First task of 'IRPA TG on the Revision of the System of Radiological Protection'

Feedback on the paper "Keeping the ICRP Recommendations Fit for Purpose" from the Italian Association of Radiation 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

1. General comments

The Italian Association recognises this is the right time for the starting phase to identify and choose the areas that need attention, and not only on the new and ongoing scientific knowledge, but also in relation to the needs and challenges perceived and encountered in RP in the practice. Thus, the discussion and possible reassessment, developed together with the interested parties, could give a view about the significance and adaptability on the considered and proposed choices, within the framework of the System, and also the approaches and methods to make them implementable from a practical point of view.
Particularly appreciated is the attention dedicated, in this paper, to the stakeholder involvement, considering that the consultation with stakeholders is launched already at the beginning of the process towards the ICRP review of the current System, and the co-expertise and co-operation approaches with professionals and stakeholders are well recognised in the practical implementation of protection and towards a continuous development of a RP Culture. Moreover, it is appreciated to continue in taking into account scientific, ethical and practical aspects all together, and at the same time the consideration to identify how explicit incorporation of the ethical basis of the System would be beneficial. In any case a full agreement is well recognised for: "*The System must stay true to the best scientific knowledge and robust ethical principles, while remaining practical to implement"*, as cited in the conclusion of the paper.

2. Specific comments, with reference to the ICRP paper

1 - Background and purpose - Pag. 3, lines 43-44. "*The better the System is understood, the more effectively it can be applied, . . .*". COMMENT - Probably it would be also useful, in particular considering the stakeholders cited in the line before, to refer that: '*The better the System is understood*, in relation to the aspects, motivation and modality to be activated in the practice, *the more effectively it can be applied, . . '.* Thus, taking into consideration the specificities of the different areas, as the case of medical and nuclear fields, we can see 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. The understanding of the System is crucial, but the protection is embedded in a deep knowledge, experience and ethical view for a proper ability and behaviour in its application.

2 – Objectives and principles of the System

2.2 - Protection of people - Pag. 4, lines 26-30. *"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."*. COMMENT - In medical field and in response to emergencies, the prevention

of tissue reactions is well known, and the cases of tissue reactions side effects are considered related to the recognised benefits for persons and communities. The significant possible '*some less severe tissues reactions*' in human space exploration seems not so much really considered and internalized in the whole RP community, as the activity, even if could be attractive, is not related to a day by day practice.

2.3 -Protection of the environment and non-human biota – Pag. 5, lines 4-40. COMMENT - The attention on this argument is considered of great significance either for environment itself as for the impact and related effects on human. It is recognized the issue needs a new push despite the commitment and the important work done so far. In relation to the specificities and complexities involved in this field and keeping in mind the goals that are considered to be addressed, an effort on this issue is certainly welcome. Moreover, as already evidenced in paragraph 5.8, this is the time to consider to take the opportunity to open the view of this thematic by including a wide environmental protection and taking into account the natural ecosystem and also of the parts more related to human activities.

3. Overarching considerations

3.1 Ethical aspects of radiological protection – Pag. 9, lines 26-31." *ICRP Publication 138 …… ethical values underlying the System."*. COMMENT - 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 really more evident the presentation of 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. Ethical aspects are already included in the paper paragraphs, e.g., 2.4 , 3.2, and 5.4, not only in 3.1, and this, once again, gives the view on how the ethical basis really lies at the basis of the System.

4. Dose

4.1 Dose quantities – Pag.11, lines 37-40. "*Introduction of this change would mean the equivalent dose (in sievert, Sv) would not longer be used to set limits in relation to tissue reactions but would remain as an intermediate step in the calculation of effective dose*. " - lines 44-47. " . . . *simplify radiation protection, with a clear distinction between organ/tissue doses in absorbed dose in Gy and effective dose in Sv."* COMMENT – This new approach is welcome, and appreciated by our community, and it is well clear the use of the absorbed dose for skin and lens.

4.2 Effective dose, including age-, sex-, and individual-specific doses - Pag. 12, lines 25-29. " . . . *it would be possible to specify detriment and relative detriment separately for males and female of different age groups. Effective dose and associated detriment could then be calculated separately for each group, using best science, thus increasing transparency.* " COMMENT – It is considered with a real attention this possibility of evaluating effective dose in a more realistic framework regarding the subject exposed, and capable of allowing information aimed at a more sensible evaluation of the risk to which the subject is subjected. An issue that could be delicate is an application of the dose limit for the worker which, compatibly with the effective dose value, could be considered different for gender and age, and this could create different assessments in the workplace, according to the characteristics of the worker.

5. Effects and risk

This part, dedicated to effects and risks turns out to be the one that opens a deep discussion, attracts more and larger interest, and represents a great challenge. Great efforts are well recognised to be undertaken in this thematic towards an update with related improvements.

5.1 Classification of radiation-induced effects – Pag. 14, lines 55-56; lines Pag.15, lines 2-5. '*Some health effects may not fit well into either category (e.g. cataract, diseases of the circulatory system)*.' '*Any reclassication will not affect the fundamental requirements to prevent severe tissue reactions . . . and optimise protection against effect at low dose and low dose rates . .* '. COMMENT - There is a recognised agreement, among professionals, that health effects should be reviewed with coherence and knowledge and, at the same time, is recognised the need for a clear explanation of the basis of possible new performed schemes, and in particular the need for a clearable view for the community, towards the modalities for their implementation. In this sense it could be appreciated to report examples, if possible in form of scenarios accompanied with the approaches for evaluation.

5.2 Tissue reactions - Pag. 15, lines 46-51. "*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*.". COMMENT - The question of considering different or the same dose values as limits for workers and members of the public is a general aspect, probably not so clearly discussed, that could be seen also in relation to different type of risks, and ethical considerations. We can also remember the Sievert Lecture by G. Silini, 1992, "I would eventually like to see a system in which each person is protected as a human being, irrespective of any working condition".
The presentation of this new view could take advantage from discussion with the involved parties. Another point of discussion could also start from the two different numbers existing now (15 for people and 20 for workers) and the single value proposed of 20 for both, and why not 15, for example?

Pag. 15, lines 40-44. "*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*." COMMENT – Research and literature (e.g., PROCARDIO EU Project - Cardiovascular Risk from Exposure to Low-dose and Low-dose rate Ionizing Radiation) evidence heart as an organ with great tolerance dose for 20 Gy, but even below 2 Gy a long term damage could be, and also adverse effects related to doses above 500 mGy. At the moment, it seems not so clearly evident if a dose below 500 mGy represents no risk for cardiovascular diseases.

5.3 Cancer at low doses and dose rates - Pag. 16, lines 44-51. "*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 . . . . However, it should be recognised that while low dose may be measured or estimated with reasonable reliability, the associated risk for stochastic health effects is uncertain, and become increasingly uncertain as the dose decreases*." COMMENT - From the practical point of view, the use of LNT is considered a very good, easy and well-known approach in the practice. The research and the studies that are being carried out, will give probably on the bases of the due time, more clarifications. The question seems still related to the increase of uncertainty as dose is lower, as already discussed during the preparation of the text of the previous 2007 Recommendations. It is important to have a view about and to evaluate the level of possible foreseen

related advantages, considering changes to risk at low dose, and possible difficulties related to a change from the linear no-threshold dose response.

5.4 Individual response of people - Pag. 17, lines 11-18. *". . . . 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.".* COMMENT – This is considered as a very important and significant aspect to be included in the next ICRP Recommendations. The individualise RP of patients has articulated bases identified, as in the paper, in science, ethics and practice, and moreover in many aspects related to the shift to the protection of an individual patient, thus contributing towards the best approach to choose and to follow for that patient. At individual level a number of elements as age, gender, and radiosensitivity factors could increase the uncertainties, and for example the need for tacking individual patient's dose and history over times arises and the development of procedures to identify radiosensitive patients is already a challenge.

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ARPS Feedback on the ICRP Paper

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Introduction

The International Commission on Radiological Protection (ICRP) produced the paper *Keeping the ICRP Recommendations Fit for Purpose* (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.

Request for feedback and virtual webinar

An initial email was sent out to the ARPS membership asking for feedback on the ICRP paper, and this was followed up with a virtual webinar on the topic of the review and revision of the system of radiological protection.

The webinar was well attended with radiation protection professionals from both Australia and New Zealand, and included presentations from Christopher Clement the Scientific Secretariat of the ICRP and Dr Gillian Hirth of the Australian Commonwealth regulator the Australasian Radiation Protection and Nuclear Safety Agency (ARPANSA) and as a member of the ICRP main commission.

A call was also put out for feedback through representatives of other professional societies that have members with an interest in radiation protection including the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM), Australian Institute of Occupational Hygienists (AIOH), South Pacific Environmental Radioactivity Association (SPERA) and Radiation Safety Users Group (RSUG). Despite the breadth of professional societies from which feedback was sought, only ARPS members provided concerted written feedback.

Discussion

The ICRP system of radiation protection is the foundation and framework for radiation protection and is therefore of great importance to ARPS members. This was evident in the aforementioned recent webinar, as well as during ARPS annual conferences and general discussions of the ARPS executive and members.

