

A Radiological Protection Policy Under Discussion

by

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Annex 3. Ulla Swarén, Lars Ehrenberg, Gun Astri Swedjemark and Fredrik Granath: **Indoor Radon - a background document to the report 'A Radiological Protection Policy Under Discussion'**

Six case studies The case studies associated with the report are presented in a special document

Executive summary

Section 1

This section presents the Swedish ICRP Project (SwIP), with the full terms of reference given in Annex 1. The project was initiated by the Analysis Group connected to the Nuclear Training and Safety Centre (KSU AB) in Sweden, against the background of an ongoing international discussion on the recommendations by the International Commission on Radiological Protection (ICRP) and, in particular, a new proposal by the Commission. The purpose of SwIP was to study the available material from the debate on the ICRP risk model, to describe the situation and analyse different out-comes of policy changes and their consequences. Members of the project group should be independent experts.

In the following, 'we' refer to the four members of the project group although we have benefited from a wide range of contacts. As part of the project, six separate case studies have also been carried out, mainly by experts outside the project group. The present report is the result of a step-by-step process, where ***our main ambition has been to present interested parties with structured information and a tool for further thinking, in addition to the conclusions and recommendations that we thought would be relevant and helpful.***

Section 2

Section 2 summarises the overall current principles of radiological protection (RP for short) according to the ICRP as well as the characteristics of the modified protection system as suggested by the same organisation. It should be noted that there seems to be no change in the judgement of the main scientific basis for an RP system; in both cases we find that it is considered prudent by the ICRP to apply the Linear No Threshold (LNT) hypothesis, see Section 6 in this report.

As concerns a 'practice' the present system has three major components: justification of the source of radiation, optimisation of protective actions at the source, and dose limits for individual exposures. Interventions as regards other sources, for example indoor radon, should be justified as well, in the sense that they should 'do more good than harm', all relevant circumstances considered. Reduction of the total dose to all exposed populations taken together (the collective dose) is central to this model, which thus stresses the 'social aspects' of RP.

The new thinking within the ICRP is primarily directed more towards the individual, and places individual doses on a scale where they are compared with normally occurring background radiation doses. After the application of individual-oriented 'Protective Action Levels', there should normally be a second step, that is an optimisation of protection to ensure that the residual doses are kept 'as low as reasonably practicable'. This requirement would apply both to individuals and to exposed groups, with the latter being 'limited to individuals receiving specified ranges of dose over specified periods of time'. In this context, the ICRP speaks of 'group dose' rather than 'collective dose' since this term has been widely used to denote the dose over the world population and over all times. In principle, a modified system would cover all radiation sources where the source or exposure pathways are amenable to control. However, protective actions would be different for 'optional sources' and 'unavoidable sources' (where not the source but the exposure pathways are controllable).

Section 3

Besides purely scientific bodies and the ICRP, there are several actors in the international arena working directly or indirectly with RP. We have focussed on the OECD Nuclear Energy Agency (NEA), and its Committee on Radiation Protection and Public Health (CRPPH) in particular, and on the International Radiation Protection Association (IRPA) as a representative of the RP practitioner community. The section summarises some studies or opinions from these organisations, based on both published and unpublished information. It follows from this overview that

- much work has already gone into comparing present and proposed RP system, partly in a dialogue with the ICRP, and that
- the views have differed widely in many respects.

We have made a special reference to a NEA/CRPPH report from 2000 "A Critical Review of the System of Radiation Protection" where areas have been identified for improvement, and to an ongoing follow-up project by the Expert Group on the Evolution of the System of Radiation Protection (EGRP). We think **the forthcoming report from the EGRP project will be a major contribution to the international discussion** once it has been approved and made public, which we expect to happen in the late spring of 2002.

