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Keeping the ICRP Recommendations Fit for Purpose

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Abstract

The International Commission on Radiological Protection (ICRP) has embarked on a review and revision of the System of Radiological Protection that will update the 2007 General Recommendations in ICRP *Publication 103*. This is the beginning of a process that will take several years, involving open and transparent engagement with organisations and individuals around the world. While the System is robust and has performed well, it must adapt to address changes in science and society to remain fit for purpose. The aim of this paper is to encourage discussions on which areas of the System might gain the greatest benefit from review, and to initiate collaborative efforts. Increased clarity and consistency are high priorities. The better the System is understood, the more effectively it can be applied, resulting in improved protection and increased harmonisation. Many areas are identified for potential review including: classification of effects, with particular focus on tissue reactions; reformulation of detriment, potentially including non-cancer diseases; re-evaluation of the relationship between detriment and effective dose, and the possibility of defining detriments for males and females of different ages; individual variation in the response to radiation

exposure; heritable effects; and effects and risks in non-human biota and ecosystems. Some of the basic concepts are also being considered, including the framework for bringing together protection of people and the environment, incremental improvements to the fundamental principles of justification and optimisation, a broader approach to protection of individuals, and clarification of the exposure situations introduced in 2007. In addition, ICRP is considering identifying where explicit incorporation of the ethical basis of the System would be beneficial, how to better reflect the importance of communications and stakeholder involvement, and further advice on education and training. ICRP invites responses on these and other areas relating to the review of the System of Radiological Protection.

1. Background and purpose

The International Commission on Radiological Protection (ICRP) is an independent, non-governmental organisation registered as a charity under the Charity Commission of England and Wales and has acted at the interface between science and policy for almost a century. Thanks to the expertise and largely voluntary work of its members from across the world, ICRP's Recommendations on protection against the harmful effects of ionising radiation to human health and the environment form the basis of standards, regulations, legislation, and the practice of radiological protection worldwide.

On occasion, ICRP publishes General Recommendations which set out the entire System of Radiological Protection ('the System'). The first General Recommendations were produced in 1928 (ICR, 1929). Subsequent updates were produced, prior to the current practice of numbering publications, in 1931 (ICR, 1931), 1934 (IXRPC, 1934), 1937 (IXRPC, 1938), 1950 (ICRP 1951), 1954 (ICRP, 1955), and 1956 (ICRP, 1958), and then in ICRP *Publications 1* (ICRP, 1959), *6* (ICRP, 1964), *9* (ICRP, 1966), *26* (ICRP, 1977), *60* (ICRP, 1991), and *103* (ICRP, 2007).

The effort to review ICRP *Publication 60* (ICRP, 1991) that led to ICRP *Publication 103* (ICRP, 2007) began more than two decades ago and took about a decade to complete. Given this timing, and more than a decade of experience with the General Recommendations of ICRP *Publication 103*, ICRP is initiating, in consultation with stakeholders, a review of the current System to assess which areas may need further attention given the lessons of the past decade and advances in scientific knowledge, the evolution of societal values, and progress in the practical implementation of radiological protection.

While it is safe to conclude that the System is robust and has performed well in relation to the protection objectives, the System must adapt to address changes in science and society to remain fit for purpose.

This paper sets out initial reflections of the ICRP Main Commission and Scientific Secretary (the authors) on the core elements of the System in order to identify issues that may require attention. The views expressed are not set ICRP positions but have been informed by the experience of ICRP members across the Committees, and initial discussions with experts

worldwide, including representatives of the 30 organisations in formal relations with ICRP. The point of departure is ICRP *Publication 103*, the 2007 General Recommendations, noting that some likely changes to the System or its components have already been foreshadowed in ICRP publications released since ICRP *Publication 103* (ICRP, 2007).

This paper should be regarded as the beginning of a process that will take several years and involve open and transparent engagement with organisations and individuals around the world. In this process, we seek to engage all interested parties on how the System is functioning, areas in which there is a need for clarity and adjustment, and suggestions for addressing these challenges. Thus, the purposes of this paper are to:

- encourage discussions throughout the radiological protection community and beyond on which areas of the System might gain the greatest benefit from detailed review and refinement;
- initiate and shape collaborative efforts to examine prioritised areas and develop improvements; and
- help define the ICRP programme of work for the coming years.

The planned approach is to review the System to identify elements which may need attention, and subsequently address each of these elements in depth through broad engagement of stakeholders. When this process is complete, it will be possible to revise the System as a whole and develop revised General Recommendations to supersede ICRP *Publication 103* (ICRP, 2007). In parallel, ICRP will publish an analysis of research needs, considering short-term requirements in advance of revised General Recommendations as well as longer-term objectives.

Development of revised General Recommendations is an opportunity to produce a single internally consistent reference incorporating the incremental updates since ICRP *Publication 103* (ICRP, 2007), and other considerations such as those described in this paper.

Stakeholders have also called for clarity of language in describing the System. Increased consistency and clarity are high priorities. The better the System is understood, the more effectively it can be applied, resulting in improved radiological protection and increased global harmonisation. Some clarity may be achieved through simplification, although there is a danger in oversimplification of the System that must continue to handle substantially different, complex, and unforeseen situations. It should be as simple as possible but as complex as necessary to cope with a wide range of situations, applications, and scenarios.

2. Objectives and principles of the System

2.1. Objectives

The objective of the System, as expressed in ICRP *Publication 103* (ICRP, 2007) is ‘to contribute to an appropriate level of protection for people and the environment against the detrimental effects of radiation exposure without unduly limiting the desirable human actions

that may be associated with such exposure'. To achieve this primary aim, ICRP has stated two overarching protection objectives: one related to protection of people, and the other related to protection of the environment.