It is worth noting that there is diversity in the ARPS membership, with members from medical, industrial, mining, health, nuclear, research and environmental fields. In addition to this, multiple independent radiation protection regulatory authorities govern Australia and New Zealand. This diversity of member perspectives can present as a diversity of views amongst individual members and reflects debate on these topics in general.

Consolidated feedback of the ARPS membership is provided below. Key topics that evoked lively discussion are:

- Ensuring that the review of the system leads to simplification rather than increased complexity.
- Being careful about a single framework (it was noted that usually "a one size fits all approach" does not work in practice).
- Practical regulation and management of radiation risk at low doses and ensuring that low risks are not over regulated.
- The practical difficulties with LNT and consideration of adopting a threshold.
- Radiation risk perceptions, ethics and communications.
- The risks and ethical aspects of over conservatism when considering radiation impacts.

General Comments

1. ARPS in this submission to the IRPA task group on the Review of the System of Radiological Protection RPS acknowledge that the current system appears effective and robust.

2. ARPS supports the approach to the review outlined in the ICRP paper given that the current recommendations are effective and the future recommendations should be evolutionary rather than revolutionary. It is agreed that the system should evolve in response to further data.

3. There is a consensus view 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, and feedback indicates that this is contributing to the difficulty experienced by front line practitioners implementing the system. This is exemplified by the discussion in sections 4.1 and 4.2 of the paper which could be viewed as a push to make the system more complex. In general, ARPS does not support revisions that further complicate the system.

4. ARPS members expressed concern that there is an apparent drive to get all radiation risks under one system. There is a need to rethink how the system is applied – and whether a "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. The IAEA is making analogous changes in that there is recognition that the systems for radiation protection of nuclear facilities are not appropriate for NORM facilities.

5. ARPS proposes that further work is undertaken to assess the appropriateness of conducting assessments based on “worst case”. Over conservatism results in misinformation.

Specific comments with reference to sections and lines in the ICRP paper

Section 2.2 Protection of people

6. Tissue reactions may be tolerated to achieve a net benefit. However, should this be restricted to situations where the benefit is received by the individual who may receive the tissue reactions e.g. in the case of teletherapy. (Page 4 lines 19-30)

7. An ARPS member commented that the definitions of low dose - < 100mGy low LET radiation and < 5mSv.h^{-1} remain appropriate based on relevant data. (Page 4 lines 50-52)

8. ARPS members conveyed a breadth of feedback in regards to the concept of human health objectives being based on the World Health Organisation (WHO) definition of health as ‘a state of complete physical, mental and social well-being, not merely the absence of disease or infirmity’. It was recognised that exposure or potential exposure to radiation can impact mental and social well-being. Some feedback agreed that these factors should be included in the system of radiation protection, albeit at the cost of a greater emphasis required for data based communication of radiation risks to mitigate unwarranted mental and social impacts. On the other hand, there was also feedback that introducing mental health into radiation protection requirements was ‘a bridge too far’. While well intended, the concept permits the possibility of psychological aspects dominating public radiation protection discussions. Governments considered such in the wider context of overall responsibilities and the potential introduction of mental health aspects takes radiation protection into areas where radiation protection specialists do not have the skill sets to inform decisions or advice. Similarly it was stated that immediate health impacts of the Fukushima evacuation surpassed the chronic radiation risk. This flaw in the system of radiation protection should be addressed. As such, a shift to using the WHO definition of health is expected to be problematic to implement. In summary, ARPS recognises that mental health issues can be associated with radiation, particularly anxiety and fears. ARPS thinks that strategies such as system simplicity, public engagement, education and ensuring that the risks of low level radiation are described appropriately (Page 4 lines 56-60)

Section 2.3 Protection of the environment and non-human biota

9. The approach is focussed on detriment related to habitats and ecosystems. The absence of considering net benefit was raised. Reducing the impact or retarding the progression of climate change through application of nuclear science and technology is likely to have a far greater positive impact on habitats and ecosystems. The system of radiation protection should ensure this consideration is apparent to governments and policy and decision makers.

10. ARPS members recognise that protection of the environment is an expanding area. And that care should be taken to avoid one overriding system for workers, public and the environment. Care should also be taken regarding any shift towards protecting individual animals or plants over the current requirement to protect species and habitats.

11. Introducing concepts such as sustainability into radiation protection requirements is considered to be a bridge too far for radiation protection practitioners. The concept permits the possibility of sustainability aspects dominating public radiation protection discussions. And the potential introduction of sustainability aspects takes radiation protection into areas where radiation protection specialists do not have the skill sets to inform decisions or advice. The wider context of amalgamating 'sustainable development' and 'quality of life' with radiation protection priorities lies with governments. The system of radiation protection should not extend beyond alerting governments and policy and decision makers to such considerations. (Page 5 lines 35-42)

Section 2.4 Fundamental principle of justification

12. Any justified practice will (by virtue of LNT) do harm; the question is whether such harm remains acceptably low for the benefit derived. ARPS members note that "justification" should remain a core pillar of the system and note that the justification process may involve more than just the costs or benefits of the radiation component. It was also noted that the "justification" process for, as an example, a nuclear facility is very different from a medical procedure. (Page 5 lines 48-51)

Section 2.5 Fundamental principle of optimisation

13. Optimisation should not be just about minimising exposures to ALARA, but also taking into account societal, economic, environmental and general wellbeing factors. The adoption of a holistic approach to the reduction of overall detriment or impact is a natural extension of the optimisation principle since its inception. Consideration also needs to be given to optimisation of the protection.

14. The paper emphasises a focus on risk and risk assessments. The nuclear industry has moved from risk (defined as 'consequence' x 'likelihood of consequence being realised') to deterministic assessments, which focus on consequence from postulated initiating events and controls to prevent the event leading to the consequence or mitigate the consequence to an acceptable level. Risk models vary across industries and sectors.

15. The paper advises 'Reasonable Caution' whilst avoiding undue conservatism. ARPS note that in practice, in a legislative process, this is difficult to implement. In cases where the dose may be significant, but the likelihood is assessed as low, the subjectivity or contextualisation of the assessment of likelihood is important.

16. It is considered that the remit of the ICRP should be solely centred upon radiation protection. Extending it to a holistic approach invites dilution of the purity of advice expected from the ICRP. Holistic decision making will occur when governments input any/all factors beyond the radiological. (Page 7 lines 7-15)

Section 2.6 Fundamental principle of application of dose limits

17. It is considered that seeking perfection due to the ethical desire to protect individuals in all circumstances would result in potentially tighter radiation protection controls being applied.

Careful selection of the distinction between limits, constraints and reference levels is essential to avoid tightening controls excessively thereby preventing or reducing benefits or potentially prohibiting beneficial practices.

Section 2.7 Categories of exposure and exposure situations

18. The application of exposure situations (and the subsequent requirements) has caused confusion in practice and does not integrate well with regulatory systems and legislation in a way that is easily implemented. While the situations may be clear in “documents”, there is ambiguity in the application particularly between planned and existing. ARPS proposes that the categorisation of exposure situations is reviewed.

19. Any suggestion that dose limits should apply to purely natural exposure would not be expected to get much support. Increases in adventitious public exposure such as flying or dwelling construction is an integral part of the benefits of life. Similarly for unmodified natural environments. (Page 9 lines 17-19)

Section 3.1 Ethical aspects of radiological protection

20. Would this approach be considered to take the ICRP from being the penultimate source of radiation protection advice to it being open to ethical challenge of its scientific advice? It is considered that there would be few areas where any explanation of an ethical basis would detract from the science. (Page 9 lines 45-47)

Section 3.2 Communications and stakeholder involvement

21. The inclusion of informed community opinion is important, but is also a risk if not managed properly or codifies a right of veto. (Page 10 lines 17-18)

Section 3.3 Education and training

22. This should also focus on risk theory to contextualise risks from low doses of radiation. Practitioners should be trained in a challenge culture – both giving and receiving; as that is where true optimisation lies.

23. Health risk management in radiation protection is trending towards case-by-case assessments instead of a one size fits all approach. This is appropriate for optimised outcomes, however it puts significant pressure on justification of radiation protection decisions. Effective case-by-case assessments require competent radiation professionals supported by methodology tools for a uniform approach to these assessments. Consideration should be given to development of these tools and accreditation standards for competency of radiation professionals.

Sections 4.1 and 4.2 Dose

24. While the derivation of sex and age specific detriments and hence effective doses are possible, this level of specificity is not mirrored in other health protection schema. It is understood that the science is continually maturing in radiation effects and biological knowledge of same, however there might be a natural "optimisation point" as to the complexity adopted. ARPS asserts that while further increasing specificity and accuracy may be the best science, the benefits would be outweighed by the added complexity. (Page 12 lines 22-30)

Section 4.4 Effective Dose Coefficients

25. ARPS propose that injection dose coefficients are produced as these are significant exposure pathways for medical procedures and decommissioning.

Section 5.1 Effects and risks

26. Tissue reactions require greater stratification as they range from lethal effects to transient impacts.

Section 5.3 Cancer at low doses and dose rates

27. ARPS agrees that the risk at low doses is very uncertain as there is no evidence of risk at low dose, and asserts that there needs to be a balance in 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.