Section 4

The six case studies are summarised in Section 4, the full reports being available elsewhere. The cases are doses from normal operation of nuclear power plants in Sweden: environmental doses and occupational doses; post-Chernobyl decisions taken by Swedish authorities; radiation protection criteria applied to geological disposal of spent nuclear fuel; residential radon; consumer products. According to the conclusions arrived at by the authors, **in many respects a modified RP policy would probably not have had any significant influence on the actual RP decisions taken or planned.** However, it also turned out that comparing the present ICRP recommendations with the proposed system is an issue that can be difficult to get a firm grasp on, and, besides, RP situations are different and manifold. Therefore, we have not attempted to draw any general conclusions from the case studies in this section, but certain results have been directly relevant to our further deliberations.

Although some of the case studies are rather limited, we also think that they have a value in themselves, beyond the aim of SwIP, since they provide background information on certain types of radiation sources in Sweden and an insight into national or local RP policies and routines.

Section 5

In this section, we have attempted to set a scene for our further discussions of an RP policy and its application by taking **an overview of certain important issues** besides making a few general conclusions. Some of these issues (though not all of them) are taken up more in-depth in the following sections. Without setting priorities, the following - partly overlapping - issues or aspects may be derived from these first deliberations:

- whether or not to base an RP policy on the Linear No Threshold (LNT) hypothesis (the main scientific issue)
- uncertainty, scientific as well as practical, with regard to dose and risk
- low individual doses; low doses to large populations
- risk quantification ; risk comparisons; risk communication
- consistency and transparency of an RP policy

- medical use of ionising radiation (a separate issue but encompassed by the RP system)
- protection of the environment as an objective to be further developed
- ethical principles as a necessary requirement (e.g. the Precautionary Principle that should be undisputed but that does not work well without being further qualified)
- radiation risks in a wider context (possible imbalances between risk management of different types of risk)
- the role of the ICRP and their recommendations from a global and a national perspective.

Section 6

In Section 6, we address the scientific basis for a radiological protection policy (as concerns human beings), i.e. biological effects of ionising radiation, dose concepts, exposure analyses, and the main uncertainties in these contexts, and we have endeavoured to make the discussion clear to the non-expert as well. Two separate annexes provide more in-depth analysis and information.

High radiation doses and dose rates will exert toxic effects (that are scientifically well understood) in the form of acute organ/tissue damage which may even be fatal. There is a threshold dose for this type of harm since it requires death or malfunction of many cells. At low doses and dose rates, the focus is on the single cell. The known capacity of ionising radiation to cause permanent changes in the DNA, a genotoxic effect, should be seen in the context of spontaneous and otherwise acquired or inherited mutations with regard to effects on the off-spring, and to risks - especially of a cancer disease - as the possible end result of a multi-stage change of the genome. Here the application of *the LNT hypothesis* to obtain estimates for the dose-response relations between effective dose and cancer risk *provides RP with an indispensable tool*. We are of the opinion that for the time being *this is the best method available, considering the indirect support for the LNT hypothesis provided both experimentally and theoretically*. However, quantitative risk estimates obtained in the dose regions below the range where epidemiological data are available, present major uncertainties that must be considered both in application and presentation.

The LNT concept allows for radiation doses to an individual from different sources to be considered independently as well as added to a total dose. It also allows for radiation doses to a population from different sources and at different times to be added to provide a collective dose, with due regard to uncertainties in the exposure assessment.

As concerns risk estimates, the LNT concept is applicable to populations only and not to an individual. Thus, at low doses or dose rates, the risk to a specific person could range between zero and considerably above an estimated (average) risk to a member of a population, at the same dose level.

One subsection deals exclusively with indoor radon, which is a major source of radiation exposure in many countries, and cancer risk assessments. In contrast to radiation exposures in general, it is possible to obtain meaningful information (on lung cancer risks) from epidemiological studies at actually occurring environmental exposure levels. However, uncertainties in, for example, calculations of exposures over long periods of time must be recognised, even as confounding factors - tobacco smoke in particular - must be. In Sweden, the Radiation Protection Authority (SSI) has recently, in 2001, revised an earlier lung cancer risk estimate, mainly in the light of available studies on residential radon. This has led to an estimate that is lower compared with that of, say, the US BEIR VI and especially that of ICRP, both of which have based their somewhat earlier estimates on studies of miners.