2.2. Protection of people

The objectives for protection of human health are 'to manage and control exposures to ionising radiation so that tissue reactions are prevented, and the risks of stochastic effects are reduced to the extent reasonably achievable' (ICRP, 2007). The distinction between stochastic endpoints and tissue reactions (previously termed 'deterministic effects') should be reviewed, drawing on scientific advancement in the understanding of radiation-induced health effects since ICRP *Publication 103* (ICRP, 2007) (e.g., ICRP, 2012, Section 6.1).

The objective to prevent tissue reactions remains sound, but there are specific circumstances where tissue reactions may be tolerated to achieve the desirable benefit of a particular activity. In some medical cases, tissue reactions are an undesirable but tolerable side effect, such as in lifesaving treatments involving high doses of ionising radiation. Similar judgements apply to some aspects of occupational exposure, particularly in response to emergencies. Taking another example, human space exploration beyond the moon might be impossible without incurring some less severe tissue reactions. In cases like these, measures such as enhanced medical follow-up might be preferable to absolute avoidance of tissue reactions.

The impact of stochastic effects is reflected by the radiation detriment, which is based on the sum of lifetime risk from several cancers, weighted by the severity of these cancers, and integrates the possibility of heritable effects. This detriment concept was elaborated in ICRP *Publication 60* (ICRP, 1991), and needs to be revised and updated to reflect the evolution of scientific knowledge of risks and expert judgement concerning lethality, quality of life, and years of life lost. In addition, explicit recognition of differences in detriment with age at exposure and between males and females could improve the clarity of application of the System, showing, in particular, that risks to young children are greater than risks to adults, and that risks to older individuals are low.

Protection is accomplished using the well-established dose quantities – absorbed and equivalent dose to organs and tissues in the prevention of tissue reactions, and effective dose in the optimisation of protection against stochastic effects at low doses and low dose rates. The use of these quantities has been presented in ICRP *Publication 147* (ICRP, 2021a) where low doses are referred to as < 100 mGy of low-LET radiation to organs and tissues and low dose rates as < 5 mGy h^{-1}.

The System principally deals with health effects resulting directly from exposure to radiation, such as cancer and tissue reactions. It is also worth considering how the World Health Organisation's definition of health as 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' (WHO, 1946) could be reflected in the human health objectives.

2.3. Protection of the environment and non-human biota

ICRP *Publication 103* (ICRP, 2007) states that the objective of protection is '…preventing or reducing the frequency of deleterious radiation effects to a level where they would have a negligible impact on the maintenance of biological diversity, the conservation of species, or the health and status of natural habitats, communities and ecosystems…'. However, at the time ICRP *Publication 103* was developed, ICRP's work on environmental protection was still in its infancy; hence, ICRP *Publication 103* does not provide more than this objective and a few considerations for environmental protection.

Since then, a significant amount of work has been completed and is ready for integration in new General Recommendations. ICRP has approached protection of the environment in a similar manner to protection of people, namely by establishing the characteristics of the object of protection [by establishing databases for 12 Reference Animals and Plants (RAPs) of broad generality and defined at family level], exposure scenarios, dose and effect relationships, and by defining derived consideration reference levels (DCRLs) indicating absorbed dose rate bands where some detrimental effects could be anticipated for a particular RAP (ICRP, 2008, 2009d, 2014a).

In developing the approach to radiological protection of the environment, ICRP largely took the existing approaches to conservation of species as its point of departure, with focus on organisms in the natural environment. However, this methodology may not be sufficient when considering ecosystems that are created and managed by people for the purposes of delivering goods, services, and cultural value for human populations. These considerations extend to domesticised species and include veterinary patients, the subject of ICRP Task Group 110 on Radiological Protection in Veterinary Practice. While the work already undertaken by ICRP will remain a cornerstone, inclusion of more global considerations of environmental protection in the context of 'sustainable development' and concerns about the 'quality of life', including the services provided by the environment and ecosystems as well as the impacts of the implementation of protective actions, may be considered for inclusion in future General Recommendations.

2.4. Fundamental principle of justification

The recent evaluation of the ethical values inherent in the System (ICRP, 2018) has been helpful in re-examining the three fundamental principles of radiological protection. In particular, justification could be clarified further to emphasise that net benefit reflects the imperative to both do good and avoid doing harm.

The series of recent publications relating to existing exposure situations, particularly ICRP *Publications 126* (ICRP, 2014b), *142* (ICRP, 2019), and *146* (ICRP, 2020b), have highlighted the need to take into account the quality of life in the justification of many decisions. In medicine, challenges related to justification arise from increased healthcare complexity and increased use of imaging, with wider stakeholder expectations, participation, and demands. Increased use of artificial intelligence in medicine has transformed and blurred

the lines between research and clinical practice. For example, the relationship between clinical referral guidelines and electronic decision support may warrant clarification.

Application of the justification principle to biomedical research involving radiation beyond clinical use also needs to be considered.

2.5. Fundamental principle of optimisation

The principle of optimisation of protection and safety states that 'the likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors' (ICRP, 2007).

There have been many requests for more guidance on how to balance societal, economic, and other factors in the optimisation of protection and safety, requiring input from many fields of expertise. ICRP *Publication 101b* (ICRP, 2006) includes the most recent examination of general optimisation, and ICRP is aware of various efforts that may help to make the balancing of factors more transparent. ICRP *Publication 146* (ICRP, 2020b) identifies the environment as one of the factors to be taken into account, and guidance for optimisation in environmental radiological protection is provided in ICRP *Publication 124* (ICRP, 2014a). Although ICRP cannot judge specific circumstances, additional advice on factors to be considered and possible processes to be employed may be helpful.