28. ARPS accepts that the LNT model may continue to form the basis of the system of radiological protection for the foreseeable future, however it is emphasised that in practice you need to manage risk, and above all the system needs to be practical. It is difficult to see how the LNT could ever be tested at low doses any time soon given a background of such high natural cancer rates. The LNT approach prevents practitioners saying that a radiation practice is safe and leads to unnecessary effort at low doses. This contributes to mental health impacts from radiation protection.

29. ARPS proposes that the introduction of a low dose threshold is investigated, e.g. between 1 and 5 mSv, with planned exposures below this threshold subject to no regulatory governance.

30. Incorporating age and gender specific effective doses is unnecessary at low doses and implies an unwarranted degree of precision. Such additional complexity may make necessary beneficial practices impossible and compound public anxiety. (Page 16 lines 47-51)

5.4 Individual response of people

31. ARPS recognises the incorporation of potential response modifiers as a significant ethical challenge. It is not clear how this can be integrated into a clear system of protection. Just as optimisation is not just focussed on the lowest dose, so responses of people to other physical, mental, economic factors also need to be accounted for. Care must be taken to ensure that individual dose limits do not become the norm as this would be totally impractical.

5.5 Heritable Effects

32. ARPS supports the establishment of a task group to reconsider the commission's current position on the inclusion of heritable risk in overall stochastic risk.

5.7 Radiation Detriment

33. Although greater specificity in dose determinations is possible via incorporating age and gender, it is the view of ARPS that there is limited merit in doing so at low doses. The increased scientific accuracy may not outweigh the efforts of enacting this and the associated need to communicate further radiation hazard complexities and nuances to stakeholders.

Additional issues that should be considered by the ICRP

34. Nothing in addition to the comments above.

Thoughts on direction for improvement of the system

35. Nothing in addition to the comments above.

Other

36. Nothing in addition to the comments above.

Input Belgian Radiation Protection Society (BVS-ABR) transmitted by Augustin Janssens

Comments to IRPA on the paper "*Keeping the ICRP Recommendations Fit for Purpose*".

a) General comments

The overall approach is sound, and the project is ambitious. ICRP recognises that there is need for clarification on the exposure situations, in particular with regard to situations with a pre-existing source where activities generate new exposures. ICRP further pursues the integration of the different tools for the protection of the individual, but there is no indication that this issue may actually be related to the previous problem area, on exposure situations. With regard to dose limitation there is as yet no indication of the different purpose, and ethical basis, of occupational limits and of limits on public exposure. The planned reviews on the concept of dose and of detriment are welcome. It is also welcome that ICRP intends to elaborate on the idea of potential exposures, but this may be a perilous project, embarking on nuclear safety and waste management in a "holistic" approach.

b) Specific comments, with reference to line/lines in ICRP paper.

1. ch. 2.4: Principle of Justification
   - the principle of justification will need to be explained according to the exposure situations and pre-existence of the source
   - ICRP should not avoid a discussion on the concepts of exemption (graded approach to regulatory control) and clearance. Criteria for clearance ought to be discussed in the light of justification.
2. ch. 2.6
   - line 7.51: it would be welcome to abandon the current conceptual overlap between *constraint* and *reference level*, but the conservative view that dose limits only apply in planned exposure situations may need to be reconsidered.
   - line 7.55: it is in fact unfortunate that DCRL's are a kind of reference level, while they are not related to the protection of the individual
   - line 8.12: the tolerability of exposures is being examined in TG115, but this examination should distinguish between the grounds for limitation of doses to workers and members of the public.
   - line 8.22: it is confusing to associate the exposure in space with "potential exposures".
3. ch. 2.7
   - line 9.09: the issue with NORM is not only their possible concentration in industrial processes, but also the causation of new exposures occurring in industrial applications or by their use as building materials.
4. ch. 3.2
   - it is welcome that Stakeholder Involvement is emphasised, but one should differentiate its application along the exposure situations.
5. ch. 3.3
   - the need for building on safety culture and on understanding risks has been emphasised by the COVID pandemic.
6. ch. 4.2
   - line 12.18: the idea of simplifying dose concepts only at the end of the assessment process, for instance when applying dose limits, enhances transparency and gives flexibility in the definition of doses for regulatory purposes; in particular for occupational exposures to radon this may be an important consideration.
7. ch. 4.5
   - it is welcome to offer guidance on veterinary radiation protection

8. ch. 5.2
    - line 15.18: not only with in-utero exposure, but also the exposure of small children ought to be managed with caution
    - line 15.49: the current situation with regard to dose limits to the lens of the eye is indeed unpleasant, but it may be even more disturbing to have the same dose limit for members of the public, if these are at all needed, as for workers.
9. ch. 5.6
    - a possible higher RBE for alpha particles exposing the lung should be considered prudently, in order not to be in conflict with the management of radon exposures.

c) Additional issues that should be considered by the ICRP - with rationale.

- cf. point b: address the principles of exemption, even more so the criteria for clearance; while so far ICRP dismissed these as being regulatory issues, there is need for guidance on the ethical basis and on the criteria.
- discuss communication on overall population exposures, and the resulting health consequences of low doses and their “discernability” (as opposed to attributability)

d) Thoughts on direction for improvement of the system.

Take the opportunity for fully integrating publication 138 in explaining the RP System and pursue lines of communication on the basis of ethics rather than “the System”. Include thereby not only the ethical values underlying the System of Protection, but also the values on which society rests to manage emergency and post-accidental situations, in particular the value of solidarity.

e) Other

We recommend looking into the transposition of the general recommendations of Publication 103 in the international standards (IAEA and Euratom) as well as in national legislations. While ICRP should not embark on regulatory issues as such, it would be wise to encompass the legislative and regulatory experience.

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

Feedback of Cameroon Radiological Protection Society

a. General comments

The revision of the System of Radiological Protection is welcome to update the 2007 General Recommendations in ICRP 103. Several areas of the System requires more clarity and consistency. Cameroon Radiological Protection Society (CRPS) will focus its feedback on:

- Fundamental principle of application of dose limits (Paragraph 2.6)
- Categories of exposure and exposure situations (Paragraph 2.7)
- Effective dose coefficients (Paragraph 4.4)
- Dose quantities for non-human biota and ecosystems (Paragraph 4.5).

b. Specific comments

Fundamental principle of application of dose limits

- Should consider the existing exposure situation because exposure to natural radiation could reach dose levels higher than 100 $mSv.yr^{-1}$. It is for instance the case of radon exposure indoors.
- Should consider thoron in the definition of radon reference level and regulation. Thoron is neglected in dose assessment. However many reported studies in the world proved the importance of thoron.

Categories of exposure and exposure situations

- More emphasis should be given to existing exposure situation. Currently it appears as the least important between the three exposure situations. However, existing exposure is the most common situation met in the world without any consideration of country, urban or rural areas.

Effective dose coefficients

- Harmonization of inhalation dose coefficients of radon and thoron published by ICRP and UNSCEAR by using dosimetric and biokinetic models. ICRP and UNSCEAR have worked in the recent years to harmonize their views on the effective dose coefficients of radon and thoron. Unfortunately there is still divergence between the two scientific commissions. Professionals and members of the public are not well protected against harmful effects of radon exposure in case of misunderstanding between ICRP and UNSCEAR. As consequence, the System of Radiological Protection is weakened.
- More effort is required on the uncertainty assessment of dose coefficients. By convention, ICRP has decided to give dose coefficients as reference values, without any uncertainty. However more clarity is welcome on uncertainty in dose coefficients.

Dose quantities for non-human biota and ecosystems

Currently there are 12 RAPs typical of marine, aquatic and terrestrial environments. It will be important to increase the number of RAPs to take into account common terrestrial animals met in all continents.

IRPA TG on Revision of the System of Radiological Protection

Based on our review of the article (Clement et al, 2021), we recommend the following:

Page No	Lines	General Comments
		The manuscript is a good one and in the right direction. A concious effort has been made to improve the protection level of man based on sound science and current research findings Access to some of the reviewed articles could be useful in understanding the rationale and conclusions reached in the article

Page No	Lines	Specific comments with reference to line/lines in ICRP paper
8	L41	We agree with recommendation for the addition of at least one category of exposure to address non-human biota
9	L 3- 9	Exposure to naturally occuring sources needs some addition attention in how it is quantified in terms of risk assessment
9	L 38- 42	We agree with the objective of the ICRP Task Group 109 to harmonize the various ethical values into a set for scenarios encounted in daily practice.
10	L 59-60	We agree to education and training in radiological protection being an essential part of undergraduate and other studies in relevant domains
11	L 35-36	We agree with the concept of absorbed dose as propossed by ICRP for the control of doses to individual organs and tissues for the avoidance or minimisation of tissue reaction
12	L 4	We agree with the implementation of phantom specific effective dose for age, sex and individals
13	L 34	It is always useful to have dose coefficient for all procedures and these coefficient, will additionally, serve the purpose of modeling and simulation of radiation exposures
16	L 31-35	For radiation protection purpose, we support the use of linear no-thresshold model for risk analysis.

