Second task of 'IRPA TG on the Revision of the System of Radiological Protection' Feedback from the Italian Association of Radiological Protection (AIRP)

Marie Claire Cantone (member of the IRPA TG) with the support of Mauro Magnoni (President of AIRP) and Celso Osimani (President of AIRP International Committee)

General comments

The process stated by ICRP towards a comprehensive analysis of the points present in the current System of RP, considered critical and candidate for update, is appreciated by the Italian Association. Considering the complexity related to this process, it clearly emerges as useful to focalise, first on the three issues identified as most important/critical, and then obviously to continue the process.

The three considered most important issues by AIRP

a) Stakeholders' involvement and communication (why is it still important and critical today?)

It is appreciated that the consultation with stakeholders is launched, already at the beginning of the process towards the ICRP review of the current System, and that the significance of co-expertise and co-operation approaches with professionals and stakeholders are in general well recognised in the practical implementation of protection and towards a continuous development of a RP Culture. In taking into consideration the specificities of the different areas, as the case of medical and nuclear fields, and past-accident situation, it emerges that the professionals, stakeholders and interested parties are in general related to different environments and specific approaches, depending on their role and relationship with the parties. Thus, there is the need to better identify and develop approaches for the engagement of the stakeholders in consideration of the different situations, roles, and level of engagement in the view of day-by-day practice in different possible fields of interest, including aspects of communication of risk and participation in decision-making.

b) Ethical aspects in Radiological Protection (essential ingredient in decision making)

It is recognised a great significance for the explicit introduction of ethics in RP System, that was already present in the past, but now it is more evident with the presentation of the related ethical values in a comprehensive view. A broader basis of discussion, considering different situations and specificities in the different RP field, is desirable for helping professionals to be aware and confident towards a concrete implementation in the practice, as appropriate. Now, there is the need to continue to work going forward, since it is not sufficient to have explicitly introduced the aspects related to ethical values in the RP System, but there is an evident need to use the ethical values in the practice, with attention to the specificities of the RP situation. ICRP has done and is doing a great work on ethics in RP, but the mission now is on how to transmit, as extensively as possible to the RP community, the application of value judgement when dealing with real questions in the process of making appropriate decisions.

For example, it is important to consider that the knowledge and understanding of the principles of RP are very important and necessary pre-requisite, but at the same time could be not sufficient

when not accompanied by adequate training for all the RP professionals, that includes ethics as an essential ingredient in decision making process.

c) Effective dose, including age-, sex-, and individual-specific doses (what about the implementation approach?)

It is considered of great interest the possibility of evaluating effective dose in a more realistic framework regarding the subject exposed, and capable of allowing information aimed at a more sensitive evaluation of the risk to which the person, as part of specific group, could be subject. This is an important approach, particularly in the case of medical exposure, as it allows to take into consideration the difference in radiation exposure responses, from the point of view of the effects in relation to age and gender. At the same time, a concern emerges about aspects that could be delicate, probably not previously considered and discussed by the community, regarding a possible discrimination related, for example, to different assessments in the workplace, with different dose limits for specific workers groups. The process of implementing a more realistic effective dose, that is very important, requires clarification of some points and an effective involvement of the interested parties.

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ARPS Revised Feedback Focusing on 3 Highest Priorities

15 December 2021

This document presents the three highest priorities of the Australasian Radiation Protection Society with regards to invited feedback on the paper *Keeping the ICRP Recommendations Fit for Purpose* (the paper).

Introduction

The International Commission on Radiological Protection (ICRP) produced the paper to initiate the process of revising the system of radiological protection. IRPA has convened a task group to promulgate the paper and to encourage feedback from Associate Societies. Drew Watson and Brent LeVert are Australasian Radiation Protection Society (ARPS) representatives on the IRPA task group for the review of the system of radiological protection.