ICRP Task Group 114 on Reasonableness and Tolerability in the System of Radiological Protection is already looking at essential elements of optimisation. Too often centred on the acronym 'ALARA' (As Low As Reasonably Achievable, taking social and economic considerations into account), optimisation of protection and safety should not consistently seek the lowest exposures or risks possible, but a balance of factors including dose, risk, and other considerations. ICRP Task Group 114 aims to clarify how to take into account these other considerations including societal, environmental, economic, and general wellbeing.

In the medical context, optimisation of protection is seen as keeping exposure commensurate with the medical purpose, implying keeping patient exposure to the minimum necessary to achieve the required medical objective. Given the increasing population exposures from medical imaging, and the increasing complexity of health care, ICRP Task Group 108 on Optimisation of Radiological Protection in Digital Radiography, Fluoroscopy, and CT in Medical Imaging is developing guidance on the need for integration, teamwork, peer learning, and the use of decision sciences.

Several main questions arise, including how to approach optimisation holistically, considering the duality of the principle which relates equally to protection and safety, and the implicit consideration of risk as it relates to the level of exposure and the likelihood of an event causing exposure (potential exposure). The review of the System could further explore the applicability and use of the optimisation principle when considering the safety of sources,

facilities, and practices, basing this analysis on risk, and emphasising the role of risk (safety) assessments.

A holistic approach could also consider factors beyond the radiological, including how to promote reasonable caution while avoiding undue conservatism within the System and its implementation. Further guidance may be needed on decision-making where doses are very low (e.g., well within normal variations in natural background), and the inferred risks for people and the environment are very low. Likewise, further guidance may be needed on decision-making when the likelihood of an event causing (potential) exposure is low, and the resulting risk is low although the exposure resulting from that event may be significant.

Security events leading to radiation exposure, triggered by unawareness/mistakes, negligence, or acts with malicious intent, have received heightened attention in recent years. The likelihood of such events is difficult to assess, and threat levels and associated scenarios may vary over time or be essentially unpredictable and unquantifiable in terms of estimates of likelihood. However, optimisation by design has a role in managing and reducing the likelihood of such events, as well as the radiological consequences should the event occur. These aspects can either be considered in isolation or in an aggregated manner to provide information on the approximate magnitude of risk.

2.6. Fundamental principle of application of dose limits

The concept of individual dose limitation is crucial in the System because justification and optimisation of protection are, broadly, principles that seek the best solutions for society, but may not take due account of the duty to protect individuals.

In the System as it stands today, this principle applies only for occupational and public exposures in planned exposure situations, because its strict application in other areas may not result in the best outcomes for society or for specific individuals. However, there is an ethical obligation to protect individual people under all circumstances.

In emergency and existing exposure situations, this is achieved using reference levels which aim to restrict inequities among individual exposures that might otherwise result from the implementation of protective actions, while providing the flexibility needed in these circumstances that limits would not allow.

The obligation to protect individuals could be reflected in a broader principle, generalised to apply in all situations, and encompassing the concepts of limits, constraints, and reference levels. It may also be possible to simplify further by combining the latter two concepts, with reference levels applying in all exposure situations, and dose limits only applying in planned exposure situations. It should also be noted that ICRP's dose criteria for protection of the environment, the DCRLs, are effectively reference levels and should be applied as such, as outlined in ICRP *Publication 124* (ICRP, 2014a).

Defining a fundamental principle to protect the individual would result in a System where all three fundamental principles apply under all circumstances regardless of the exposure

situation or category. This change would require the re-examination and clarification of the distinctions between limits, constraints, and reference levels. There is a need to revisit how dose criteria might be applied in different circumstances on an annual, 5-year cumulative, lifetime, etc., basis. It may also be helpful to provide additional advice on the selection of values for these criteria, including whether the present specification of the bands for constraints and reference levels should be continued; this is currently being considered by ICRP Task Group 114 on Reasonableness and Tolerability in the System of Radiological Protection and ICRP Task Group 99 on Reference Animals and Plants (RAPs) Monographs.

Risk criteria are used in some circumstances of potential exposure, such as waste disposal. *Publication 103* (ICRP, 2007) describes potential exposure as a mechanism for understanding and including the possibility of exposures. These considerations are often associated with nuclear safety, but the underlying concepts are more broadly applicable.

Risk criteria have also been used in the case of planned exposures, at least in the highly specialised area of radiological protection of human spaceflight, currently being considered by ICRP Task Group 115 on Risk and Dose Assessment for Radiological Protection of Astronauts. These approaches deserve further consideration to see whether risk criteria might have broader application beyond circumstances of potential exposure.

2.7. Categories of exposure and exposure situations

While the categories of exposure (medical, occupational, and public) have long been used to help organise radiological protection, the exposure situations (planned, existing, and emergency) were introduced in the 2007 General Recommendations (ICRP, 2007). More than a decade of experience with the exposure situations has revealed a need to revisit their definitions to improve clarity, and to review how they can be best applied.

The categories of exposure are generally understood, although clearer guidance may be needed in unusual circumstances such as emergencies. Some guidance can be found in ICRP *Publication 146* (ICRP, 2020b). In addition, integration of protection of non-human biota into the System may require the addition of at least one category of exposure as the current three categories were designed specifically for humans, as suggested in ICRP *Publication 124* (ICRP, 2014a). The US National Council on Radiation Protection and Measurements (NCRP), for example, introduced new categories for emergency workers and non-human biota (NCRP, 2018a).

