

HERCA Task Force Strategy

Reflections on the Revision of the System of Radiological Protection

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Title:Reflections on the Revision of the System of Radiological Protection.

Summary: This document provides HERCA's reflections on the revision of the System of Radiological Protection in the context of ICRP's project (*International Commission on Radiological Protection*) to review and revise its general recommendations.

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Reflections on the Revision of the System of Radiological Protection

1. Introduction and background

ICRP has embarked on a review and revision of the System of Radiological Protection (referred to below as the RP System) that will eventually lead to new General Recommendations refining and superseding ICRP *Publication 103* The 2007 Recommendations of ICRP'. It is anticipated that this process will take several years. The first major milestone in ICRP's work was the publication of the paper Keeping the ICRP Recommendations Fit for Purpose, in the summer of 2021. The aim of the ICRP paper is to encourage discussions on which areas of the RP System might benefit most from review, and to initiate collaborative efforts.

HERCA welcomes the ICRP initiative to open and maintain transparent stakeholder engagement in the multi-year revision process. HERCA aims to be actively involved providing a regulatory perspective, which is of fundamental importance since regulatory frameworks constitute one of the primary applications of the System of RP.

HERCA established a drafting group in December 2021 with the aim of developing a position paper providing HERCA's perspective on the revision of the RP System in time for the ICRP Symposium, scheduled to take place in November 2022.

The drafting group built upon the work of the HERCA e-group that developed the discussion paper <u>HERCA suggestions for ICRP future work areas</u>, adopted by the Board of HERCA in November 2020. This paper was based on inputs from HERCA members on experience in the practical application of the RP System in their organisations and countries. This HERCA discussion paper identified four main topics for future work by ICRP: (1. Simplification of the RP System; 2. Justification and optimisation, use of reference levels; 3. Radon; 4. Communication). The discussion paper was further developed for the presentation by the HERCA chair at the ICRP Online workshop on the future of the System of Radiological Protection, in October 2021.

In January 2022, HERCA members were invited to provide additional inputs, in view of developments since early 2020, focusing on the four main topics identified in the HERCA discussion paper. They were also invited to raise other topics of importance and to make comments on the ICRP "Fit for purpose" paper.

This position paper provides the HERCA perspective on the revision of the RP System, based on the inputs received from HERCA members.

The position paper contains 5 sections in addition to the introduction and background sections.

- 1. Simplification, clarification and other general issues.
- 2. Justification and optimisation, use of reference levels.
- 3. Radon.
- 4. Communication.
- 5. Other issues.



The issues raised by HERCA members address the application of the ICRP RP System in regulatory frameworks. HERCA has highlighted issues or challenges in this paper, which are relevant for ICRP in further developing the RP System. However, HERCA also recognises that addressing some of these issues or challenges is likely to involve or be the responsibility of other international organisations such as UNSCEAR¹, IAEA², the European Commission, etc. HERCA aims to continue its discussions with ICRP and other organisations on the issues within their areas of responsibility.

2. Simplification, clarification, and other general issues

Regulators need a science based comprehensive and clear RP System that can be applied in the regulatory frameworks in an efficient way. HERCA is of the view that dramatic changes to the RP System are not warranted at this time; fine tuning is needed but rewriting should be resisted. In other words, the approach should be evolutionary rather than revolutionary, with a focus on consolidation and clarification rather than expansion. It takes time to implement international standards and to stabilize national regulations, and there is a need for continued stability. Furthermore, it is essential that any changes in the RP System, especially those likely to lead to a change in national regulatory frameworks, are justified as leading to a clear proportionate benefit, outweighing any drawbacks, in comparison with the current system. ICRP should therefore ensure that an impact assessment of any proposed change regarding implementation in regulatory frameworks is undertaken before recommendations are issued. The situation with the adoption of new dose conversion factors, see section 4.1, underscores the importance of a regulatory impact assessment (RIA), before recommendations are issued. HERCA could be of assistance to ICRP in this regard.

2.1 Simplification and clarification

HERCA members recognise that the current system is complex and often difficult to explain. In some cases, the RP System is also difficult to transform into regulations that can be implemented and enforced in an effective way.

It is recognised that the system is also robust and sophisticated, having evolved over a long period of time based on accumulated experience and knowledge. The RP System is, in general effective and fit for purpose. However, several issues need to be clarified, and addressing these may lead to a level of simplification, which could improve communication and enhance effective application. HERCA proposes that the focus of the revision should be to apply ethical concepts and new scientific knowledge to improve the system, seeking simplification where possible. In this process, the possible negative impacts of any proposed simplifications on the RP System need to be considered and justified.

It is important to avoid over-regulation, and greater clarity may be achieved by recognition of a graded approach to and within the RP System. This would involve explanations of the magnitude and nature of risks from radiation and clarifying the rationale for different approaches to regulation in different situations, considering other hazards in those situations.