However, in absolute numbers the estimate for Sweden is still considerable. The SSI also notes that an overwhelming majority of persons with radon-related cancer are also smokers.

Another subsection addresses uncertainties and that which is amenable to analysis, in an integrated perspective. Uncertainties are divided into three broad categories: those pertinent to factors or qualities that may not be measured directly; those involving potential exposure; and those that concern exposure-risk, or dose-risk relationships. Within these categories one should observe whether an exposure situation or a relationship may be verified or not. Two conditions involving major uncertainties are pointed out: one is connected with potential exposure far into the future, where no direct verification of quantitative estimates is possible, although analysis of sensitivity and uncertainty may be useful in indicating the probable degree of error. The other is the LNT relationship between dose and certain detrimental effects. Although these relationships may be validated by theoretical considerations of the radiobiological phenomena below the range of empirical or experimental evidence, we mean to emphasise that the LNT hypothesis has not been and is not likely to be verified in humans, for statistical reasons and based on epidemiological data.

Section 7

Ionising radiation is one among several risk factors in society, and this fact, although well known, ought to be given special attention. This is the reason for a separate section on this issue, with a stress on risk comparisons.

We think ***a major aim for the 21st century should be to break up non-justified borders between thinking and acting with regard to the various types of health and environmental risk factors and risk situations.*** A more integrated approach to risk control, including radiological protection, presumes that risk comparisons are not only possible, they are meaningful. (The same applies to the 'benefits' to be considered in a trade-off situation.)

As part of the background to more deliberations on risk comparisons, we have looked at the EU ExternE project on comparative environmental studies on energy production by the use of external costs, including certain applications to Swedish conditions, and at a special study on costs and effects of certain measures for risk reduction in Sweden illustrated by eight cases. These examinations illustrate that there are great differences in risk perception as well as in allocation of resources in society to mitigate different kinds of risk.

Although risk may be characterised not only in quantitative terms, semi-quantitative or otherwise descriptive terms do not usually suffice in risk comparisons. ***Irrespective of the weight that collective dose and risk estimates will be given in future recommendations by the ICRP, we strongly urge the Commission to maintain some recommendations on how to calculate and quantify radiation risks in an appropriate manner - including all the caveats - and to give more guidance on the use of collective doses for different purposes.***

The biological effects of chemical genotoxic agents are directly comparable to low dose radiation risks and a 'dose equivalent' for each substance is in principle additive to that of other such substances and to ionising radiation. We therefore ***see a need for the future to seek a holistic view of all genotoxic agents although there is a long way to go yet,*** not least with regard to further development of scientific methods for quantifying chemical genotoxic risks. However, some policy aspects in different sectors of society are readily comparable as illustrated by some examples.

Section 8

The message in section 8 is that ***there is a need for a well defined, well presented and easily understood platform for international recommendations on RP, by the ICRP.*** It would ideally deal with issues such as

- the purpose of RP (who and what is to be protected, why and, in general terms, to what extent – with the basic ethical principles specified)
- the system of protection and the main tools for RP and the implications of using these tools
- flexibility vs. ‘stability’ and the role of the ICRP vis à vis regional and/or national authorities.

International recommendations should aim at providing a clear framework for RP, particularly because development levels vary between countries with regard to transparency, as well as in regard to scientific competence and experience in making decisions of this type. Flexibility, within the framework, is a natural approach when doses/risks are local or refer mainly to a national population, whereas the threat of significant doses across borders would call for more stringent recommendations. A logically built and consistent RP system is desirable but should be no end in itself. A clear distinction is also needed between decision-aiding and decision-making, where the latter is expected to normally include more of value judgements.

We have noted with satisfaction that protection of the environment as such, with regard to ionising radiation, is now being increasingly seen by many national authorities and a number of international bodies as an area in need of development in terms of specific science as well as policy. We have also noted that work within the ICRP on environment RP in connection with the new recommendations is well under way. ***Issues to be observed as concerns environment protection are convergence of efforts and early considerations of how an environmental protection policy may be combined with human health RP policy,*** either in an integrated system or with the two in parallel.