Page No	Lines	Additional issues that should be considered by ICRP- with Rationale
8	L41	Separate categories of exposure should be established for animals and for plants because of the differences in susceptibility to radiation

Page No	Lines	Thought on direction for improvement of the system
8	41	There should be one category of exposure for animal and another for plants
10	L 59-60	This could be in the form of train the trainers (lecturers or teachers) just as being done by the IAEA There could be schorlarship scheme for Phd in such desciplines, Also modular training packages for workers and media education for the general public
12	L 4	Implementation of phantom specific effective dose for age, sex and individal specific doses is in the right direction, this will be very useful in research work, however future effort should make simpler and practicable in daily usage.

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Comments on (Clement et al. 2021)
Brant Ulsh, Health Physics Society (USA)
2021-08-05

Dear Professor Magnuson:

As requested in your 30 August message, I am enclosing my comments on the paper, "*Keeping the ICRP Recommendations Fit for Purpose*", by Chris Clement. All of my comments are constructed to reference specific lines in the paper. Please feel free to contact me if you have any questions, require any clarifications, or need any other input from me on this assignment. Thank you for the opportunity to serve on this important IRPA Task Group, and I look forward to future assignments.

Best Regards,

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Specific comments, with reference to line/lines in ICRP paper

Page 1, lines 44-47: "This is the beginning of a process that will take several years, involving open and transparent engagement with organisations and individuals around the world". Excellent – open and transparent engagement is exactly what has been lacking in the past, and what is needed now to increase confidence and buy-in from stakeholders.

Page 1, lines 51-54, and Pg. 3, lines 41-46: "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 harmonization". Yes – exactly right! It is not enough to simply make recommendations, but the rationale behind the recommendations must be clearly and succinctly stated.

Page 2, line 3 and Page 4, line 35, and Section 5.5: "Many areas are identified for potential review including:…heritable effects". Why are heritable effects listed as a focus for the upcoming review? I encourage the ICRP to consider the existing substantial body of evidence which has not observed heritable effects (i.e. radiogenic effects in germline stem cells which are then passed to offspring) in humans (Brent 2015). UNSCEAR has concluded,

> "There have been many studies of possible heritable effects following radiation exposure; such studies were reviewed by the Committee in 2001. It has been generally concluded that no heritable effects in humans due to radiation exposure have been explicitly identified (specifically in studies of offspring of survivors of the atomic bombings). Over the past decade, there have been additional studies that have focused on survivors of childhood and adolescent cancer following radiotherapy, where gonadal doses are often very high. There is essentially no evidence of an increase in chromosomal instability, minisatellite mutations, transgenerational genomic instability, change in sex ratio of offspring, congenital anomalies or increased cancer risk in the offspring of parents exposed to radiation. One reason for this is the large fluctuation in the spontaneous incidence of these effects". (UNSCEAR 2013)

What evidence suggests heritable effects should be considered a focus of continued research, rather than an answered question?

Page 4, line 42: "…risks to young children are greater than risks to adults". This is a common assertion, based on children having a greater expected remaining lifespan in which to express radiogenic cancer. However, another important factor to consider in determining the relative risk of children vs. adults is susceptibility for specific types of cancer. As discussed in (Ulsh 2015),

> "UNSCEAR recently reviewed the epidemiologic evidence on the sensitivity of pediatric subjects relative to adults (UNSCEAR 2013), and concluded:
> • For 25% of the cancer types, children appear to be more sensitive than adults;
> • Children appear to have the same radiosensitivity as adults for 15% of cancer types;
> • For 10% of the cancer types, children appear to be less sensitive than adults;
> • For 20% of cancer types, no conclusion can be drawn about the sensitivity of children relative to adults because the evidence is too weak; and
> • For about 30% of cancer types there is only a weak relationship or no relationship at all to radiation exposure".

Uncritically relying on the rule of thumb that "children are more radiosensitive" can lead healthcare providers to make incorrect decisions about pediatric imaging, for example. I encourage the ICRP to recommend that the situation be considered on a case-by-case basis (particularly in the pediatric imaging setting), taking into account children's longer expected

lifespan, cancer-type specific susceptibility, and the specific tissues which will be exposed in a particular imaging procedure. Comprehensive guidance from an organization like The Joint Commission that takes these factors into account would be especially welcome.

Page 4, lines 56-60: "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". This is absolutely critical, and should be one of the main points of the paper, not just casually mentioned and not further developed. 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 linear no-threshold model of radiation effects at very low doses (i.e. close to background).

Page 6, Lines 36-40: "…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". This should be the central recommendation, as it 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.

Page 7, Lines 7-12: "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". This is absolutely critical. As recommended by 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)"

IRPA should recommend a suitable stopping point for ALARA (Abelquist 2019), where in general, radiation risks are so small as to be unobservable (or may not exist at all), and are almost always outweighed by nonradiological risks, costs, and other social factors. Radiation doses within the normal variations in natural background are certainly below this point.

Page 10, Lines 11-24: The paper states,

> "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".

I enthusiastically agree with these points. On this basis, the Health Physics Society requests that these comments be transmitted by IRPA to the ICRP. If, through the deliberative process, IRPA rejects or modifies these comments, we request that the rationale be explained in a transparent and publicly available record. Similarly, we encourage IRPA to request the same from the ICRP – a publicly available and transparent record of the disposition of the comments IRPA provides to the ICRP. It is imperative that the ICRP holds itself to the same standards of transparency and accountability it recommends for others involved in advising and setting public policy.

Page 10, Section 3.3: A welcome addition to this section would be a discussion of title protection. Radiation protection duties are increasingly being performed by individuals from allied fields (e.g. industrial hygiene), who may lack specific training, experience, or expertise in radiation protection. IRPA should vigorously advocate for recognition of the unique qualifications of radiation protection professionals.

Page 16, Lines 21-25: The paper states, "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". None of the cited studies demonstrate the absence of a threshold. As discussed in (Ulsh 2018), the cited study by (Lubin et al. 2017) did in fact present data consistent with a threshold of 0.03 Gy in the incidence of childhood thyroid cancer. The (Little et al. 2018) study did not formally test for thresholds, nor did they consider the hormetic dose-response suggested by the data they presented. They reported relative risk values <0 (though not statistically significantly so) for the lowest dose bins they considered for: (1) all myeloid malignant neoplasms, (2) acute myeloid leukaemia and myelodysplastic syndromes, (3) acute myeloid leukaemia, (4) chronic myeloid leukaemia, and (5) acute leukemia. Only acute lymphoblastic leukaemia and leukaemia, excluding chronic lymphocytic leukaemia showed no obvious suggestion of a hormetic response. Nonetheless, the authors did not remark on this pattern and did not report testing hormetic or linear with threshold dose-response models. (Hauptmann et al. 2020) did not report formal tests for thresholds. To be clear – I am not advocating hormetic or threshold models. Rather, I am advocating recognizing these as alternative hypotheses to be tested along with a LNT model. Further, I dispute the conclusion that these studies provide, "little evidence of a threshold", when one of the three did in fact present data consistent with a threshold, and the other two did not report testing for thresholds.

Page 16, Lines 27-35: This section states, "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 2018)". The NCRP's review has

been strongly criticized for, "…setting the LNT as the null hypothesis, and shifting the burden of proof onto LNT skeptics… arbitrary exclusion of alternative hypotheses, ignoring criticisms of the LNT, cherry-picking evidence, and making policy judgements without foundation" (Ulsh 2018). Specifically, (Ulsh 2018) disputed the argument that no other dose-response model is more pragmatic than the LNT model,

> "Alternative dose-response models (e.g. linear with threshold, hormetic, etc.) don't have to be "more pragmatic or prudent" than the LNT. Rather, they have to be tested against the appropriate no effect null hypothesis. If the evidence in favor of any tested alternatives is insufficient to reject the no-effect null, then the null stands. Furthermore, when testing the other, non-LNT alternative hypotheses, the correct null of no-effect has to be excluded in favor of one (or more) alternative hypotheses".