¹ United Nations Scientific Committee on the Effects of Atomic Radiation.

² International Atomic Energy Agency.



2.2 Exposure situations

The move from a process-based to a situation-based RP System, recommended in ICRP Publication 103, should be maintained but there is a need for clear and unambiguous description of the underlying principles of protection, for each exposure situation. There is also a need for greater clarity concerning the transitions between the three exposure situations, especially those involving existing exposure situations. In this context, managing exposure to NORM or radon continues to be more challenging than managing exposures to human-made radiation sources. The transition from an emergency exposure situation to an existing exposure situation, following a nuclear accident, is a particular challenge for the ICRP to address. Further consideration is needed of not only public exposures, but also the management of occupational exposures as planned activities, following a nuclear accident. Further clarity on the inclusion of potential exposures as part of planned exposure situations is also needed.

2.3 Interpretation of information on radiation-induced effects

Some HERCA members highlighted the need to review and possibly reconsider the threshold for deterministic effects in the light of recent scientific knowledge on cataract formation and diseases of the circulatory system. Other relevant issues include the definition of the Dose and Dose Rate Effectiveness Factor (DDREF) and the Linear No-threshold-(LNT) assumption related to the dose-response relationship for stochastic effects. A consensus at the international level is needed on these issues and their influence on ICRP recommendations and international standards needs to be clearly explained.

2.4 Dose and risk criteria

The existence of various criteria and concepts for limiting exposure and/or optimising protection (dose limits, dose constraints, reference levels, diagnostic reference levels and operational limits) is perceived as one of the main sources of complexity. These criteria have solid scientific and conceptual bases justifying their existence, but they are also difficult to understand and to explain. There is a need for further guidance and clarification in the application of the concepts of limits, reference levels and constraints in different exposure situations. However, any simplification of these concepts may also lead to unintentional results and further confusion and such consequences need to be evaluated in advance.

For clarity and to improve communication, it is important that ICRP explains, in simple terms, why the public is considered to be protected by applying reference levels of the order 10 or 100 mSv in some cases (existing exposure or emergency situations), while in planned exposure situations lower dose limits are applied.

There are practical and ethical difficulties associated with implementing some aspects of the RP System, on which further guidance from ICRP would be helpful, for example: application of restrictions on lifetime dose to workers who have received an elevated dose; constraints for itinerant workers and risk criteria related to radiation-induced thyroid cancers.

2.5 Dosimetry and detriment

The concept of detriment is a fundamental aspect of the RP System and new and proposed ICRP publications deal with the use of dose quantities, based on new insights on and more detailed calculation of detriment. There may be good scientific reasons for seeking better quantification of



the effects of radiation. However, it is less clear whether there is a sufficient justification for changing the dose quantities or risk models that are used in practical radiation protection and regulations. Again, there is a need to consider the consequences of making such fundamental changes to ensure that there is a real benefit.

There have been discussions regarding the application of detailed dosimetry modelling for individuals. The consideration of age- and sex-dependence of radiation sensitivity, and the differentiation of tissue weighting factors by sex and age groups, are positive developments. However, it is necessary to provide guidance on those situations where such approaches are of added value (e.g. for medical exposures). In many cases, such detailed modelling may add to uncertainties in assessment and measurement in a way that would not lead to an improvement in radiation protection. There is also a need to address ethical and practical difficulties in any implementation of individual risk estimates in the regulatory framework.

3. Justification and optimisation: use of reference levels

Justification and optimisation of protection are two of the three fundamental principles of the system of radiological protection. While the principles and their practical implementation have evolved over time, HERCA sees the need for further improvement and guidance to enhance their effective implementation in regulatory frameworks.

The use of reference levels as a tool in optimisation is complex. Reference levels are interpreted in several ways, and for variety different purposes within regulatory frameworks, such that their nature and meaning may vary. The variety of reference levels used in different exposure situations is also a challenge in communicating with the public. A simplified system, combined with clear guidance on how to use and explain reference levels, would facilitate effective implementation and a more harmonised approach. A further aspect is how to combine the classic justification and optimisation approach of radiation protection with a holistic risk-benefit approach in which other risks are considered, in addition to radiation risks, while taking to societal and economic factors. This could include considering the definitions and concepts of 'sustainable development', 'health' and the 'quality of life', promoted by UNEP³ and WHO⁴.