There are some grey areas between the three exposure situations. This has been particularly true for existing exposure situations, where the source may have been pre-existing, but exposures in a particular circumstance may be new. Further clarity is needed on the interpretation and use of the exposure situations, and transitions between them. It is also worth considering how potential exposures, or safety, fit into this scheme.

Despite the development of a coherent System with three exposure situations, difficulties remain in dealing effectively with sources that are naturally present in the environment

compared with those that have been created by human activity. For many naturally occurring sources, the exposure is modified in some way by human activity, such as an increase in cosmic radiation during air or space travel, increases in radon concentrations through energy-efficient building construction, or the concentration of radioactive materials by industrial processes. Examples have been treated in several ICRP publications, including protection in post-accident situations in ICRP *Publications 111* and *146* (ICRP, 2009b, 2020b), radon exposure in ICRP *Publication 126* (ICRP, 2014b), aviation in ICRP *Publication 132* (ICRP, 2016), and naturally occurring radioactive material industries in ICRP *Publication 142* (ICRP, 2019). These publications point towards a more unified approach that facilitates coherence across all exposure situations, but the principles developed through these examples need to be further consolidated and clarified. At issue, for example, has been the use of dose limits, which are currently applicable in planned exposure situations alone.

3. Overarching considerations

3.1. Ethical aspects of radiological protection

ICRP *Publication 138* (ICRP, 2018) was ICRP's first comprehensive review of the ethical basis of the System. It clarifies the concepts behind the value judgements necessary to develop and advance the System and sets out a framework and common vocabulary to support communications and discussions on the questions of the ethical values underlying the System.

Other related efforts are already expanding on this foundation, such as ICRP Task Group 109 on Ethics in Radiological Protection for Medical Diagnosis and Treatment, and ICRP Task Group 114 on Reasonableness and Tolerability in the System of Radiological Protection. For example, ICRP Task Group 109 might bring together the ethical values elaborated in ICRP *Publication 138* (ICRP, 2018) and those established within medical practice to develop a wider set of values for scenarios encountered in daily practice and to inform case studies for education and training of health professionals. ICRP welcomes additional initiatives to help provide practical advice for implementation of the System in various circumstances.

The review of the System should identify areas where explicit incorporation of the ethical basis alongside the scientific basis would be beneficial.

Challenges appear both in the communication and understanding of radiological risks and in applying the System. It is well known that perception of risk is related to the extent to which it is understood and familiar, whether the activities are perceived as beneficial, and whether the risks are voluntary or are involuntarily imposed. While physically the same, the perception and ethical viewpoints have remained different. For example, some stakeholders have suggested that 'normal' natural background exposures could provide a useful context when communicating about risks from radiation exposure, while others have cautioned against such approaches.

3.2. Communications and stakeholder involvement

ICRP *Publication 103* (ICRP, 2007) recognised communications and the involvement of stakeholders as important to the implementation of the System. Communication and engagement are mechanisms by which the knowledge and expertise of stakeholders can be accessed and shared to achieve the best possible and sustainable outcome for all, given the circumstances and different viewpoints. Specifically, ICRP considers that 'the involvement of stakeholders is a proven means to ensure incorporation of values in the decision-making process, improvement of the substantive quality of decisions, resolution of conflicts among competing interests, building of shared understanding …, and building of trust in institutions' (ICRP, 2006).

ICRP recently clarified the ethical foundations of the System in ICRP *Publication 138* (ICRP, 2018). The procedural values of inclusiveness, accountability, and transparency are directly related to stakeholder engagement which can support and broaden the decision-making processes, such as by highlighting considerations beyond the direct effects of radiation exposure.

The Commission also introduced, in ICRP *Publication 146* (ICRP, 2020b), the 'co-expertise' process as an integral part of the practical implementation of the principle of optimisation of protection based on the involvement and empowerment of stakeholders. This process of co-operation between experts, professionals, and stakeholders aims to share stakeholder knowledge and scientific expertise for the purpose of assessing and better understanding the radiological situation, developing protective actions for people and the environment, and improving living and working conditions.

Co-expertise also fosters the development of a radiological protection culture, in which knowledge and skills are developed to make well-informed choices and behave wisely in situations involving potential or actual exposures to ionising radiation. It allows people to interpret radiation measurements, to build their own benchmarks in relation to the radioactivity present in their daily life, to make their own decisions to protect themselves and their loved ones, and to assess the relevance and effectiveness of the protective actions implemented by authorities, organisations, or themselves.

It is expected that the clarified ethical framework and the co-expertise process can lead to more specific advice from ICRP on engaging all stakeholders and on communication, in particular as it applies to optimisation in relation to contentious facilities and activities, use of radiation in medical applications, management of accidents, and remediation.

3.3. Education and training

It is important to recognise that it is the practice of radiological protection that safeguards the health of people, animals, and the environment. Inappropriate use of radiation technologies may increase risks, and result in harm to patients, workers, or members of the public. Education and training in radiological protection should be an essential part of undergraduate and other studies in relevant domains.

ICRP *Publication 103* (ICRP, 2007) mentions education for members of the public, and education and training for workers to ensure radiological protection and safety. Later, ICRP developed recommendations on education and training specific to the medical field in ICRP *Publication 113* (ICRP, 2009c). Further work in education and training may be beneficial.

Modern education and training in radiological protection should be accredited and should include measurable assessments of the knowledge, skills, and competencies of workers throughout their career. This may include education and training of professionals who act as educational/information multipliers, such as teachers.