Finally, while underlining that the ICRP is and should be an RP expert organisation, we would also like to see the organisation considering the issue of integrated risk control as discussed in Section 7. ***By showing its determination to promote the integration of radiation health risks into the context of other health risks, the ICRP could be an important player particularly in helping to shape a coherent and ‘objective’ scientific view of the risk panorama in modern society.***

Section 9

In this section we discuss the system of protection with special regard to the feasibility of the ICRP proposal, both as to principles and to the practical operation.

- a) ***The scope of an RP system should conceptually cover all radiation sources.*** As in the proposal by the ICRP, this would mean sources directly amenable to control or where exposure pathways may be controlled. The ICRP should indicate types of sources meeting such requirements and recommend that all or at least some of these targets always be controlled. We think this would also trigger a system for inventory of radiation sources, throwing more light on naturally occurring radioactive material (NORM) and technologically enhanced such material (TENORM), as well as enable us to view presently controlled sources in a wider perspective.

- b) We strongly support the principle that ***justification of all optional sources (practices) should still be the first requirement in radiological protection.*** Contrary to the proposal, we mean that ***any international or national RP system should also explicitly include this principle,*** although we agree with the proposal that certain justification decisions, especially when taken at a high political level, may not focus on RP aspects. It is essential, though, that such aspects be part of the information that serves as input to decision-making. Besides, there are many practical situations, in which justification will focus directly on the radiation risks and on RP, and in which it may also be difficult to separate justification from some form of optimisation. We think the ICRP should thoroughly analyse the concept of justification, clearly define its own role, and give guidance when appropriate.
- c) For justified sources, *step one* in the proposed system involves restricting the dose to individuals by means of Protective Action Levels, PALs for short. (PALs are related to ‘bands of concern about individual effective doses in a year’, which are described as multiples or fractions of the natural background radiation.). We think this approach has the advantage of making individual protection more visible and perhaps more understandable. However, ***the concept of PALs needs to be further developed to allow for a complete analysis of its applicability.*** For example, we are not quite sure how the PALs concept might be used to allow the RP system to deal with effective doses from a particular source and at the same time take the sum of effective doses to an individual from many sources into consideration.
- d) The status of PALs will no doubt depend on how they are justified and presented and how they are seen as compared to more formal limit values, that might be needed in any case. Whether it be limit values or (numerical) PALs that will be used in the future, the criteria for setting such values will have to be transparent and widely acceptable. ***Using the normally occurring natural background radiation as a reference in accordance with the ICRP proposal would no doubt be of value in risk communication, but it does not seem altogether adequate for individual protection criteria.*** In spite of the uncertainties in risk quantification, we think the ICRP should reconsider the possibility of also looking i.a. at occupational safety standards for other risk factors than ionising radiation.
- e) With a reference in its proposal to ‘the recognition that there is likely to be some risk to health, even at small doses’ the ICRP sees ‘a moral requirement, for each controllable source, to take all reasonable steps to restrict both the individual doses to levels below the action level and the number of exposed individuals’. This raises the problem of what may be called ‘small doses’, which in our opinion warrants a special analysis, and where we have begun with the exposed individual. First of all, it should be realised that there is no such thing as a general level of risk acceptance among the general public; instead there are more or less acceptable ‘risk conditions’. However, ***we agree that there is a need to indicate a low dose level below which society may legitimately maintain that an individual is adequately protected.*** It is desirable that the ICRP indicate what this level might be and we note that the suggested level of 0.01 mSv per year is already being used, for example, in the IAEA Basic Safety Standards (BSS). On the other hand, ***we do not agree with the suggested construction of the protective system on this point, whereby a pre-set individual dose would govern whether or not the number of exposed people may be considered in the RP process*** (This is because, in the proposal, such low individual doses - in ‘step one’- are intended to ‘be excluded from the ICRP system of protection’, which in turn would mean that protection ‘step two’ /cf. paragraph f below/ is not applicable. However, we have no difficulty with the other BSS requisite for exclusion,

that the low individual dose is to be combined with a collective dose of no more than 1manSv/y.) – Finally, we are doubtful at generally excluding even very low doses in medical care, should this be the intention in the ICRP proposal, cf. Section 10.