ARPS provided IRPA with the document *ARPS Feedback on the ICRP Paper*, 3rd October 2021. IRPA presented feedback from ARPS and other Associated Societies at the ICRP November 2021 Symposium in the presentation *IRPA perspective on the Review of the System of Radiological Protection* by Sigurður M Magnússon (IRPA Chair). Subsequent to this symposium, IRPA requested task group members to "revisit your initial feedback, considering the ICRP web event, and further develop your feedback focusing on what you consider to be the three most important issues to address with rationale and proposals for the way forward." This will provide prioritized issues for IRPA to discuss in an executive committee meeting in February and to develop further before the ICRP November 2022 Symposium. In addition to this, IRPA asked that the paper *IRPA Perspective on 'Reasonableness' in the Optimisation of Radiation Protection* be considered as it is an important aspect of IRPA work.

Consultation

The top three priorities for ARPS are provided below based on feedback from the ARPS community of members. Feedback was primarily received via discussion within ARPS executive meetings and correspondence from email circulars to ARPS members inviting feedback for this list of priorities.

Top 3 Priorities

1. There is consensus among ARPS members that the system of protection must be clear, logical and practical. Although the system is generally effective, in its current form it is viewed as complex. Feedback indicates that this contributes to difficulty implementing the system. In general, ARPS does not support revisions that further complicate the system. The introduction of a threshold however has the potential to simplify the system and improve practicality.

2. ARPS proposes the introduction of a low dose threshold, e.g. between 1 and 5 mSv, with planned exposures below this threshold subject to no regulatory governance as a means to address the important issue of reasonableness. The objective is to balance managing risks at low doses to the degree that the efforts of regulatory governance and financial burden is commensurate with comparable risks in other industries.

   Applying the LNT model for radiation regulation communicates that any dose of radiation, no matter how small, is harmful and potentially carcinogenic. This should not be the message that the radiation protection industry promotes, given that "in practice there is a wide consensus that at low exposure levels typically around 'a few mSv' or less, all we know is that if there is a risk, then it is very small and is equivalent to many risks in situations commonly accepted in society" (IRPA 2021 'reasonableness' paper).

   The rationale for introducing a threshold is that aside from a growing body of modern molecular biology studies not supporting a linear non-threshold dose-response model, there is a dose level (1 to 5 mSv almost certainly) where the risk is so low as to make it almost impossible to measure actual risk beyond an assumption of linearity. While it is commendable to seek the answer, our profession is trapped by the current scientific uncertainty. Radiation protection needs to reduce the impost of regulating at dose levels with such scientific uncertainty. One way to achieve this is to set a threshold at a reasonable level.

3. There is a need to rethink whether "one system for all" is the right approach. By trying to bring everything under one system, it is getting more complicated and difficult to enact. It may be advantageous to have different systems for medical, natural, and nuclear. A system of protection categorised by exposure context has potential for simplifying optimisation and applying a holistic approach by grouping radiation practices that have attributes in common.

Austrian_Revised feedback_Dec_2021

I had solicited thoughts on our priorities for ICRP. We finally came to the conclusion that for our non-native speaking members, a careful choice of language for ICRP would be most important. It at times can be difficult to translate (or comprehend, in the original) subtleties associated with the formal content of the ICRP Publications, such as

1. Theory
2. Hypotheses
3. Data, conclusions, and interprtation

In particular, when “qualifiers” are utilized, they can provide grounds for significant mis-interpretation (e.g., “it cannot be excluded that …”, “seems to indicate …”, or etc.).

HEALTH PHYSICS SOCIETY

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10 November 2021

Dear Professor Magnuson:

As requested in your 29 October 2021 message, I have enclosed what I consider to be the top three priorities for the International Radiation Protection Association (IRPA) to take forward to the International Commission on Radiological Protection (ICRP).

Priority 1: A holistic approach

A holistic approach should consider factors beyond the radiological, including how to promote reasonable caution while avoiding undue conservatism within the System and its implementation.