Relevant disciplines should be made attractive for students interested in natural sciences. Establishment of long-term research programmes on topics relevant to radiological protection can facilitate attractive PhD projects.

Education and training in multi-media communication, cultural competency, and safety culture improve radiological protection and safety. This can help build shared understanding and trust, and support an interested public in understanding the basics of radiation and radiation-induced health effects.

4. Dose

4.1. Dose quantities

New General Recommendations will provide the opportunity to simplify the use of dose quantities for protection against tissue reactions and stochastic effects. In ICRP *Publication 147* (ICRP, 2021a), ICRP explains proposals to use absorbed dose (in gray, Gy) for the control of doses to individual organs and tissues for the avoidance or minimisation of tissue reactions. Introduction of this change would mean that equivalent dose (in sievert, Sv) would no longer be used to set limits in relation to tissue reactions but would remain as an intermediate step in the calculation of effective dose. Radiation weighting could then be considered separately for tissue reactions and stochastic effects for the calculation of radiation-weighted absorbed dose in Gy and effective dose in Sv, respectively. These anticipated changes will apply scientific knowledge more appropriately and simplify radiological protection, with a clearer distinction between organ/tissue doses in absorbed dose in Gy and effective dose in Sv. Similar conclusions have been reached by NCRP (2018a).

The International Commission on Radiation Units and Measurements (ICRU) proposes parallel changes to the operational quantities for occupational exposures to external sources. As discussed in a recent report issued jointly with ICRP (ICRU, 2020), the intention is that the measured quantities for the estimation of effective dose would be related directly to effective dose in the reference phantoms, renamed as ‘dose quantities’ (ambient and personal dose) rather than ‘dose equivalent quantities’. Operational quantities for the measurement of doses to the skin and lens of the eye will become ‘absorbed dose quantities’. Changes to the operational quantities would be introduced on the same timescale as changes to the protection quantities, after new ICRP General Recommendations are issued.

4.2. Effective dose, including age-, sex-, and individual-specific doses

ICRP *Publication 103* (ICRP, 2007) introduced the use of anthropomorphic phantoms based on medical imaging; reference adult phantoms were provided in ICRP *Publication 110* (ICRP, 2009a). Absorbed and equivalent doses are now calculated separately for the reference male and female and averaged in the calculation of effective dose to the sex-averaged reference person. In addition, ICRP has developed a set of reference phantoms for children of different ages (ICRP, 2020a), and will also provide reference phantoms for the pregnant woman and fetus.

While effective dose remains the central protection quantity, aspects of its calculation are likely to change, and others will be considered. It might be that it is not necessary to apply simplifications in these calculations – simplifications can come later in the application of the System. Thus, radiation weighting values can be specified that apply the scientific evidence to the best of our current knowledge. The same applies to tissue weighting factors that can represent relative detriment, or an alternative, more accurately. Furthermore, rather than calculating just two values of detriment and relative detriment for workers and members of the public, averaged over age groups and both sexes, it would be possible to specify detriment and relative detriment separately for males and females of different age groups. Effective dose and the associated detriment could then be calculated separately for each group, using best science, thus increasing transparency. Simplifications, for example the setting of appropriately averaged dose criteria such as limits, could be made at the end of the whole process. The link between effective dose and stochastic risk that drives the System and the optimisation of protection would then be clearer. Such evolution would obviously have implications for the management of radiation risks that should be identified and assessed.

In this context, ICRP (2021a) has judged effective dose in its current formulation to provide ‘an approximate indicator of possible health risks’. Revisions to the methodology of calculation of effective dose could improve its suitability for the assessment of risk. Best estimates of health risk should be calculated using estimates of absorbed doses to organs/tissues and age- and sex-specific risk models for individual types of cancer, but risk estimates at low doses will still be subject to the uncertainties inherent in risk projection models.

4.3. Use of effective dose in medicine

The original and accepted purpose of effective dose is the quantification of radiation exposures of workers, including medical staff, and members of the public to demonstrate compliance with dose limits and optimise protection against stochastic effects, mainly cancer (ICRP, 2007, 2021a). For this purpose, the requirement has been for a single quantity with which to measure and sum doses from all sources, applicable for all workers or all members of the public. Effective dose currently has more limited use in patient care, where it is chiefly used in nuclear medicine dosimetry and for comparing dose estimates across differing choices of imaging examinations. However, a more individual-specific quantity could be

more useful. ICRP has developed male and female reference phantoms with reference effective dose coefficients, but these calculations do not yet take account of differences between individuals in body and organ masses and dimensions. Modern dosimetric phantoms are readily adjustable to the sizes and dimensions of different patients and can be used to calculate a size-specific or patient-specific derivative of effective dose (see ICRP Task Group 113 on Reference Organ and Effective Dose Coefficients for Common Diagnostic X-ray Imaging Examinations). Separate tables of detriment for males and females and for different ages at exposure could then be used in considering potential risks from exposures. These data would allow a patient-specific quantity, while recognising that more precise estimates of radiation risk are possible for an individual patient with more specific information.

4.4. Effective dose coefficients

ICRP provides sets of dose coefficients (dose per unit exposure or intake) for exposures to external radiation sources, for intakes of radionuclides by inhalation and ingestion, and for administration of radiopharmaceuticals. Changes in methodology inevitably mean that all dose coefficients require revision following new General Recommendations. The work that is currently in progress to provide dose coefficients based on ICRP *Publication 103* (ICRP, 2007) methodology should also facilitate more rapid recalculation after the next General Recommendations. It is intended that a full set of dosimetric phantoms will be ready in advance, and it is anticipated that there will be no or very limited requirement to revise biokinetic models for inhaled and ingested radionuclides. It is possible that many organ/tissue doses may not need recalculating.

