal clarity, ICRP should clarify justification, optimisation and the standard of care for health and accelerate developing reflections on precaution.

The new system is source directed and could be easier to apply by operators. The obligation of results could decrease due to reduced power of non measurable abstract dose indicators of (public) health effects. Responsibilities could be more diffuse.

For the environment the proportionality regime in European civil law could have difficulties with the ICRP proposed exclusion which is not treating risk of natural and artificial radioactivity equally.

The new approach of ICRP can be considered in principle as less prescriptive and more framed in Common law. In a phase where normative variability (uncertainty, species) depends on science input this will require another role for judges, lawyers and experts, which should be prepared and negotiated in society. Courts and judges will play a more important role in the practise of law. The enforcement of law will more be based on agreements and trade-offs. This could favour utilitarianism again.

The application of Anglo-Saxon Common law regime could create a number of difficulties in continental Europe, where Civil law prevails. Statutes and constitutions are set by the legislative branch of governments. The governmental authorities and the agencies are the first level of enforcement of obligations. But more delegation of responsibilities from the state to the different groups of experts occurs. The definition and treatment of public interests shift to experts without deliberations in representative democracy. Moreover the utilitarian view of Common law is mainly addressing the economic interests and does less take care of a larger definition of the common good.

The common good will be organised mainly by operators and experts, starting from their own practical concerns. So, the global legal coherence articulated in written norms could change in a regulatory system, based on agreements and trade-offs.

5.5 Conclusions

Due to fundamental changes in the hierarchy of principles and dose concepts the new ICRP draft will create ethical and legal difficulties particularly in Europe.

The fading away of the pillar of the system justification is very controversial while optimisation should remain individual as well as collective, mainly to improve the level of protection, which can not be guaranteed by a simple tool of dose constraints.

The pretended move from utilitarian approach to concern for the individual only reflects more concern for a virtual average individual. The draft is positioning itself in liberal utilitarian ethics with loss of equity, poor attention for individual rights and the common good (not based on the market but on fairness and justification).

The anthropocentric extension to other species is missing an ecosystem view and coherence on principles with nuclear climate discourses, used by the nuclear sector and IAEA.

ICRP should reconsider its legitimacy by looking over the nuclear edge and by opening its scope to non nuclear environmental visions and by positioning its strong case in a precaution approach.

5.6 Acknowledgements

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5.8 Glossary

AEC: Atomic Energy Commission, USA

ALARA: As low as reasonably achievable

BATNEEC: Best available technology not entailing excessive costs

BEAR/BEIR: Biological Effects Atomic (Ionising) Radiation, USA

CEPN: Centre d'Etude sur l'Evaluation de la Protection dans le domaine nucléaire

CITES: Centre de Recherche Inter facultaire 'Techniques, Sciences et Sociétés'

Common good: Specific "good" shared by or beneficial for most members of a community (ex. social security, drinking water) – general welfare

CT: Computer Tomography

DOE: Department of Energy, USA

EAN: European ALARA Network

EC-DGTREN: European Commission, Directorate General Transport and Energy

ECRR: European Committee on Radiation Risks

Egalitarianism: Doctrine to treat people the same, as equals in value or status (different types of equality exist), characterised by belief in equal political, economic, social and or civil rights for all people

EPA: Environmental Protection Agency, USA

EU: European Union

EURATOM: EU Treaty on Atomic Energy Agency

FANC/AFCN: Belgian Federal Agency of Nuclear Control

FANC: Belgian Federal Agency of Nuclear Control

GMO: Genetically Modified Organism

IAEA: International Atomic Energy Agency, Vienna

ICRP: International Commission Radiological Protection

ICRU: International Commission on Radiation Units and Measurements

ILO: International Labour Organisation (UN), Geneva

INLA: International Nuclear Law Association

IRPA: International Radiation Protection Association

IRSN: Institut de Radioprotection et de Sûreté Nucléaire

IXRPC: International X-Ray Protection Committee

LNT: Linear non threshold hypothesis

MIT: Massachusetts Institute of Technology, USA

NAS: National Academy Sciences, USA

NCRP: National Commission Radiological Protection, USA

NEA: Nuclear Energy Agency (OECD)

NGO: Non governmental organisation

NRC: National Research Council, USA

NORM: Naturally Occurring Radioactive Materials

NPP: Nuclear Power Plant

NRC: Nuclear Regulatory Commission, USA

PISA: Programme of Integration of Social Aspects into Nuclear Research

PP: Precaution principle

PSA: Probabilistic safety assessment

R: Roentgen, unit of exposure

RIHSS: Research Implication on Health and Safety Standards

RISCOM: Risk Communication

RP: Radiation Protection

SCK•CEN: Nuclear Research Centre, Mol, Belgium

Soft law: Rules of conduct that are laid down in instruments which have not been attributed legally binding force as such, but nevertheless may have certain (indirect legal effects, and may produce practical effects

UCL: Université Catholique de Louvain, Louvain-La-Neuve

UNSCEAR: United Nations Scientific Committee on Effects of Atomic (Ionising) Radiation

Utilitarianism: A theory of ethics based on quantitative maximization of a form of good for society or humanity (greatest happiness for the greatest number). It's a form of consequentialism and can be reduced to a balance of costs and advantages. (from Latin *utilis*, useful)

VUB: Vrije Universiteit Brussel

WHO: World Health Organisation (UN)

6 CONCLUSIONS

6.1 Meaning of this document

This document presents in brief the highlights of the EU Conference on 4 November 2004 dedicated to the critical review of the draft 2005 ICRP Recommendations. These highlights have to be regarded as **major and pertinent issues** that were discussed during the Conference.