Rationale: 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. As recommended by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR),

> "In general, increases in the incidence of health effects in populations cannot be attributed reliably to chronic exposure to radiation at levels that are typical of the global average background levels of radiation. … the Scientific Committee does not recommend multiplying very low doses by large numbers of individuals to estimate numbers of radiation-induced health effects within a population exposed to incremental doses at levels equivalent to or lower than natural background levels" (UNSCEAR 2012)"

Near background radiation dose-rates, hypothetical radiation risks – even those calculated using an assumed linear no-threshold (LNT) dose-response - are so small as to be unobservable. Given the uncertainty in dose-response at low doses and dose-rates, there may not be any radiation risks at all. Calculated radiation risks are almost always outweighed by nonradiological risks, costs, and other social factors when doses and dose-rates are near background. Attention should be given to the integration of hypothetical risks from radiation doses and dose-rates near the normal variations in natural background with real, observable nonradiological risks.

Priority 2: Optimisation, not minimization

Optimisation of protection and safety should not consistently seek the lowest radiation exposures or risks possible, but a balance of factors including dose, risk, and other

considerations. By its very definition, the ALARA (as low as reasonably achievable) principle posits a level of residual exposure and risk below which it is unreasonable to pursue.

Rationale: This is the most significant challenge of the current system of radiation protection. Regulators pay lip-service to this concept, but when an emergency actually happens, they inevitably resort to driving doses as low as possible and ignore other factors in the face of political pressure.

Priority 3: Adoption of the World Health Organisation's definition of health

The World Health Organisation has defined health as, 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' (WHO, 1946), and the ICRP should consider how this definition can be incorporated into the system of radiation protection.

Rationale: An important health effect in both the Fukushima and Chernobyl accidents was the mental health effects resulting from exaggerated fear, which was in turn a direct product of the current system's unsupportable application of the LNT model of radiation effects at very low doses (i.e. close to background).

Please let me know if you have any questions or need any clarifications on the above, or if you need further input from the Health Physics Society. Again, thank you for the opportunity to participate in this very important effort.

Best Regards,

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Michiya Sasaki Japan HPS

The International Correspondence Committee of JHPS organized a session, entitled “Issues for the development of the next ICRP General Recommendations and the activities of the Japan Health Physic Society” in the 3rd Joint Meeting of JRSM (Japanese Society of Radiation Safety Management) and JHPS (54th JHPS Annual Meeting) was held on 1-3 December 2021.

During its panel discussion*, following three issues were stressed by the panelists and participants:

- Understandability

The next General Recommendations will need to be written and structured in a clear and understandable manner. In the past, the intended audience for the ICRP Recommendations was only radiation protection experts, but now there are many readers other than radiation protection experts. Furthermore, given the importance of stakeholder involvement, efforts must be made to ensure that it is widely understood by all concerned. For example, the LNT model and the concept of optimization, although advanced, have not yet penetrated among society. In the 2007 General recommendation, exposure category was introduced; however, occupational, public, and medical (patient) doses were treated separately, and it is necessary to discuss how the additivity of such doses can be explained.

- Radiation risk estimation

Needs for risk estimation is shifting from society to the individual. From the perspective of optimizing the radiation protection, there is a hierarchy of national, local, community, family, and individual, and it may be difficult to reconcile risks across the hierarchy. The closer to the individual, the more delicate the issue can become. The biological effects of the underlying radiation on humans include individual and offspring. It is necessary to pay attention how the late effects, such as diseases of circulatory system and cataracts will be handled in the risk calculation. On the other hand, it is also important to discuss what biological and scientific data are appropriate for radiation protection and radiation risk estimation. In the risk management, since there are two types of management: normal risk estimation and risk estimation assuming an accident, discussions should be held with experts from various fields.