- f) After the first step of Protective Actions, the new ICRP model implies ‘a necessary but less prescriptive’ second step: an optimisation (with regard both to the individual and to exposed groups) to a level of exposure As Low As Reasonably Practicable (ALARP). As regards a fairly limited number of exposed persons such as a workforce or people living close to a radiation source, the situation in terms of optimisation might not be much different from that of today. As far as the larger (but still delimited) groups in the proposal are concerned, the situation is less clear so far, not least in complex situations of combined concern for individuals ‘with faces’ and exposed groups in which individuals are statistical persons and therefore ‘without faces’. ***The Commission should devote sufficient resources to elaborate on the ‘ALARP optimisation’*** and make its intentions highly visible. The other obvious need for clarification concerns the delimitation of exposed groups to be considered in the optimisation.
- g) We have already identified low doses to large populations as a key issue in RP policy, and mean that it needs much more of analysis than can be inferred from the recent ICRP proposal. In a situation where each individual is presumably adequately protected – or more than that – what is the relevance of the total radiation risk? Recognition of legitimate societal concern for the possibility of ‘unnecessary harm’ in this context would mean ***a) Low doses to large populations should not be à priori excluded, and b) Where there are calculable or potential exposures to large populations, especially across borders and including future generations, an additional ‘third step’ seems necessary to modify the proposed system.*** A third step, when applicable, need not mean the use of a collective dose that is unlimited in time and space, or very formalised mathematical procedures for doing cost-benefit analyses in optimisation. The current ICRP recommendations have been criticised for this, although not altogether fairly because they contain nuances that have not always been properly observed. However, it may not even be necessary to always approach the issue of large populations/small doses in the traditional manner. For example, we have discussed a possible role in this context of a general information database regarding radiation sources providing information on a regular basis on released radioactivity and/or total doses and allowing for keeping track of trends, etc. - To the extent that conceptual differences actually exist between the proposed optimisation by the ICRP (step two in the protection process) and step three as discussed here, these differences ought to be made plain by the ICRP. Either way, the ***further development and illustration of how to combine quantitative or semi-quantitative information on doses or risks, with ‘judgements’ under various circumstances is a major challenge facing the ICRP.***
- h) So far we have looked at the RP process mainly in terms of optional sources. The ‘unavoidable sources’ have been seen in many respects as a major problem, if not *the* major problem, in the implementation of the present ICRP policy. The new proposal contains few details on how the issue might be addressed but gives some indications of ‘typical protective actions for unavoidable sources’ with regard to the various ‘bands/levels of concern’. ***We agree that in actual practice, protective actions and, in many cases, the attainable level of protection to be achieved must differ from what applies to optional sources.*** We also believe that many exposures from unavoidable sources are national in character, which requires flexibility in the ICRP recommendations. While not being quite sure about the intended use of PALs for unavoidable sources, ***we think there ought not to be more than one set of ‘minimal health protection standards’***

if the credibility of an RP system is to be maintained, and that they must be set in the context of optional sources. Although such standards are expected to allow higher individual exposures than may be achieved after optimisation of an optimal source, they might well be seen as unrealistic by decision-makers in certain situations of exposures from unavoidable sources, either over the short time or permanently. This could no doubt cause both anxiety and anger among the public but in any case it would force the decision-makers to produce a plausible explanation of the grounds for their decision and the value judgements on which it was based. Given our idea of common health protection standards, these would not be as formally applicable in the RP system to unavoidable sources as they would be to optional ones. Focus must be on what is reasonable under the circumstances. While it seems essential that the ICRP gives advice on protective actions where individual risks from unavoidable sources are of obvious concern, ***we do not think that the ICRP should give indications of ‘no protective action’ that are different to those of optional sources at the same dose levels.***

- i) The ICRP proposal contains no discussion specifically on public trust in the RP system and the role of risk communication although it is bound to be an important underlying issue. It is essential that an RP system be widely accepted and reasonably well understood. However, when reality is complex, the RP system must inevitably reflect some of that complexity, whereas, for example, a minimum of (clearly defined) concepts that apply to the system's operation should be used.