This document is not intended to give an exhaustive list of all the issues brought up during this Conference.

The highlights have been identified by the Working Party on Research Implications on Health and Safety Standards (WP RIHSS) of the Article 31 Group of Experts after the Conference. The Article 31 Group of Experts recommended the Commission to submit this document to ICRP for consideration.

6.2 Biological issues

- There was concern about the new risk coefficient for radiation induced **hereditary diseases**.

Reasons for concern:

- *When evaluated on comparable bases (risk for the first generation, for 2 generations, ...) , the genetic risk is not reduced in the UNSCEAR 2001 Report by comparison with the UNSCEAR 1993 Report. Nevertheless, based on the existence of large uncertainties, ICRP takes now the effect on the generations farther than the second as being zero. Can this decision be considered as a balanced acceptable position according to the present scientific knowledge?*
- *According to the challenging speaker, the main problem is the radiation induction of small deletions leading to recessive mutations and diseases of which the phenotypes might frequently not be recognized by the physicians. Such cumulative small genetic disorders may propagate in the future generations with the risk of leading to more important pathological consequences. This is hardly taken into account by ICRP (and UNSCEAR) in the risk coefficient, as they are of the opinion that the major contribution to the genetic risk comes from large deletions expressing themselves essentially in the first generations. The basic question is whether we know enough about the radiation induced hereditary effects to close the matter.*
- Are the persisting uncertainties and the new experimental evidences in the field of the effects of in utero exposure (exposure of zygotes, genetic susceptibility to congenital malformations, subtle IQ effects,) sufficiently emphasized and taken into account in the draft 2005 ICRP recommendations? In particular, the reduced attention for the protection of **pregnant women**, for instance in the section concerning the medical exposures, has been challenged.
- Other issues are:
 - *Is a value of 2 for the DDREF in high dose rate exposures (incl. medical) warranted?*
 - *The differences due to age and gender are not appropriately taken into account. In particular, the use of specific w_T to calculate the effective dose should be discussed.*

6.3 Dosimetric issues

- The **limitations** in the scope and the use of **effective dose** are not sufficiently underlined.
- **Uncertainties** may be significant in **internal exposures**. Currently these are hardly mentioned and taken into account.
- The introduction of **organ/tissue dose constraints or limits** should be considered and evaluated as regards their practical application. The reason is that effective dose does not reflect the actual risk and health consequences in all situations.
- The introduction of specific w_R for **low-energy electrons** should be considered, as for tritium and Auger electrons.

6.4 Issues regarding the system of dose limitation

- ICRP should consider confirming strongly the current **three-principle system**, without fading out any principle, in particular as regards the justification principle.
- The **rationale/coherence/justification** of the proposed scale/values for dose constraints (with situations to which they apply) have been challenged and should be carefully reassessed. The "reference to background" approach is mainly useful for public communication. The fundamental input should remain a risk based approach.
- The method that will be chosen to define reference groups or "**representative individuals**" should take into consideration the principle of equity for the real (legal) individuals.

6.5 Issues regarding the proposed system of exclusion levels

- The principle of exclusion levels for **artificial** radionuclides was strongly challenged. Are such exclusion levels **justified**?
- Exclusion levels for **natural** radionuclides should be reassessed **carefully** as the currently proposed values may lead in some particular situations to very high exposures.

6.6 Ethical and legal issues

- Some of the issues mentioned above relate to ethical considerations: management of uncertainty, responsibility, precaution, equity, The **value judgments** made by ICRP have been challenged.
- Are **individuals** really better protected with the new recommendations? Paradoxally, despite claiming that more attention is now given to the protection of individuals, the new ICRP recommendations could be considered as globally decreasing individual protection because of:
 - new priorities in the three-principle system of dose limitation

- very large scale of numerical values for the dose constraints
 - insufficiency of precautionary approach in some fields
 - new approach of collective dose
 - limited consideration of genetic susceptibilities even in high doses situations
 - introduction of exclusion levels,...
- Although ICRP is not supposed to write regulatory texts, it should be aware that there could be legal enforcement problems with its new recommendations in the EU (**common vs. civil law** systems). This could undermine their acceptability.
 - Is the environment **really protected** with the proposed approach? ICRP should continue working on the development of a more efficient system of protection of the environment, clearly involving stakeholders.

6.7 General issues

- Are the **reasons to modify** the current system sufficient? In particular, will radiological protection really be improved with the new recommendations? If so, these reasons or potential improvements should be clearly explained and developed, taking into account the issues that were raised during this Conference.
- Moreover, **continuity** between the previous and the future recommendations should be ensured. Important examples are the modifications in terminology, the meaning of the dose constraints and the suppression of the dual system of practices/interventions.
- As regards the work schedule, the new recommendations would be really understood only **after** the **foundation documents** have been made available and discussed.