- The Fukushima Daiichi Nuclear Power Station accident It is necessary to incorporate what has been learned from the Fukushima Daiichi Nuclear Power Station accident into the system of radiation protection. In this case, it is also necessary to discuss the direction of radiation protection for the members of the public, considering the past experience from nuclear tests and accidents in the future. This is related to the discussion on risk assessment and optimization, but there is a gap between the subjective nature of individual risk and the objective nature of social risk, which is the main focus of the system of radiological protection. In particular, it may be necessary to consider politics in order to make the system of radiological protection work effectively.

The JHPS proposes that the discussion on the next ICRP General Recommendations be carried out by theme of each TG and Building Blocks separately, since it is difficult to focus on the overall target. A symposium in conjunction with a regional IRPA conference or TG meeting could be a good venue for such discussions.

Although, IRPA requested to report three issues to the Associate Societies, the above three points are not systematically collected by soliciting opinions from JHPS members widely, for example, through questionnaires or polls. However, JHPS believes that they contain important elements and will provide valuable input for the future activities of the IRPA TG.

* Panelist: Hiroko Yoshida (President of JHPS), Yasuhito Sasaki (Former member of ICRP Main Commission), Ohtsura Niwa (Former member of ICRP Main Commission), Satoru Nakashima (President of JRSM), Yoshiya Shimada (President of Japan Radiation Research Society), Takehiko Murayama (President of the Society for Risk Analysis Japan), Michiaki Kai (Member of ICRP Main Commission)

Best regards

Michiya

Feedback from Nordic Society for Radiation Protection (NSFS)

The feedback was collated by sending an e-mail to all registered members of the Society, asking for feedback on the previously sent feedback (in connection to the ICRP seminar). Based on the responses, the following issues were identified as the most important.

1. The detriment-adjusted nominal risk coefficients given in e.g. ICRP103, are frequently used in RP to assess the radiation risk. However, the nominal risk of incidence, also given in ICRP103, may need more emphasis in risk assessment, both in respect of societal and personal detriment. It would also provide a more solid assessment with time, since it does not include lethality fraction adjustment, which is changing with time due to steadily improving health care/treatment outcomes. In this context risk coefficients should also be given separately for each gender, also in respect of tissue weighting factors, and specified for different age (age groups) at exposure.

We also believe it useful to explore the possibility of using QALY or DALY for severity adjustment.

2. Thorough elaboration on uncertainties involved in estimating the total detriment, based on nominal incidence risk, weighted for lethality and life impairment [and including DDREF] is needed, in particular quantification of uncertainties regarding the nominal [organ] risk coefficients based on cancer incidence data.

3. ICRP give recommendations on dose limits for occupational and public exposure, limits that are often adopted in national legislations. It may be valuable to discuss/describe the foundation for setting the value of dose limits, in particular the limits for effective dose.

4. We support the inclusion of other late effects/endpoints than cancer and hereditary effects in the detriment.

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Mats Isaksson & Håkan Pettersson

Eduardo Sollet the Spanish Radiation Protection Association (SEPR)

These are the three most relevant aspects from the point of view of the Spanish Radiation Protection Association (SEPR) concerning the potential future revision of the ICRP Publication 103 recommendations.

The choice was based on ICRP's own arguments (Clement's paper) to propose its consideration (below in blue) in the next revision of the recommendations.

1) The holistic approach of the Optmization principle:

ICRP *Publication 146* (ICRP, 2020b) identifies the environment as one of the factors to be taken into account. Other factors as such as societal, environmental, economic, and general wellbeing may also be included in the optimization considerations.

Several others main questions arise, including how to approach optimization 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 optimization principle when considering the safety of sources, facilities, and practices, basing this analysis on risk, and emphasizing 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, optimization 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) The new definition of the effective dose and the the possibility of individualizing the risk / detriment by sex, age groups and types of exposure:

In ICRP *Publication 147*, ICRP explains proposals to use absorbed dose (in gray, Gy) for the control of doses to individual organs and tissues for the avoidance or minimization 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.