A gap in the provision of dose coefficients has been values for exposures of patients in diagnostic x-ray procedures, including computed tomography. ICRP Task Group 113 on Reference Organ and Effective Dose Coefficients for Common Diagnostic X-ray Imaging Examinations is currently developing reference effective dose coefficients for a range of examinations, to parallel work on dose coefficients for the diagnostic use of radiopharmaceuticals.

Dose coefficients will be provided for exposures at all ages, including the developing fetus, to include exposures following intakes of radionuclides by the mother and the use of radiopharmaceuticals.

A further initiative in progress is the development of methodology for emergency dosimetry (ICRP Task Group 112 on Emergency Dosimetry) for which there is the need to consider prospective and retrospective dosimetry for evaluation of both stochastic effects and tissue reactions.

4.5. Dose quantities for non-human biota and ecosystems

Dosimetry for the purpose of protection of non-human biota and – implicitly – ecosystems, was first considered by the Commission in ICRP *Publication 108* (ICRP, 2008) and was subsequently refined in ICRP *Publication 136* (ICRP, 2008, 2017). There were several

challenges, including variability of size and shape, anatomy and density, and surrounding media; and, in many cases, significant transformations during the life cycle (e.g., eggs, larvae, metamorphosis). Unless measurement data are available, exposure analysis also requires estimates of environmental levels of radionuclides and their transfer to organisms in the environment; this was considered in ICRP *Publication 114* (ICRP, 2009d).

To develop a workable dosimetric approach, simplifications and generalisations had to be made, including:

- relying on absorbed dose when relating dose to effect (and risk) – there is currently no alternative that provides an understanding of risk in relation to dose, such as effective dose for radiological protection of people;
- development of dose coefficients for 12 RAPs typical of marine, aquatic, and terrestrial environments, represented by simplified geometries such as spheres and ellipsoids; and
- establishing datasets for steady-state concentration ratios for a range of elements to assist assessments of radionuclide transfer in different environmental media for the 12 RAPs, taking no account of anatomy and organ distribution of radionuclides for the purpose of internal dosimetry.

In general, it is considered that the current approach to calculation of dose coefficients is both reasonable and practicable. Factors such as the transfer of radionuclides through the environment, delineation of the external radiation field and exposed group, and concentration ratios between the organism and environment may, in many cases, introduce uncertainties into dose assessments that are greater than those in the dose coefficients. ICRP intends to collaborate in planned international work to pursue best techniques for different exposure situations.

More detailed dosimetry is likely to be necessary when considering animals as veterinary patients. While not always warranting the sophistication of the anatomical models used in human dosimetry, some simplified versions of such models could be developed and refined as necessary (e.g., for the purpose of translational research).

5. Effects and risks

5.1. Classification of radiation-induced effects

The classification of harmful radiation-induced health effects into ‘stochastic effects’ (cancer and heritable diseases) and ‘harmful tissue reactions’ for protection purposes should be revisited to ensure that it remains fit for purpose. For example, for protection purposes, it may be useful to distinguish between severe and other tissue reactions, or between short-term and long-term health effects. Some health effects may not fit well into either category (e.g., cataract, diseases of the circulatory system). Whatever classification is adopted, it will be necessary to assess the impact on the management of radiological risks in terms of the tolerability of risks and putting them into perspective with other risks. Any reclassification

will not affect the fundamental requirements to prevent severe tissue reactions (using organ/tissue doses) and optimise protection against effects at low doses and low dose rates, principally cancer (using effective dose).

5.2. Tissue reactions

At high whole-body doses (>0.5 Gy) for acute and protracted exposure (ICRP, 2012), severe irreversible damage occurs in organs and tissues. These high-dose effects, called 'tissue reactions', include the acute radiation syndromes that may result in irreversible damage to the haemopoietic bone marrow, intestinal tract, and brain, but also include direct damage to other organs and tissues. The current System stipulates that tissue reactions should be prevented; a clarification could be that prevention applies to severe irreversible tissue reactions (generally occurring at doses >0.5 Gy other than for in-utero exposures). In such considerations, the developing embryo/fetus should be considered as a special case for which lower thresholds apply (ICRP, 2003, 2007).

It is possible that tissue reactions resulting from damage to cell function may result in less severe tissue reactions at lower doses (<0.5 Gy) for acute and protracted exposure (ICRP, 2012). For both cataract formation and diseases of the circulatory system, evidence suggests that thresholds of approximately 0.5 Gy may apply, and data can also be interpreted to suggest non-threshold dose–response relationships (ICRP, 2012; Little et al., 2012; Bouffler et al., 2015; Tapio et al., 2021). ICRP *Publication 103* (ICRP, 2007) made no changes to previously recommended annual dose limits for tissue reactions in relation to planned exposure situations, set in terms of equivalent dose, of 150 mSv for the lens of the eye and 500 mSv for the skin and the hands and feet for occupational exposures; and 15 mSv for the lens of the eye and 50 mSv for the skin for public exposures. Subsequently, ICRP (2012) issued a Statement on Tissue Reactions recommending that the annual limit on equivalent dose to the lens of the eye for occupational exposures should be reduced to 20 mSv, averaged over 5 years with the dose not exceeding 50 mSv in any year. This Statement also drew attention to the need for medical practitioners to be aware that doses as low as 0.5 Gy to the heart or brain may affect the circulatory system, as doses of this magnitude could be reached during some complex interventional procedures.