These criticisms were submitted to the NCRP under the auspices of the American Academy of Health Physics as 117 comments on the NCRP's draft report, and in a peer-reviewed publication following NCRP publication of its final report. The NCRP did not respond to the pre-publication comments and did not make any discernable corresponding changes to its draft report, nor has any response been forthcoming to the same criticisms presented in (Ulsh 2018). The NCRP's nonresponsiveness is not consistent with the recommendations on transparency and stakeholder involvement presented in (ICRP 2018), discussed above. Furthermore, this is just the latest example of a longstanding pattern of stakeholder criticisms of the LNT being ignored by expert advisory bodies and regulators. I again refer to comments the HPS has previously provided to IRPA regarding the application of the LNT model, and I request that these comments be conveyed by IRPA to the ICRP (Goldin 2020, Goldin 2021), especially:

- The HPS position statement, Radiation Risk in Perspective (https://hps.org/documents/radiationrisk.pdf) advises against estimating health risks to people from exposure to ionizing radiation that are near or less than natural background levels because of the large statistical uncertainties at these low levels. We state "...below levels of about 100 mSv above background from all sources combined, the observed radiation effects in people are not statistically different from zero." Also "...the LNT hypothesis cannot provide reliable projection of future cancer incidence from low-level radiation exposure." This position is based on known scientific evidence that (1) molecular-level radiation effects are non-linear, (2) radiogenic health effects have not been consistently demonstrated below 100 mSv, (3) dose-rate is a known factor that has demonstrated non-linear responses, and (4) misuse of collective dose in radiation protection planning and risk assessment decisions where "...the multiplication of small risk coefficients by large population numbers leads inevitably to unsupportable claims of cancer risk from ionizing radiation." The last factor is central to much of the regulatory problems encountered in the United States, and noted in the IRPA statement, regarding cleanup of contaminated sites.
- The HPS position statement, Uncertainty in Risk Assessment (https://hps.org/documents/riskassessment_ps008-2.pdf) states "…the expenditure of public and private funds to mitigate these risks should be commensurate with the public health benefits expected to be achieved" Examples of problem areas include (1) 100- to 1,000-fold discrepancies in permissible exposure levels among various

regulations, all based on much the same scientific risk-assessment data, (2) proposed expenditures of billions of public and private dollars to clean up radioactively contaminated federal and commercial sites without careful consideration of the proportionality of costs to the public health benefits to be achieved, and (3) extensive delays in licensing facilities for the disposal of radioactive wastes and other applications of nuclear technologies. Perhaps most notable is the acknowledgement that cancer and other health effects have not been observed consistently at low doses (< 0.1 Gy), much less at the even lower doses (< 0.01 Gy) typical of most occupational and environmental exposures. We continue to recommend that regulations intended to achieve very low levels of radiation exposure should take full account of the uncertainties in risk estimates; otherwise, they may result in enormous expenditure of limited resources with no demonstrable public health benefits. In fact, some regulatory positions may increase overall public health risk when extreme measures, such as population relocation, to avoid effective doses of 50 mSv are imposed, due to physical injuries, mental health, and somatic illness induced by the stress of relocation, as appears to have occurred at Fukushima".

I also note that there are thousands of biological studies suggesting nonlinear dose-responses that have never, to the best of my knowledge, been systematically evaluated by ICRP or other expert advisory bodies [e.g. the 1269 references listed in (Luckey 1980), 1018 references listed in (Luckey 1991), and another 1092 more contemporary peer-reviewed references in the my personal library, several of which are discussed in (Cardarelli and Ulsh 2018)]. These references span from the late 1800s to today. I encourage the ICRP to evaluate this substantial body of evidence as part of their upcoming review.

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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 issues below. The paper from Clement et al (2021) was attached to this e-mail.

a. General comments

- The paper by Clement et al (2021) presents a number of changes with the potential to keep the recommendations fit-for-purpose.

b. Specific comments, with reference to line/lines in ICRP paper.

- Guidance on balanced optimization would be helpful (section 2.5), in particular in the medical diagnostic field (ICRP Task Group 108)
- A clarification is needed regarding quantities used for tissue reactions and stochastic effects (section 4.1). The use of equivalent dose as dose limit for e.g. skin has caused confusion since the quantity is derived for stochastic effects.
- The introduction of age- and sex-specific risk estimates would be of great value (section 4.2).
- We support a revision of the DDREF (section 5.3).
- The risk coefficient (ca 5%/Sv) gives the total detriment (section 5.3). However, this is often interpreted, and communicated, as the number of cancer incidences and we believe that this could be more clearly stressed, for example by giving some examples.
- We also support the inclusion of other late effects than cancer and hereditary effects in the detriment (section 5.7).
-

c. Additional issues that should be considered by the ICRP - with rationale.

- Thorough elaboration on uncertainties involved in estimating the total detriment, based on nominal incidence risk, weighted for lethality and life impairment is needed, in particular quantification of uncertainties regarding the nominal [organ] risk coefficients based on cancer incidence data.
- Since most estimations of radiation dose, especially internal radiation dose, are quite uncertain, quantification of uncertainties in estimation of radiation dose needs to be more clearly addressed in the new recommendations.
- 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.

d. Thoughts on direction for improvement of the system.

- None

e. Other

- None

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Mats Isaksson & Håkan Pettersson

Thoughts on the ICRP paper 'Keeping the ICRP Recommendations Fit for Purpose'

General Comments

I welcome very much the process that ICRP starts in revising its general recommendations – the involvement of all relevant stakeholders from the outset will in the end lead to widely accepted and up-to-date general recommendations on RP.

The paper itself gives a comprehensive summary of the current general recommendations and the topics that are most likely to be discussed in the process leading to the new recommendations.

With the authors I agree that increased consistency and – maybe above all – clarity of the RP system should be high priorities. The paper gives clear hints in what respect the system might become more transparent (e.g. by abandoning the equivalent dose), but also contains proposals that will lead to more complexity (e.g. when incorporating RP for non-human biota). It will be a challenge to keep the recommendations consistent and clear!

Specific Comments

p.4, line 54-60. The concept of detriment at least takes into account some aspects of the WHOs definition (see e.g. first paragraph of 5.7)

p.5, line 47-51. With its publication 138 ICRP has set the real (ethical) basis for all fundamental principles of RP (and not only for justification). In my opinion, the new recommendations should clearly indicate /mention / describe this ethical basis as a starting point for the System. As a consequence, a question which should also be asked is: 'is there any reason to review this ethical basis?' prior to changing the (rest of the) general recommendations? In my opinion, there might be reasons (see below).

p.7, line 51. I welcome the suggestion to study the possibility of combining dose reference levels and dose constraints into one 'optimization reference level' that distinguishes 'acceptable' from 'tolerable' exposures from a source. Introduction of such a concept would in my opinion clearly improve the clarity of the system.

p.8 line 45-47. The suggestion to introduce a new category of exposure for non-human biota might be unavoidable, but will complicate the system considerably. This complication should be justified, taking into account the (reviewed?) ethical foundation of the RP System. In first reaction, I would object against a further extension of the categories of exposure with emergency workers – we should try to deal with this as occupational workers in emergency situations (as it is done now). Introduction of this new category also raises the question why there is no category for members of the public in emergency situations. In my opinion, introduction of emergency workers as an exposure category leads to a possible inconsistency in the System.

p.11 line 42 and further (and p.18, line 7-14). The proposal to abandon the equivalent organ dose (in Sv) is welcomed. However, the suggestion to replace it by a radiation weighted absorbed dose (in Gy) leaves us again with two fundamentally different quantities with the same unit. My simple question would be: why do we not introduce a new unit for the radiation weighted absorbed dose for tissue reactions? It makes the system so much more transparent.

p.12 line 43-45: The large uncertainties of risk estimates at low doses make me feel a little uncomfortable with very detailed risk assessments as they are mentioned indicated in this paragraph. When these calculations are used for a better foundation of general risk numbers, that is fine of course, but for communication / explanation of risk of ionizing radiation to members of the public, the system should be as simple as possible and one risk number might be adequate.

p.13, line 15-16. Would ICRP also think about individual patient quantities for detriment at doses (far) below 1 mSv/1mGy?

p.13 line 24-32. I fully support this intention.

p.14, line 49 and further. From the discussions I understood that ICRP so far has decided not to distinguish between e.g. severe and other tissue reactions, possibly based on the ethical basis of the System. I welcome a renewed discussion on this topic and think that at the start of it, the ethical basis should be reviewed.

p.15, line 46-50. I fully agree on this preliminary conclusion – this aspect of the current System cannot be explained.

Additional Issues

Chapter 3 of the paper is devoted to 'overarching considerations', focusing on ethical aspects, communication & stakeholder involvement and education & training. Whereas the ethical aspects are actually preconditions for the system of radiation protection, both other topics are very relevant to operational radiation protection. Recent years have shown an increasing interest in two other aspects of operational RP: the discussion on what is reasonable in the implementation of ALARA on one hand, and the ongoing concern for a sustainable work force on the other hand. The first topic especially, is an essential aspect of the implementation of the System of RP, while the second is a precondition for the System to be implemented in practice. The authors in their paper only mention that ICRP welcomes additional initiatives to help provide practical advice for this implementation. Personally, I would suggest ICRP to include recommendations on both topics (for reasonableness, this implies that the work of TG 114 should be included). Maybe IRPA could discuss with ICRP whether a new TG should be established, that addresses the sustainability of the work force – including e.g. the results of studies on the preconditions for attracting new/young people to the field of radiation protection.

Thoughts on improvement and others

The previous comments reflect my first thoughts on the review of the current system of RP based on the ICRP paper. When I think of the future '4th General Recommendation of the ICRP', I see a publication that starts with a short description of the ethical basis of radiation protection, continues with an extensive description of the recommended System and ends with recommendations concerning the implementation of the System – fit for purpose for the next two decades.

Hielke Freerk Boersma, September 27, 2021

SOCIEDAD ESPAÑOLA DE PROTECCIÓN RADIOLÓGICA

Afiliada a la
International Radiation Protection Association (I.R.P.A.)