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.

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'.

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.

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.

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 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.

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.

Also, 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.

3) The extension of the dose limitation principle to all exposure situations.

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, generalized to apply in all situations, and encompassing the concepts of limits, constraints, and reference levels. (SI) 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.

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. Further consideration should be considered to see whether risk criteria might have broader application beyond circumstances of potential exposure.

IRPA Task Group on the Revision of the System of Radiological Protection

The 3 major issues to be addressed by ICRP upon revision of its general recommendations.

Contribution from French Society for Radiation Protection (SFRP), France

Date: 15 December 2021
Authors, on behalf of SFRP. Sylvain Andresz, Nuclear Protection Evaluation Centre
Anne Cordelle, Radiation Protection and Nuclear Safety Institute

Approach. The authors took the opportunity of the upload of a web-questionnaire[1] about the '*issues at stake in radiation protection*', which was developed by the French Nuclear Safety Authority and circulated in October 2021 among the SFRP members to identify the key areas of interest.
Furthermore, previous reflection from the analysis of the ICRP article and discussions of the members were used.

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1. Considerations on health effects, with assessment of the radiation detriment

- It could be interesting and useful to specify radiation detriment and relative detriment separately from males and females, of different age groups.
- It would especially improve the detriment suitability for the assessment of risk, which is a topical concept, subject of many works around the world.
- More references to epidemiological studies should be given (notably needed for risk coefficients).
- The different values for detriment could then lead to the calculation of effective dose for each group (gender, age), which would be more correct scientifically and more useful - in the medical field in particular - with a more individual-specific quantity.
- However, we should take care of its application in practice: getting several values for the effective dose, depending on the gender and the age of exposition, could lead to practical and ethical difficulties for the management of radiation risks (separate dose limits for each group ? which could be discriminatory when hiring a person, because the dose limits would be higher for a 50-year-old man than for a 25-year-old woman…).
- In addition, the question to set a dose criteria based on lifetime exposure should be raised.
- Finally, to investigate the use of DALY (for example) as a measure of radiation-induced harm seems to be a good way. Noting that, all in all, the expected changes in DDREF, RBE etc. and the unit of detriment, would lead to a complete change in the radiological detriment as we known it.

2. Should ICRP reframe the 3 exposures situations?

- The application of the planned-existing-emergency exposure situations (PES, ExES and EmES) scheme proved to be difficult in practice. During the last decade, many ICRP TG, especially those

[1] Questionnaire (in French) : https://framaforms.org/vos-propositions-sur-les-enjeux-de-radioprotection-1632467706

working under Committee 4, faced difficulties in deciding in which ES a situation fall: NORM, cosmic radiation, radon…

- Most users of the system (and nuclear Authorities) only considers the ES as an entry point to calibrate their radiation protection requirements. Globally, it can be said with some confidence that more requirements apply to workers exposed under a PES than those exposed under ExES; despite comparable exposure levels.
- Without necessarily coming back to the former intervention-practice scheme, it is definitively necessary to frame a system that limit ambiguities in deciding in which category an exposure situation falls and inequities in the radiation protection.
- (All in all, does ICRP really need the 3 ES?)
- The system will benefit from such clarification: outreach, communication, education & training etc. purposes.

3. Looking for clarity and homogeneity in the optimization principle: holistic approach?

- The optimization principle is the cornerstone of the radiation protection system. The system is now being (or should be) applied under many situations and topics. Other situations are currently under scrutiny: non-human biotas, astronauts, medical exposure with new techniques … etc.
- How to ensure that the radiation protection is optimized "*social and economic considerations taken into account*" from a cross sectors/cross situation perspective? (and avoid a radiation protection jungle)?
- And are there other considerations to take into account in the decision (the so-called 'prevailing circumstances')?
- Practical recommendation for a holistic approach (beyond the traditional cost-benefit analysis), should be needed to find the most adequate protection, in light of what it at stake and evaluated on a common and consensual basis (to be found).
- Such an holistic approach can be designed to consider to some extent elements and rationale coming from other sectors and risks (industrial sectors, chemical)