Consideration should be given to the justification for having different limits for workers and members of the public which may not be supported by the scientific evidence. Single limits of, for example, 500 mGy to the skin and 20 mGy to the lens of the eye would then apply to all exposures of workers and members of the public.

5.3. Cancer at low doses and dose rates

Several assumptions and judgements are made in quantifying the risk of low doses and dose rates for cancer (ICRP, 2007). Based on epidemiological analyses from the 1990s, a dose and dose rate effectiveness factor (DDREF) of 2 was applied to the risk of solid cancer derived from the atomic bomb survivor studies. Currently, epidemiology may provide some evidence of a DDREF >1 for solid cancer in humans, but with considerable statistical and

methodological uncertainties involved in that estimate; as such, analyses continue (Rühm et al., 2016; Shore et al., 2017). Animal and in-vitro data indicate curvilinear dose–response relationships that provide some support for the use of a DDREF >1. As discussed in ICRP *Publication 131* (ICRP, 2015), the component factors of DDREF – dose effectiveness factor and dose rate effectiveness factor – may be considered mechanistically distinct, with the former applying to low acute doses, and the latter applying to protracted doses for which long-term kinetics of target stem cells may modify responses.

In the current system, linear models are used to reflect the relationship between dose and the risk of solid cancer, and a linear-quadratic model is used to reflect the relationship between dose and the risk of leukaemia (ICRP, 2005, 2007). Many epidemiological results have been published in recent years that have improved our knowledge on the shape of the dose–risk relationship for specific cancer sites, and the impact of modifying factors of this relationship (e.g., sex, age at exposure, attained age). Even if there are still large uncertainties at low doses (UNSCEAR, 2012), some recent results demonstrate relationships at doses <0.1 Gy (Lubin et al., 2017; Little et al., 2018; Hauptmann 2020) with little evidence of the existence of a threshold.

In a review of all relevant epidemiological studies, NCRP concluded that current epidemiological data support the continued use of the linear no-threshold (LNT) dose–response relationship for radiological protection purposes, with no other model representing a more pragmatic interpretation (NCRP, 2018b). A recent review of biological mechanisms relevant for the inference of risk of cancer from low dose and low dose rate radiation also concluded that there remains good justification for the use of a no-threshold model for risk inference for radiological protection purposes (UNSCEAR, 2021b). A critical review of recent scientific results on the shape of dose–risk relationships and the influence of dose rate is being performed by ICRP Task Group 91 on Radiation Risk Inference at Low-dose and Low-dose Rate Exposure for Radiological Protection Purposes. This is needed to ensure that LNT is the most appropriate evidence-based assumption to use for radiological protection purposes.

The LNT dose–response assumption underpins the use of effective dose as a protection quantity, allowing the addition and comparison of external and internal doses of different magnitudes, with different temporal and spatial patterns of delivery. However, it should be recognised that while low doses may be measured or estimated with reasonable reliability, the associated risk for stochastic health effects is uncertain, and becomes increasingly uncertain as the dose decreases.

5.4. Individual response of people

ICRP Task Group 111 on Factors Governing the Individual Response of Humans to Ionising Radiation is reviewing the scientific literature in relation to both tissue reactions and stochastic effects to assess potential implications on the System. Some factors are already very clear, such as the influence of smoking, age, and sex (ICRP, 2021a). Other factors,

including genetic factors and lifestyle factors, are emerging as potential modifiers of responses but these are less well defined. The current System does not make formal distinctions between people based on such factors, although optimisation of radiological protection takes these factors into account in some cases, such as by protecting children preferentially.

It is not clear that there will be sufficient scientific evidence in the next few years to fundamentally change the way that the System protects workers and members of the public. However, there are already efforts to individualise radiological protection of patients which should be considered in the review of the System, taking into account scientific, ethical, and practical aspects. More generally, there are ethical questions that need to be discussed as individual characteristics and response information become more widely available.

5.5. Heritable effects

ICRP *Publication 103* (ICRP, 2007) notes that there is no reliable direct evidence from human epidemiological studies of deleterious heritable effects of radiation but considers the inclusion of heritable risk in overall stochastic risk to be a prudent interpretation of the evidence of heritable effects in experimental animals. Following a detailed analysis by UNSCEAR (2001) and ICRP (2007), estimates of heritable risk over two generations have been applied in calculations of radiation detriment. The validity of this assumption 20 years later should be reviewed considering new knowledge on genetic and epigenetic mechanisms. An ICRP task group on the effects of ionising radiation exposure in offspring and next generations is being considered to review the scientific literature to assess potential implications on the System.

5.6. Radiation weighting for different effects

There is good evidence, consistent with physical characteristics, that radiation types differ in their effectiveness per Gy in causing biological effects. The 2007 General Recommendations (ICRP, 2007) use a simple table of radiation weighting factors to account for this difference, primarily using evidence related to the risk of radiogenic cancer.

However, the current radiation weighting factors do not fully reflect the available evidence of the relative biological effectiveness (RBE) of different types of radiation. For example, there is some limited evidence that low-energy photons and electrons show greater effectiveness per Gy than reference ^{60}Co gamma rays by factors up to 2–3 when considering cancer-related endpoints (NCRP, 2018c). There is also evidence that alpha-particle RBE values differ for different types of cancer, with a low value for leukaemia and higher values for lung and liver cancer. The use of a single value of 20 for heavy ions will overestimate risk in many cases, and a more sophisticated approach is warranted when considering doses in outer space. In line with the overall approach being presented in this paper to encourage discussion, it is appropriate to use the most up-to-date science in the calculation of protection quantities rather than applying simplifications. ICRP Task Group 118 on Relative Biological

Effectiveness (RBE), Quality Factor (Q), and Radiation Weighting Factor (w_R) is reviewing the scientific literature to assess potential implications for the System.