SEPR (Spanish Radiation Protection Association) comments to the ICRP paper:
Keeping the ICRP Recommendations Fit for Purpose

General comments

As a general initial reflection document to undertake the revision of the ICRP-103 recommendations, it is good, complete and it does not leave any important point to consider. However, several different aspects are discussed and with different impact on the potential future changes to the recommendations and some questions arises whether at the end of this period of reflection all those aspects considered to be incorporated in the changes will have the same or similar consensus or will be available with sufficient scientific, epidemiological or calculation development basis for inclusion in the future recommendations. For these reasons, it is submitted for consideration that perhaps it could be of interest to list all the changes that are suggested in the document and classify them in order of relevance or importance from 1 to 10 and initially to work with all those that have a value greater than 3 and after finished the period of work with the most relevant, if there is still time for more, then deal with the rest of the aspects of value equal to or less than 3.

Specific comments

1. Background and purpose

The SEPR very favorably supports that the objectives of the review are those indicated in this section: 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 harmonization. But also, it is indicated that the System that must continue to handle substantially different, complex, and unforeseen situations; while the SEPR agrees with this statement, also it believes that may be one of the problems of the current system is its complication in some aspects.

2.2 Protection of the people

The SEPR strongly supports working to differentiate these aspects: The distinction between stochastic endpoints and tissue reactions (previously termed 'deterministic effects') should be reviewed.

As well as also on: 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.

Although the SEPR agrees with the content of this paragraph: "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", but it suggests, however, that it should be proceeded with caution, not so much in its evolution and scientific development, which will always be welcome in order to better characterize radiological risks, but in its application in the recommendations, especially in what may affect dosimetry. The effect of any external dose exposure should be independent of the age and sex of the irradiated person. The LNT hypothesis should not have different slopes depending on the sex or the age of irradiated person.

Even with some caution, especially in the quantification of the effect, the SEPR considers very timely and appropriate that these other aspects be included in the quantification of the detriment and health effects: It is also worth considering how the World Health Organization'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.

For the discussions on this subject, it may help thse two UNSCEAR publications; the annex A "*Evaluation of selected health effects and inference of risk due to radiation exposure*" of the 2019 Report to the General

Assembly and the forthcoming annex C of the 2020 Report to the General Assembly "*Biological mechanisms relevant for the inference of cancer risks from low-dose and low-dose-rate radiation*"

2.3 Protection of the environment and non-human biota

The SEPR supports working on and clarifying these aspects mentioned in this paragraph: 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 domesticized 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.

However, its inclusion in the new recommendations should not mean a complication in its practical application. The assessment or quantification of the environmental protection must be elementary, straightforward or almost trivial, and not deviate to much from what is indicated here: by establishing the characteristics of the object of protection, 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.

2.4 Fundamental principle of justification

The SEPR strongly supports that the principle of justification will also include "the quality of life in the justification of many decisions"

2.5 Fundamental principle of optimization

The SEPR supports this: "ICRP *Publication 146* (ICRP, 2020b) identifies the environment as one of the factors to be taken into account. Although ICRP cannot judge specific circumstances, additional advice on factors to be considered and possible processes to be employed may be helpful". Any practical recommendation of simple application and understanding that helps to consider the environment in the optimization principle will be welcome.

The SEPR considers that this aspect should be perfectly clear and unambiguous in the new recommendations: optimization 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. There is an obvious risk for some regulators to confuse optimization with minimization through the introduction of BAT's "Best Achievable Technique" concept in the optimization process.

As long as the optimization process is not so complicated and difficult to apply that its practical implementation will be impossible, the SEPR supports the inclusion of other aspects such as: societal, environmental, economic, and general wellbeing.

The SEPR strongly supports working on and exploring these aspects: Several 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.

Regarding the holistic approach to optimization, the SEPR is a strong supporter of it and in particular in the example included in this paragraph, especially in relation to the protection of the public: 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. There is enough information and experience to consider, for example, that the public exposure from radioactivity releases in the liquid and gaseous effluents of nuclear power plants can be considered optimized without any further assessment or consideration if such exposure is less than a few μSv/yr. Work should be done to reach a general consensus on what this value of μSv/yr could be for the most exposed and/or most at-risk person in the exposed population and to reflect it in the new recommendations.

In the same way, work should be done to address optimization in this other important aspect reflected in the same paragraph: 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.

Yes also to work or give practical recommendations for optimization in the design phases when circumstances such as these reflected here may arise: 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.

2.6 Fundamental principle of application of dose limits

The SEPR totally agrees with the aspects indicated here, although again it suggests that I should be proceeded prudently so that the extension of the dose limits to all exposure circumstances will serve to clarify the System and not to make it more confusing: 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.

However, the SEPR considers that it should be very cautious with the changes to be applied in the dose limit: There is a need to revisit how dose criteria might be applied in different circumstances on an annual, 5-year cumulative, lifetime, etc., basis. During the last years, every time new recommendations appeared, there was a change, not always entirely and well justified or understood, in the dose criteria applicable to the limits. The current dose limit for exposed workers of 100 mSv in 5 years has been widely accepted and applied in all cases of occupational exposure and has shown enough flexibility in its application so that any change made to it should be very well justified and its application should bring more benefits than disadvantages. Nevertheless, it should be clarified what is the dose limit to apply in occupational exposure. Currently there are 3 very similar approaches among them: ICRP-103 of 100 mSv in 5 years; International Basic safety Standards of the IAEA of 20 mSv/year averaged over 5 years and European Directive 2013/59 EURATOM that establishes 20 mSv/year, but in special circumstances and for certain exposure situations specified in national legislation, a higher effective dose of up to 50 mSv may be authorized in a single year, provided that the average annual dose over any five consecutive years, including the year for which the limit has been exceeded, does not exceed 20 mSv.

The SEPR also supports this and that work should be done to develop these aspects: 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

The paragraph shows this: 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; although it does not detail which aspects are concerned or it refers to in particular.

It is specified that: The categories of exposure are generally understood, although clearer guidance may be needed in unusual circumstances such as emergencies; an that: 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. And it puts as an example that: The US National Council on Radiation Protection and Measurements (NCRP), for example, introduced new categories for emergency workers and non-human biota (NCRP, 2018a).

However, until further progress is made on the specific aspects of the review of the categories and situations of exposure, the SEPR will not be able to express itself as to their importance and relevance,

although it does believe that all these aspects contemplated in the paragraph should be taken into consideration in the review: 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.

Some ICRP publications are cited and it is said of them that: 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. which may help to clarify this paragraph.

3.1 Ethical aspects of radiological protection

The SEPR strongly supports what is indicated in this paragraph: The review of the System should identify areas where explicit incorporation of the ethical basis alongside the scientific basis would be beneficial.

3.2. Communications and stakeholder involvement

The SEPR agrees with the "co-expertise" process: 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 optimization 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.

However, the SEPR believes that this process is still immature and it will be necessary to work on it intensively so that the conditions indicated at the end of this paragraph could be achieved: 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 optimization in relation to contentious facilities and activities, use of radiation in medical applications, management of accidents, and remediation.

3.3. Education and training

The SEPR fully agrees with the content of this paragraph, which it is considered essential to ensure that the System is known to the majority of those interested in the process. In particular it supports that: Education and training in radiological protection should be an essential part of undergraduate and other studies in relevant domains; and that: 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.

4.1. Dose quantities

The proposed changes suggested here will imply, if finally they are taken into consideration, a very important review and update of the current recommendations and while the SEPR agrees with them as long as there is a solid scientific and epidemiological basis to support them, also proposes that it should be prudent in their adoption. There is no objection to the fact that the equivalent dose will not be associated with the control of deterministic effects and that it involves an intermediate process in the calculation of the effective dose together with the absorbed dose to be used for the control of tissue reactions (deterministic effects): 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. In any case, the SEPR suggests that the changes introduced here should not represent a drastic revolution compared with previous recommendations, since this could be interpreted as a lack of knowledge or security of the experts.

However, the SEPR proposes that caution should be taken as regards as: 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, so that its introduction should not generate more confusion than benefit, given the fact that tissue reactions for which there are thresholds of appearance are shared or combined with stochastic effects for which there are no thresholds.

However, after knowing the joint ICRU/ICRP publication of ICRU-95, the SEPR strongly supports this other proposal of this paragraph: 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'.

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

Any advance in the scientific knowledge that have an impact on the definition of the radiation protection quantities will be welcome. However, the SEPR believes that progress should be made in these aspects with caution because if many of these advances are later masked or blurred by the necessary simplifications of the System for their practical application, their introduction in the new recommendations may or could lose relevance and importance and go unnoticed: 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. Individualizing the risk and consequently the detriment should be an objective of the new recommendations, especially for medical exposures.

On the other hand, the SEPR agrees with the content of this paragraph: 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., but as long as the effective dose remains an average for both sexes and all age groups, its use to determine individual risks will remain in question.

4.3. Use of effective dose in medicine

The SEPR supports the statement of this paragraph to try to achieve a protection quantity to be used in medicine to try to improve and if possible, to individualize the risk assessment of medical exposures in patients: 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 recognizing that more precise estimates of radiation risk are possible for an individual patient with more specific information.