SRP second response to IRPA focussing on three important issues: December 2021

1. Science – what will be new and does this warrant new ICRP recommendations? A view voiced at the ICRP workshop is that while ICRP has stated the aim of issuing new recommendations by about 2030, this objective should be challenged by stakeholders – why is this necessary, will protection be improved significantly, will the considerable effort that will ensue internationally and nationally be justifiable and worthwhile?

2. Applications – focussing on reasonableness and optimisation, together with limitation. We consider that ICRP has an important role to play, working with other international organisations, in clarifying what are considered to be trivial doses in different circumstances and how optimisation should be applied at low doses.

3. Communications - including clarity over organisational responsibilities. The primary role of ICRP is to communicate the protection system to radiation protection professionals. It seems that international RP organisations could do a better job of coordinating their responsibilities (communicating with each other) and their interactions with their shared stakeholders.

1. Science and the System

SRP recognises that an important driver for new recommendations will be changes to the underlying science and its application in the system of protection. An early step in the consideration of the need for new recommendations will be an examination of the extent of the envisaged changes in risk estimates and in the use of dosimetric quantities. ICRP should be encouraged to provide greater clarity on expected changes and their implications for protection practice, as the basis for discussion of the need to proceed with new general recommendations, recognising the substantial efforts that will be required to implement changes in international safety standards and national legislation.

It is noted that low dose (< 100 mSv) risk estimates will be updated, based on thorough review of all epidemiological evidence, with consideration of whether a DDREF of 2 should be applied to solid cancer risks and whether non-cancer diseases should be included in low-dose detriment (or an alternative to detriment). ICRP should scope the likely outcome of these considerations. Is it likely that the population-averaged stochastic risk estimate of 5% per Sv used at low doses will change appreciably and how might this affect the setting of reference levels and limits?

SRP is generally supportive of the proposed changes to ICRP dose quantities and ICRU operational quantities, including the increased clarity that will be provided by using absorbed dose (Gy) to organs / tissues in the control of tissue reactions and effective dose and operational dose quantities (Sv) in the control of stochastic effects (Clement *et al* 2021, ICRP 2021; ICRU 2020). The cooperation between ICRP and ICRU is noted and welcomed. However, we also note that the present system works well and these changes do not of themselves appear to warrant the publication of new ICRP general recommendations. While we see the advantages of the proposed changes, we note that there have been concerns among practitioners regarding the costs of implementation of changes to operational quantities in the workplace, which would arguably not be justified by significant benefit in terms of improved safety. Hence, there are challenges yet to be addressed regarding the practical implementation of the proposed changes.

An important consideration for ICRP in planning new recommendations is that all ICRP organ and effective dose coefficients will require revision once new radiation and tissue weighting

factors are published, applying revised risk estimates. Following from the 2007 Recommendations (ICRP, 2007), ICRP has published a series of reports providing revised dose coefficients for external exposures and intakes of radionuclides by workers (ICRP 2010, 2015, 2016, 2017, 2019, in press) and on external exposures of members of the public (ICRP 2020). However, revised data are yet to be published for intakes of radionuclides by members of the public and for the diagnostic use of radiopharmaceuticals. ICRP should provide a timescale for these publications and consider whether further revision of all these data is justified, either in terms of the very substantial effort required by ICRP members to perform these calculations or the efforts required by users to implement the new data.

2. Application of the System

SRP considers that an important focus for the practical application of the system is to promote reasonableness in the optimisation of protection at low doses in different circumstances of exposure. The principle of optimisation is defined by ICRP (2007) as the source related process of keeping the likelihood of incurring exposures (where these are not certain to be received), the number of people exposed, and the magnitude of individual doses, as low as reasonably achievable, taking economic and social factors into account. Experience has shown that in many cases, particularly when considering very low public exposures, application of this ALARA principle over-emphasises the "as low as" without due consideration of the "reasonably achievable" and the essential caveat of "taking economic and social factors into account".