In general, RBE values for tissue reactions at high doses, involving gross cell killing in tissues, are lower than values for cancer-related endpoints at low doses. It is expected that a separate set of radiation weighting factors will be developed for tissue reactions and the calculation of radiation-weighted absorbed dose (see Section 4.1). With the increasing potential and clinical use of, and wider applications for, alpha, proton, and heavy ion radiation in medicine, there is a need to provide values for these applications.

5.7. Radiation detriment

Detriment is a concept used to quantify the harmful effects of radiation exposures at low doses or low dose rates on health, taking account of the severity of disease in terms of lethality, quality of life, and years of life lost. It currently applies to stochastic effects, including cancer and heritable effects. The System is based on the assumption of a directly proportional relationship between effective dose and radiation detriment. Calculation methodology and perspectives on the evolution of this quantity have been reviewed recently by ICRP Task Group 102 on Detriment Calculation Methodology.

The nominal risk and detriment coefficients provided in ICRP *Publication 103* (ICRP, 2007) are age-, sex-, and population-averaged values. They are calculated for both the whole population (0–89 years of age at exposure) and the working-age population (18–64 years of age at exposure). Risks for the general population are somewhat larger because risks are generally greater for exposures at younger ages and life-expectancy is greater than for adults.

For the next General Recommendations, longer follow-up of epidemiological cohorts and further analyses will have improved the basis for estimating lifetime risk values. It is likely that specific risk estimates will be available for more organs/tissues and cancer types. It should also be possible to quantify the incidence of cancer for different age groups, and separately for males and females. Thus, detriment could be calculated separately for males and females and at different ages at exposure, and the corresponding values of relative detriment could be used directly in the calculation of effective dose, rather than the current use of simplified age- and sex-averaged tissue weighting factors (see Section 4.2). Beyond considerations of cancer, other late-developing effects, such as opacities in the lens of the eye and diseases of the circulatory system, need to be evaluated in the expression of harm. Explicit treatment of detriment from irradiation *in utero* could also be re-evaluated.

Consideration will be given to alternatives to detriment as an expression of harm. For example, Breckow (2020) has suggested that the use of fatality would be simpler and clearer, and would make comparisons with other carcinogens more straightforward. Other measures of harm such as disability-adjusted life years (Shimada and Kai, 2015; WHO, 2021) have also been discussed, and their use as a measure of radiation-induced harm should be investigated.

5.8. Effects and risks in non-human biota and ecosystems

ICRP *Publication 108* (ICRP, 2008) includes a review of existing effects data for the 12 RAPs. This review focuses on the effects of radiation on mortality, morbidity, and reproductive success, which are considered most relevant for environmental protection. The review includes data from laboratory experiments and observations in the field during experimental irradiation or in contaminated environments (e.g., after accidents).

The review enabled the formulation of DCRLs, which are 'bands' of absorbed dose rate at which some deleterious effect can be expected, for specific RAPs. Rather than being prescriptive, the DCRLs provide guidance that inform decision makers on when it would be prudent to reflect on whether an undesirable impact of radiation in the environment may already be imminent or could be expected, and to consider that information in the decision-making process. This, in turn, assists in guiding the optimisation process, in the same way that reference levels are set to guide actions to protect people (ICRP, 2014a).

Further analysis of experimental data has been performed to establish weighting factors for different radiation qualities for the purpose of relating effects data for biota to absorbed dose (rate) (ICRP, 2021b). On that basis, an absorbed dose weighting factor of 10 for alpha radiation has been considered generally applicable.

While the DCRLs are not inconsistent with new data [e.g., observations from the 2011 nuclear accident in Japan (UNSCEAR, 2021a)], further analysis may need to be given to their relevance in an ecosystem context and in the context of human impact on the environment (e.g., Brechignac et al., 2016; Vandenhove et al., 2018). All this forms part of ongoing work of ICRP Task Group 99 on Reference Animals and Plants (RAPs) Monographs (see Section 4.5). Furthermore, and as alluded to in Section 2.3, a widening of the scope of ICRP's work on environmental protection could be considered to cover all ecosystems, from natural ecosystems to those heavily influenced by humankind, that provide various essential services to people. This may require a new objective for ICRP's work on environmental protection, as well as a re-evaluation of endpoints and effects categories.

6. Conclusions

The last review of the System of Radiological Protection was initiated 23 years ago, and the current General Recommendations (ICRP, 2007) were published 14 years ago. The System has performed well and remains robust, and there are significant practical benefits to stability in the System. Nonetheless, it must progress to remain fit for purpose as society evolves, scientific understanding advances, and new uses of ionising radiation emerge.

Collectively, it is important to ensure that the best elements of the System remain, and those areas that need to be refined benefit from extensive collaboration. The System must stay true to the best scientific knowledge and robust ethical principles, while remaining practical to implement.

In that effort, clarity must be the watchword, so that anyone interested in radiological protection can understand how the System works. Although professionals usually implement the System, it is fundamental for patients, workers, and others who benefit from it. Clarity will help to ensure that the System is understood, communicated, and applied worldwide. The role of effective communication in engaging on radiation risks cannot be understated, as pointed out recently by the Nuclear Energy Agency (NEA, 2021): 'to be trusted, you must communicate successfully; to communicate successfully, you must be trusted'.

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