4.4. Effective dose coefficients

The SEPR looks forward that what is indicated in this paragraph will be achieved: 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. The continuous changes in the metabolic models, making them more and more complicated and convoluted, have helped little to understand the internal exposure by inhalation and ingestion, also giving the situation that in many cases the effective dose coefficient hardly changed from the simple to the complicated model (for example, the case of H-3). The solution of the differential equations of the new biokinetic models, no longer easy to calculate, now requires complex calculation algorithms and this should not be the case, as it makes them almost inaccessible for most of users of internal dosimetry.

Instead, the SEPR strongly supports the initiative indicated in this paragraph: 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

The SEPR does not object to this paragraph, but insists that its application must be very simple and not complex at all, and therefore it hopes that it will not go beyond what is indicated here: To develop a workable dosimetric approach, simplifications and generalizations 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 (Reference Animal and Plant) 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.

5.1. Classification of radiation-induced effects

There are no comments on the content of this paragraph, indeed, what is indicated here is considered very appropriate: 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 optimize protection against effects at low doses and low dose rates, principally cancer (using effective dose). However, the new classification of effects should be used to clarify and better understand the System and not to be a source of confusion or misunderstanding.

5.2. Tissue reactions

No comments on this paragraph, but the SEPR strongly supports the distinction between severe tissue reactions with thresholds of occurrence and less severe tissue reactions at lower doses with recovery capacity: 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). 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.

It would also be of great interest if finally it is clarified whether or not there is a dose threshold for the formation of cataracts and diseases of the circulatory system. Finally, the SEPR strongly supports that there should be no differences in the dose limit for the public and exposed workers for exposure of the lens of the eyes and the skin: 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

The SEPR agrees and supports the reflection of this paragraph. In particular, it supports and applauds that the new recommendations state without any doubt that: This is needed to ensure that LNT is the most appropriate evidence-based assumption to use for radiological protection purposes.

On the other hand, even recognizing what is indicated at the end of the paragraph: 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 recognized 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.; this should never question or challenge the validity of the LNT hypothesis for low doses and dose rates.

5.4. Individual response of people

No relevant comments to this paragraph. The SEPR also believes that there will be not enough evidence in the future to justify a change in the way to protect workers and the public: 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.

And also, as it has been indicated previously, the SEPR supports the achievement of what is also indicated here at the end of this paragraph: However, there are already efforts to individualize radiological protection of patients which should be considered in the review of the System, taking into account scientific, ethical, and practical aspects.

5.5. Heritable effects

The SEPR believes that if there is enough scientific evidence to justify it, what is proposed in this paragraph should be carried out: 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 ionizing radiation exposure in offspring and next generations is being considered to review the scientific literature to assess potential implications on the System.

However, the SEPR believes that any new scientific evidence on the hereditary effects from ionizing radiation exposure should be used to improve risk estimates, but never to disregard them, and therefore the SEPR supports that this actual ICRP interpretation on heritable effects should be maintained: 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.

5.6. Radiation weighting for different effects

The SEPR supports that progress in the knowledge of this important aspect indicated in this paragraph should be continued: 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; although this could lead at the end, this other fact that could generate some kind of confusion to the users of the System: 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.

The SEPR also supports this consideration as long as it serves to clarify the application of the System and will not generate any type of confusion or misinterpretation: 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.

5.7. Radiation detriment

Once again, the SEPR agrees with the content of this paragraph, but also suggests that it should be proceeded with caution: 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. Although the SEPR believes that it would be a disservice to the System if a different effective dose calculation for men and women and for different age groups were derived from this issue.

The SEPR also supports the progress in the knowledge of new aspects other than the detriment to the expression of health damage generated by exposure to ionizing radiation will be welcome. However, it believes that any new alternative to the current expression of detriment should be very well justified: 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

No objection to further progress in the knowledge and studies of these aspects of environmental protection as indicated at the end of this paragraph: Furthermore, 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 SEPR will do their best and will support IRPA in whatever help will be necessary in the reviewing of the actual radiation protection System to achieve the objective set forth in this paragraph: 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'.

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

Review of the article "Keeping the ICRP Recommendations Fit for Purpose", C. Clement *et al* 2021 J. Radiol. Prot.

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

Date: 24 September 2021
Authors, on behalf of SFRP. Sylvain Andresz, Nuclear Protection Evaluation Centre
Anne Cordelle, Radiation Protection and Nuclear Safety Institute

Approach. A web-questionnaire[1] was developed in collaboration with the Chair and Director of SFRP, then transmitted by mail to the Administrative Board and the Chair of the Section for further distribution. This offered the opportunity to several Chairs and Members to send their analysis and comments. In addition, the topic was discussed at the occasion of two Sections meetings. Finally, this document is a collection of the views from SFRP Members and does not represent the view from the SFRP society as a whole.

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1. General and specific comments

- **Background**. (**§1, p.2**). Welcoming the call for "*open and transparent engagement*" from organizations/individuals in the process of the revision of the recommendations and hope to this work in practice.
- **Environment and non-human biota (§2.3).** The system for the protection of the environment is based on deterministic/measurable effects on the RAPs. This system had not been put in practice, nor used to decide (or not) action to protect the environment from ionizing radiation only. Extending the current system of protection for the humans to non-humans seems complex**.**
- Under that extent, the "patrimonial" approach of ICRP to bring cultural value, goods etc. into the protection of the environment is welcomed and in line with international standards (ex. UNESCO). The next approach for the protection of the environment should be practical.
- In the current Recommendations, the principle of **Justification (§2.4)** applies differently with regard to the exposure situation and this has probably not been understood well.
- This principle could be indeed reexamined, and clarity and practicality given to the concept of 'net benefit' especially if other situations of exposure (ex. veterinary animal, new imaging techniques, as proposed in the article) are to be considered.
- In particular, the justification of medical practices is a focal point: it is difficult to limit their usages, despite being a key mean of action. Guidelines and recommendation are useful but

[1] Questionnaire (in French) : La CIPR a publié des propositions d'évolution du système de protection radiologique. La SFRP est sollicitée à ce sujet. (webquest.fr)

work well with already informed professionals. We should find a way to circulate the information to the doctors, the public etc.

- **Optimization (§2.5)** is the cornerstone of the ICRP system and the most well understood by the professionals. Practical recommendation for a holistic approach (beyond the traditional cost-benefit analysis) in comparing the radiological risk with the industrial/other risks will be very welcome.
- **Fundamental principle of application of dose limits (§ 2.6, p.7):** the distinction between the concepts of dose constraints and reference level was not always clear, and has not been put in practice under the ICRP theory. So why not combining these two concepts, as proposed in the document? (or any other practical approach).
- In addition the question to set a dose criteria based on lifetime exposure should be raised.
- **Categories of exposure and exposure situations (§2.7, p.8):** again, the categories of exposure and the types of exposure situation are not always fully understood in practice, generating a lot of debates in the "grey areas" such as NORM, legacy site and cosmic radiation.
- It might be possible indeed to introduce two additional categories of exposure, for emergency workers and non-human biota, keeping in mind the need to clarify the three current exposure situations (if such distinction continues to be recommended).
- **Ethical aspects of radiological protection (§3.1, p.9):** ICRP has engaged a major work in identifying the key ethical values that were historically at the hearth of the System. The idea that the link between the future Recommendations and the ethical values be more apparent is welcomed.
- The challenges mentioned regarding the communication and understanding of radiological risks is fully supported. However, concerning the involvement and empowerment of stakeholders, it is important to think carefully about how to involve stakeholders (public distrust, scientific knowledge etc.). There is a balance between effective communication and over-communication.
- **Education and training (§3.3, p.11):** Further work in education and training may be beneficial for some practitioners– we could focus on fields such as industrial radiography (for which we have a specific training in France including a written and oral exam), with strong radiological issues.
- **Dose quantities (§4.1, p.11):** The fact that the equivalent dose would no longer be used to set limits in relation to tissue reactions is seen a good news, but it remains as an intermediate step in the calculation of effective dose. More globally, the changes presented in this paragraph could be useful, by simplifying the system (noting that introducing a new unit for the equivalent dose would have been possible too).
- Changes in operational quantities should be expected from the next Recommendations.
- **Effective dose, including age-, sex- and individual- specific doses (§4.2, p.12):** it would be interesting and useful to specify detriment and relative detriment separately from males and females of different age groups. Effective dose could be then calculated separately for each group, which would be more correct scientifically. But getting several values for the effective dose could lead to many practical and ethical difficulties for the management of radiation risks – ex. separate dose limits for each group. On the whole, revisions of the methodology of calculation of effective dose could certainly improve its suitability for the assessment of risk, but with care given to its application in practice.