SRP would welcome improved contextualisation of very low dose exposures as an aid to understanding and consideration of what is reasonable in optimisation of protection. When consideration is being given to doses of a few millisievert or fractions of a mSv, it will be helpful to consider the context of natural background radiation and the variation in doses received by individuals (Coates and Czarwinski 2018, IRPA 2021). It is important to review the general basis for decision-making at low doses. ICRP and other international organisations, including IRPA, should work together to define what is considered to be a trivial dose under different circumstances.

We also wish to stress the importance of ensuring a holistic approach to the optimisation process, whereby risks from different types of hazards potentially involved are taken into account in a balanced way. It would be helpful for ICRP to give further consideration to the importance of, and methods for, balancing risks from different types of hazard including chemical carcinogens, noting the comparisons made by Clero *et al* (2021) for example. Clarity is needed in explaining what is known about risks at low doses – that risks are inferred from observations of excess disease at higher doses with little direct evidence of risk at low doses.

Clement *et al* (2021) make the point that while optimisation is intended to establish the best solution for society, dose limitation is required to protect individuals. As discussed by Coates and Czarwinski (2018), one of the issues of greatest concern to Partner Societies is the strong perception that limits mark the boundary between safe and unsafe. It may be preferable to set limits solely for the prevention of serious tissue reactions at higher doses and use only reference levels in relation to the optimisation of protection against stochastic effects at low doses (Constraints are a sub-set of reference levels and it is not clear why two alternative words are required.)

It is not clear that such considerations of the optimisation of protection require new general recommendations from ICRP. It is important that all international stakeholders are involved in discussing and agreeing the best way forward and it may be that, rather than new ICRP recommendations, joint statements should be made by all organisations involved to help practitioners and regulators interpret and apply the existing system. IRPA will play a central role in this process.

3. Communication

There are a number of important aspects to the need for effective communication, including:
- communication between ICRP and other international organisations responsible for the development of the system
- communication of the system and its application to radiation protection practitioners worldwide
- communication with stakeholders exposed to radiation and the wider public in the application of the system of protection.

ICRP (2007) makes clear that its recommendations are "aimed principally at regulatory authorities, organisations and individuals who have responsibility for radiological protection". There is a close connection between ICRP Recommendations and the International Basic Safety Standards for Protection against Ionizing Radiation and the Safety of Radiation Sources, which are co-sponsored by UN international organisations and published by IAEA. The latest revision of these Basic Safety Standards (BSS) was published in 2014, following the ICRP 2007 Recommendations. Cosignatories of the BSS are the EC, FAO, IAEA, ILO, OECD/NEA, PAHO, UNEP and WHO (IAEA 2014).

We suggest that a better job could be done of coordinating the efforts of RP organisations in the development of the system, its dissemination to RP professionals and its communication to stakeholders who are or may be affected by the application of the system. At this critical stage of the consideration of the need for new ICRP recommendations, it would seem appropriate to seek a consensus from the responsible international organisations on this perceived need. More generally, greater delineation of the responsibilities of the various organisations would be helpful, to foster greater collaboration and reduce duplication of effort.

Communicating with stakeholders affected by the application of the system and the enhancement of public understanding of radiation risks and their control would seem to be best handled by the RP practitioners involved in application of the system at a national or local level. IRPA and its Partner Societies clearly have a central role in this process, as discussed by Coates and Czarwinski (2018) and in associated IRPA (2020) guidance. ICRP and other organisations can assist in this process by providing readily accessible explanations of their recommendations and other reports, and ICRPaedia is noted as a very welcome initiative (www.icrp.org).

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