Section 10

This section gives an overview of medical use of ionising radiation, as seen in the perspective of radiological protection. Medical exposures represent the largest contribution to the annual collective effective dose from man-made radiation sources, with a global average estimated at 0.4 mSv per person. Medical exposures also raise specific questions that warrant a separate discussion.

Diagnostic exposures of patients are typically in the range 0.1 – 20 mSv, although with a high frequency (> 1 per caput in developed countries), and the resulting collective dose is significant. By contrast, therapeutic exposures are few but involve much higher absorbed doses precisely delivered to target volumes, typically in the range 20-60 Gy, and effective dose is not a suitable measure of risk. New technology and increasing economic resources in developing countries are likely to fuel the increased use of medical exposures and increased doses in the 21st century.

Medical exposures of patients differ from occupational and public exposures in one important respect: the individual is deliberately targeted for exposure. Dose limits for exposure of members of the public are therefore not applicable in this context. The ICRP had earlier expressed concern about medical exposures (from the perspective of individuals as well as society) which has resulted in extensive efforts to reduce patient doses. According to the present ICRP recommendations, the general principles of justification and optimisation apply, including that specific procedures with specific objectives as well as – finally – the application of a procedure to an individual patient should be justified. The concept of optimisation also applies but has not been given sufficient consideration in diagnostic radiology in the past, according to the ICRP (in 1996), which implies that ‘there is considerable scope for dose reduction - - -’.

In our discussion with regard to the ICRP proposal, we think that ***the primary issue is to what extent medical exposures to patients may be included as a concept in the general RP system and which aspects of such exposures need separate considerations.*** At the moment, it is not quite clear how the ICRP intends to approach this issue in its future recommendations.

In any case we see ***justification as a key concept.*** While the principle of keeping the number of exposed individuals (or the population dose) low is obviously not valid in this context, ***optimisation in diagnostic procedures that aim at reducing doses to those actually exposed should remain compulsory in medical RP policy.*** Further ***development of diagnostic reference levels should be encouraged,*** because experience shows that comparisons between clinics indicate that there is clearly scope for lowering doses while maintaining an adequate information level. Patients are always in a vulnerable position as are healthy persons called to participate in mass-screenings. Some individuals may also be frequently diagnosed using ionising radiation. In the context of medical care ***we do not think it is morally defensible to generally exclude (from the ICRP system) very low doses to individuals from further attempts at dose reduction.***

In medicine, the cost and risk of doing something is usually compared with the benefit to be achieved and the cost or risk of not doing it. Depending on the reliability - particularly of risk assessment methods - cost and risk may also be compared between medical compartments, for example for the purpose of resource allocation. This is one of the reasons why there will no doubt be ***a need for carefully presented quantitative radiation risk estimates in the area of health care.*** The ICRP should present further guidelines in this context.

Section 11

Finally, in Section 11, we look towards the future. This study has clearly indicated that ***more needs to be done about the RP system.*** In certain respects this might be achieved by simply expressing the system more precisely, and providing more guidelines for its application. Over the short term, at least, such an approach might be practical. Nevertheless, it seems the time has come for a general and unprejudiced evaluation of the RP system. This process has already started and is now well under way, involving not only the ICRP but also other actors in the international arena and at national levels.

As to the 2001 ICRP proposal, our analysis has indicated that it has possibilities, but it also contains issues that need to be further developed. It is difficult, at this stage, to foresee the extent to which the final outcome of the ongoing work on new recommendations will be seen as a modification of the present system or as a fundamental revision of it. A revision of the present system based on a thorough evaluation seems to be no small undertaking, and it should be allowed to take time.