3.1 Holistic approach to optimisation

According to ICRP Publication 103, optimisation is "the process of determining what level of protection and safety makes exposures, and the probability and magnitude of potential exposures, as low as reasonably achievable, economic and societal factors being taken into account". Thus, optimisation of radiation protection is neither minimisation nor a standalone procedure. Ideally, a "holistic" approach, aimed at the protection of health is needed that is integrated within a wider risk-benefit approach, which also takes account of societal and economic factors. Such approaches often lead to complex trade-offs between contributing factors and further guidance is needed on how to determine and to consider such factors. This guidance should consider the existing optimisation (or ALARA⁵) principle and evolving scientific knowledge and knowledge from other domains than radiation protection, e.g., management of other hazards. The analysis of risk and benefit is especially complex in the case of NORM industries, like mining and milling practices,

³ United Nations Environment Programme.

⁴ World Health Organization.

⁵ As Low As Reasonably Achievable.



where a greater combination of radiation risks and other safety risks, chemical and environmental risks and social and economic consequences need to be balanced. In emergency exposure situations, and especially remediation of (post-emergency) existing exposure situations, the balance between the effects of countermeasures in lowering the radiation dose versus the socioeconomic effects, the mental health effects and other effects on general well-being is of great importance. This is one of the main lessons learned from the response to the accident at Fukushima Daiichi nuclear power plant. ICRP should take these lessons into consideration when providing guidance on the balance between effects of countermeasures and the broader health and socio-economic impacts.

3.2 Application of optimisation

There is need for clarification and more guidance on the application of the optimisation of protection. The focus should not be limited to the application of reference levels but should also address optimisation in situations when the actual risk is known to be very low. The explanation of the underlying principles of both optimisation and justification could be improved. This would help to focus regulatory efforts on achieving the best possible level of radiation protection. HERCA encourages ICRP to elaborate further on the differences between the use of optimisation in medical exposures and optimisation in other exposure situations.

3.3 Justification

Holistic risk-benefit analysis is also relevant in the application of the justification principle not only in relation to planned exposure situations but also in the justification of countermeasures in emergency exposure situations and for remedial actions afterwards. Especially with regards to remediation strategies, as the work around Fukushima shows, simpler explanations and argumentative lines (even international good practices?) ought to be established.

Decommissioning of large nuclear and industrial sites is in progress or will begin in many countries. The determination of the end point is an important factor in the justification step in licensing decommissioning activities. Guidance and examples are needed to develop regulations that take socio-economic impacts into account when setting criteria for regulatory acceptance of the end point.

3.4 Use of reference levels

The use of different reference levels for different exposure situations, and their different meaning and use in practice, contributes to the complexity of the RP System. The difference between dose limits, dose constraints and reference levels is difficult to explain to stakeholders, from both professional and public backgrounds. It is therefore important to improve communication on the meaning and application of reference levels, stressing that they are not delineation between "safe" and "un-safe". The system of three bands⁶ of reference levels introduces an extra level of complexity. ICRP needs to provide more clarity and guidance on these aspects of the practical implementation and use of reference levels in regulatory frameworks.

In emergency exposure situations, reference levels are a useful tool, providing flexibility in the emergency preparedness and response. ICRP could enhance the practical implementation of

⁶ See ICRP 103, table 5, page 100 – 101.



optimisation, and the use of reference levels in emergency response strategies, by developing practical guidance, notably on the use of reference levels in the early and intermediate phases of an emergency. Experience gained from exercises and the Fukushima Daiichi accident show that such guidance is needed.

4. Radon

4.1 New DCF

ICRP published new dose conversion factors (DCFs) for radon in ICRP Publication 137, which significantly changed the calculation of radon doses.

The change in DCFs is strongly influencing the ongoing work of HERCA members, and other regulators, notably on developing national radon action plans and regulations related to the newly established in "radon workplaces" (under EU legislation). Radon dose calculations are an essential input to decisions on whether further regulations are needed and the situation regarding adoption of the new DCFs is unclear.

ICRP needs to provide guidance on how to evaluate and comprehensibly explain the difference between the epidemiological approach and the micro dosimetry approach and how this translates into the actual radon detriment.

The situation demonstrates the importance of undertaking a regulatory impact assessment (RIA) before adopting such fundamental changes, in order to carefully consider the impact of proposed changes on regulatory frameworks and their practical implementation. There is a need to avoid situations where each country performs its own RIA and, depending on the national outcome, some countries adopt the change while others do not or postpone adoption. Such situations create undesirable inconsistencies between regulatory approaches, which could lead to increasing scepticism and loss of credibility of the RP System.

The situation with new DCFs was particularly unfortunate because different international organisations supported different opinions.

4.2 Radon in workplaces

The newly introduced regulatory approach to radon exposure in workplaces is a significant regulatory challenge and practical implementation is leading to difficulties. Radon exposure at the workplace is regulated in the EU as an existing exposure situation. The optimisation and implementation of remedial measures is required when the established reference level is exceeded. If radon concentrations nevertheless remain above this reference level (or in the case of EU legislation – the effective dose exceeds a certain level), some of the requirements for planned exposure situations are applied. Unfortunately, there are different international approaches related to setting reference levels and the extent to which calculation of doses for workers are used in regulatory decisions, considering e.g., working hours spent in the workplace. Differences also exist between the approaches of different regulators. There is a lack of guidance on how to deal with situations where doses are below established reference (or dose) levels. ICRP should provide more guidance on how to deal with optimisation of radiation protection in workplaces where the doses to workers from radon are below reference levels.