- Equivalent consideration and explanation might be needed when having different detriments male vs. female vs. ages for use in medicine **(§ 4.3**)
- It is noted that the Effective dose coefficients (**§4.4**) will be revised, which seems compliant with the change in scientific knowledge (bone, skin…). It is also noted that new sets will be provided for various specific groups: fetus, radiopharmaceuticals, emergency exposure etc.**,** raising again practical and ethical implications.
- The different dose limits between workers and public is indeed sometimes difficult to explain. However, the idea of "*having single limit ex. 500 mGy skin or 20 mGy eyes applying to all exposure of workers and the public*" might be difficult to explain too from a radiological protection and optimization perspectives.
- **At low doses and dose rate (§ 5.3, p.15):** the value of DDREF (=2) should be reviewed, confirmed or agued, since there is no consensus at the international level on its actual value – furthermore, the use of a single constant value could be an approach too simplified (among other ideas, why not distinguish dose effectiveness factor and dose rate effectiveness factor as proposed in the document?).
- **Individual sensibilities (§5.4, p.16)**. There are compelling evidence about individual difference in response following radiation coming from genetic defects. Up to 10% of the population might be highly sensitive, with practical implication (limitation of scanner, adaptation of breast screening). Studies are on-going in the areas of very-low dose from imaging practices. The new system should take this factor into account.
- **Radiation weighting for different effects (§ 5.6, p.17):** likewise, the current radiation weighting factors should be reviewed in light of the scientific evidences.
- **Radiation detriment (§ 5.7, p. 18):** to investigate the use of DALY etc. 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, lead to a complete change in the radiological detriment as we known it.
- The practical implications of using a radiation detriment for fetus (**p.18, L50**) are not negligible: fetus is not a legal entity (in several national legislation), it opens the box for procedures and compensation on difficult-to-justify basis considering the uncertainties. It might also generate needless fear and even deter people to be exposed under traditional medical practice.

3. Additional issues that should be considered by the ICRP - with rationale.

- On the topic of justification: it might be worthwhile to restrict the usage of radiation for medical purposes to expert only. There is a tendency in some countries to open the usage of radiation for medical usage (imaging) to non-experts, when some argues that it should be bound to an evaluation of the training.
- This comment could be reiterated to the topic of optimization.
- What about recommendations for the "holistic management of wastes"? more guidance could be useful for the management of the amount of waste that will occur with the further dismantling of installations, ex. radiation + asbestos, radiation + heavy metal (lead), radiation + fire (phosphorus) to name just three.

- More consideration of the combined effects of radiological and chemical exposure should be provided, especially at low doses.
- Overall, how to compare adequately chemical and radiation exposures? For example, will it be possible to have values set for the occurrence of stochastic effect comparable with the no-threshold effect from chemicals substances? Experiences on the development of risks comparison metrics can be considered.
- More references to epidemiological studies should be given (notably needed for the risk coefficient
- Will the rationale of what is “tolerable” and what is “reasonable” change with the expected evolutions in the system?

4. Thoughts on direction for improvement of the system.

- The terminology in ICRP Publication 103 has evolved in the next Publications, leading to uncertainties in what is the “right” definition. The ICRPedia has provided some clarity, nonetheless, the terminology in the next Recommendation should not be submitted to such changes.
- The feedbacks from the Fukushima accident is not apparent in this article and can be fruitful to be include in the next Recommendations: emergency exposure management, non-radiological sanitary effects, etc.
- Similarly, the lessons from the Covid-19 crisis could also be considered: risk communication, distrust between public and scientist/authorities, holistic approach, etc.

5. Other

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THE SOCIETY FOR RADIOLOGICAL PROTECTION

To Sigurdur Magnusson,
Chair, IRPA TG on the Future of Radiation Protection

SRP Response to IRPA regarding the ICRP Review of the System of Protection

Dear Sig,

Please find attached the SRP response to the IRPA Task Group on the future of radiation protection – preparation for the ICRP October Workshop.

The two nominated SRP members of the TG, John Harrison and Roger Coates, have worked with a small group of SRP members, essentially comprising the current and several former Presidents, to prepare this initial response to IRPA. An opportunity was given to the wider SRP membership to add views, but due to timescale constraints this input was limited.

SRP has now convened a specific Task Group to address 'the future of radiation protection', which will be the focus for further inputs on this topic as the discussions continue over the coming period.

We thank IRPA for taking the lead to ensure that the views of the radiation protection community are properly reflected in this important ongoing debate on the future of RP.

Jim Thurston, SRP President
John Harrison) SRP nominated members of the IRPA TG
Roger Coates)

24 September 2021

SRP Response to IRPA regarding the ICRP Review of the System of Protection

General

1. SRP welcomes the ICRP initiative to open dialogue on future changes to the protection system and requirements for the next general recommendations of ICRP and is generally supportive of the approaches outlined by Clement *et al* (2021).

2. SRP fully supported the IRPA Consultation on the System of Protection as published in 2018, and we expect this to form a key component of IRPA's input to ICRP.

3. SRP also fully supported the IRPA proposals on Reasonableness in Optimisation, which resulted from consultations during 2020 and early 2021. Again we expect this to form a key component of the IRPA response to ICRP. We also are disappointed that this document has not yet been formally published by IRPA, despite it being several months since we understood that the draft had been agreed.

4. SRP generally supports the paper by R Coates on 'The need to review low dose decision making in radiation protection', which has been submitted to the ICRP Workshop (as attached).

5. SRP acknowledges the importance of communicating with the public on radiation and risk, which is emphasised in the ICRP discussion paper. We fully support the recent IRPA guidance on this topic. In particular we note the importance of active engagement with all stakeholders when decisions are necessary regarding the appropriate level of protection. This may mean taking a wide perspective on who is a 'stakeholder', noting that failure to engage can promote a form of social stress that can otherwise be minimised or avoided.

6. SRP recognises that an important driver for new recommendations will be changes to the underlying science and its application in the system of protection. 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).

7. 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. The cooperation between ICRP and ICRU is noted and welcomed.

8. It is further noted that ICRP intends to consider changes to the formulation of effective dose to increase the clarity of relationships between dose and inferred risks at low doses for different groups and individuals in a population. Proposals will be followed with interest, recognising that such changes, as well as potential overall changes in low dose risk / detriment, have implications for the setting of constraints and reference levels.

9. SRP considers that the next set of ICRP recommendations should include a re-evaluation of the tolerability of dose / inferred risks in different exposure situations, with quantitative

contextualisation of radiation risks with other risks, addressing the ethical basis for the protection of groups and individuals.

10. SRP would welcome further explanation of ICRP intentions regarding protection of the environment and how and when this should be considered in practice.

Specific Issues (references are to the ICRP Clement et al discussion document - Page/Line)

11. We fully support that the focus of the ICRP review should be on increasing clarity and consistency (1/51)

12. Optimisation

We support the comments in ICRP section 2.5 on the fundamental principle of optimisation. This links generally to item 3 above:

- provide reasonable caution whilst avoiding undue conservatism (7/8)

- provide further guidance on decision making at low doses, eg with reference to normal background variations (7/11). This also links to item 2 above (the IRPA Consultation paper – see section on 'Context of natural background'), and also to item 4 above, where Coates makes the following recommendations:

a) Give greater emphasis to our 'universal radiation world' of natural background exposure, both in general decision-making and in our interactions with the public.
b) Review the approach to tolerability of risk which underpins the system of protection, taking account of broader inputs to this concept, including the scale and variability of normal background radiation exposure and the way this is considered by the public.

We also wish to stress the importance of ensuring an holistic approach to the optimisation process, whereby risks from all the different types of hazard potentially involved should be taken into account in a balanced way. Whilst the text in the ICRP discussion paper (section 2.5) refers to an holistic approach, the focus is still very radiation-centric. It would be helpful for ICRP to give further consideration to the importance of, and methods for, balancing risks from different types of hazard.

We note the somewhat different emphasis in the approach to optimisation in different exposure situations. In particular in medical exposure it is helpful to emphasize that exposure must be commensurate with the medical purpose (6/43). This clarifies that optimisation is not equal to the minimisation of exposure. Outside of medical exposure it would be helpful to have similar clear statements to support the fundamental concept that optimisation does not mean minimisation. This could help reinforce this key point to regulatory authorities: there are concerns that there is not a level playing field in regard to regulatory approaches to the application of optimisation across various sectors.

13. We support relevant comments in ICRP section 2.6 on Limits.
- it needs a broader principle to reflect all exposure situations (7/49)
- review the distinction between limits, constraints and reference levels (8/4).

The need to review our approach in this area was reflected in the 2018 IRPA consultation (item 2 above). The comments in the section on 'Dose limitation and dose limits' of the IRPA paper are very relevant and should be reflected in the present IRPA response to ICRP.

14. We note the discussion in the ICRP paper (sections 3.1 and 3.2) on ethics and communication, especially the comments on the potential to use normal natural background as a useful context for risk communication (9/58). This topic is addressed in items 2, 3, 4 and 5 above – SRP strongly supports the use of the context of natural background and its variability (including that from individual decision making) as part of ways of improving the communication of radiation risk.

15. The ICRP discussion paper seems somewhat light on emergency exposure, which is a topic receiving much attention from national authorities and regulatory bodies. Issues where guidance would be helpful include:

- clear statements on the optimisation of emergency exposures, including for workers
- the importance of communication during an emergency
- the need to take account of all hazards when setting action levels or reference levels
- the setting of standards for the remediation of land.

Whilst many of these issues have been addressed in detailed reports it is important to bring them into the mainstream recommendations.

Attachment: The need to review low-dose decision-making in radiation protection – Roger Coates (to be presented at the ICRP Workshop, October 2021)