4.3 Follow-up of people receiving high radon doses

There is a need for more recommendations and guidance for follow-up, of individuals or groups of people including children who have been, or continue to be, exposed to very high radon levels over time, and the risks this involves. This is relevant for both the public, for instance people who have been living in homes with high radon levels for years, and workers exposed for high radon levels in their workplaces. It would be useful if ICRP could discuss and explore this issue further.

5. Communication

The broad scope of the RP System, which aims to cover all types of exposures in all situations, will always be complex and difficult to communicate to stakeholders. HERCA fully acknowledges the challenges ICRP faces in communicating these complex issues. HERCA members face this daily in their role as radiation protection authorities and welcome the fact that ICRP, in its 'Fit for Purpose' paper, targets improvement of communication as an important task for the future. The approach suggested in that paper, including its emphasis on the active engagement of stakeholders, transparency and inclusiveness, is welcomed.

HERCA has identified a few specific issues for ICRP to consider improving communication with stakeholders and public.

5.1 Risk perception and risk communication in the revision of the RP system

It is likely that efforts to simplify the RP System will improve its communicability. However, simplification is limited by the need to maintain a system that is scientifically robust. Consequently, there is a need to make an additional effort to improve clarity and communicability in addition to any movement towards simplification. HERCA has indicated areas where enhanced clarity is necessary in other parts of this document.

Concerning communicability, a better understanding of the RP System is not only a matter of educating public, media, and stakeholders, but also of ensuring that the RP System is clear and understandable. It is therefore important that communication aspects, such as risk perception and risk communication, are included as an integral part of the review process and that risk assessments are explained clearly and based on a solid, fact-based approach. It is equally important to involve experts in communication in the process.

HERCA hopes that ICRP will continue to fully engage in active communication and other outreach activities with different groups of stakeholders during the revision of the RP system.

5.2 Radiation risks in perspective

When communicating about the potential adverse effects of radiation, it is necessary to be clear about the terminology used, notably the term 'risk'. It is often helpful to put such risks in context, for instance when elaborating the benefits and disadvantages or drawbacks of a certain course of action, which may involve comparing with risks from other hazards. Another way of putting radiation risks in a context is to compare with the variability of natural background or to compare the added detriment for an individual to a baseline detriment (like lifetime fatal cancer risk, not linked to a specific cause). HERCA welcomes further elaboration of these important aspects of communication of radiation risks.



5.3 Addressing certainties and uncertainties

The RP System is based on robust scientific foundations. It is important to communicate this clearly and to distinguish between what we know, what we don't know and what we assume for protection or other purposes. Increasing the transparency of the use of certainties, uncertainties, assumptions, and precautionary considerations would increase public trust. It would also be beneficial to explain the differences between science and relevant uncertainties on the one hand and value judgments (policy making) on the other hand.

Further guidance from ICRP on how to communicate the detriment potentially arising from radiation exposure would be helpful, in particular for exposures in the low dose range where the uncertainties are considerable.

6. Other issues

Through the consultation process, issues other than the four key issues addressed in sections 2-5 were identified as important by members of HERCA. A number of these issues are presented below. The order does not indicate an order of priority.

6.1 Medical exposures

In addition to optimisation of medical exposures, which was addressed in section 3.2, other issues warranting discussion in international radiation protection fora were identified, notably related to radiotherapy of children, and taking account of the increased risk of stochastic effects (secondary cancers), and emerging protection considerations resulting from the continuing development of new technologies using ionising radiation.

6.2 Radiation protection of the environment

The ICRP revision process provides an opportunity to improve the way in which radiation protection of the environment is addressed and potentially integrated within the existing RP System without adding complexity to it. It would be beneficial if this process included consideration of approaches for other hazardous agents (e.g., chemicals) in the environment.

6.3 Education and training

Education and training are essential to facilitate understanding of the ICRP RP System and its practical implementation. ICRP has developed recommendations on education and training specific to the medical field but further guidance for other fields would be helpful, especially for new practices that lead to elevated exposures of workers.

6.4 Responders in an emergency exposure situation

There is a need for ICRP to develop further the present guidance on informed consent for responders in the early and intermediate phase of an emergency. ICRP needs to address several aspects, of both philosophical and ethical nature, for instance: identification of the categories of personnel and volunteers who should be considered as responders (and when) and the circumstances under which responders have the right to refuse to work.