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Nobuhiko Ban, Ph.D. Chair, Task Group 102 (Committee 1) International Commission on Radiological Protection 280 Slater Street P.O. Box 1046, Station B Ottawa, Ontario K1P 5S9 Canada

VIA website: www.icrp.org

RE: Request for Comment: Draft Publication Entitled, "Radiation Detriment Calculation Methodology"

Dear Dr. Ban:

The American Association of Physicists in Medicine (AAPM)¹, is pleased to submit comments to the International Commission on Radiological Protection (ICRP) regarding its draft publication entitled, "Radiation Detriment Calculation Methodology."

¹ The AAPM is the premier organization in medical physics, both in the U.S. and abroad. Medical physics is a scientific and professional discipline that uses physics principles to address a wide range of biological and medical needs. The mission of the AAPM is to advance medicine through excellence in the science, education and professional practice of medical physics. Currently, the AAPM represents over 9,000 medical physicists.

Medical physicists contribute to the effectiveness of medical imaging by ensuring the safe and effective use of radiant energy (e.g., optical, ionizing, ultrasonic, or radiofrequency) to obtain detailed information about the form and function of the human body. Medical physicists continue to play a leading role in the development of novel imaging technologies, as well as in guiding the optimization of existing imaging modalities. In addition, medical physicists contribute to development of new therapeutic technologies in radiation oncology, as well as in other disciplines, such as in thermal ablation or high intensity focused ultrasound. Clinically, medical physicists work side by side with radiation oncologists to design treatment plans and monitor equipment and procedures to ensure that cancer patients receive the prescribed dose of radiation at the correct location.

The report recommends improvements for estimating key parameters for the calculation of radiation detriment. Radiation detriment is used to quantify the harmful stochastic effects of low-level radiation exposure to people. This report provides a historical review of the detriment calculation methodology adopted by the ICRP in prior publications. It addresses "data sources, risk models, computational methods and rationale for the choice of parameter values," and it delineates parameters that influence the radiation detriment calculation.

The AAPM believes this publication is an important ICRP initiative that has been carefully developed and fills a need in the radiation protection community. Several members of our organization with relevant expertise have reviewed the draft publication in detail and offer their recommendations to the committee.

Comments

In general, the report is clear, thorough, and well written. The report, which is particularly relevant for radiation workers with risk of radiation exposure, is a valuable contribution to occupational radiation safety.

We have some concerns, however, about the handling of the lethality fraction (Section 4). The lethality fraction is identified as having a "large impact," based on the consideration of all cancers being fatal. This is a dramatic assumption that does not realistically span the range of this parameter's value (i.e., it is unrealistic to imagine all thyroid, breast, etc. cancers to be fatal). While the authors acknowledge the limitations of this sensitivity analysis, medical professionals could provide a reasonable range for this estimate to better capture the true sensitivity of this model to this parameter. Given that realistic estimates are achievable, we are disappointed that this parameter did not employ a more accurate metric.

We have attached for your consideration an Addendum with some additional comments. In the Addendum, we identify areas requiring improvement or clarification.

In summary, the AAPM hopes that the ICRP will address AAPM's concerns with the draft publication. Moreover, we would be happy to provide additional expertise or resources to you to ensure that the final publication can accomplish its objectives. Thank you again for the opportunity to comment on this important document. If you have any questions or require additional information, please contact Richard J. Martin, JD, AAPM's Government Relations Program Manager, at <u>richard@aapm.org</u>.

Sincerely,

Md. Sai Hu:

M. Saiful Huq, PhD, FAAPM, FInstP President, AAPM

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Addendum

P3 L128

Should state "...having the greatest influence on the radiation detriment calculation..."

P4 L135

The purpose of this report is not explicitly stated. Please do so. It appears to be to review the current methodology, improve/correct the statements from ICRP 103, perform a selected sensitivity analyses on some parameters, and to note possible future improvements.

P4 L137

We suggest acknowledging up front that it is not considered a calculation for specific individual risk and should not be utilized as such.

P5 L185

We recommend listing what else they are based on besides expert judgement.

P5 L189

How are each of the levels of impact determined (for ex., was a quantitative range utilized?). Please specify.

P5 L198

Clarify this statement: Science-based vs. integration for radiation protection purposes (employment of expert judgement?).

P5 L201

This is confusing. Are not wT determined separately? This seems to imply that the radiation detriment calculations have some impact on the final chosen wT values. Did they per ICRP 103?

P5 L203

It is not clear whether this concept is evolving. The methodology is clear in ICRP-103. It perhaps needs to be updated based on the latest information as discussed in paragraph (h), but the concept does not appear to be evolving in a different or expanded way--Just updated with the latest science.

P5 L209

This is a very clunky sentence. We recommend that it be rewritten for clarity. We suggest referring to ICRP Publication 118 directly for best wording.

P6 L238

Is the 'methodology' called radiation detriment? Or the conceptual calculation. This is unclear and should be clarified.

P7 L272

Identified individuals should be clarified. This seems contrary to ICRP publication 103 express statement not to use effective dose for individual risk estimates. Perhaps 'identified groups of individuals or cohorts or specific populations'?

P7 L277

We recommend noting here that detriment is expressly utilized for the purposes of radiation protection and not risk assessment.

P8 LL308-9

In the review copy PDF, all of the "x" for times ten to the, were not formatted correctly

P8 L327

It is important to state that this "summed to" rather than "was about." The organ risks are summed to get to 125 E-4 per Sv.

P10 L372

Instead of "on this basis" state "on this assumed basis."

P11 L399

Publication 59 (ICRP, 1991). 1991 is listed at sagepub. "1992" is being used here and throughout the manuscript: Do the authors have a different source of information. Pub 60, which presumably followed 59, is dated 1991.

P11 L403 Should Thorotrast be capitalized?

P12 L428 Instead of "develops into" state "results in."

P13 L430

"It is not directly related to radiation exposure." This is very unclear as the estimate of fatal cancers is directly related to the exposure.

P13 L445

The improved and corrected version of ICRP 103 method should be an important purpose of this report and stated as so up front.

P14 LL459-60

"First part" and "Second part" are not capitalized above, a few sentences earlier. Should they be capitalized here?

P14 L460

Sv is used for the calculation of ... "should end with," reflecting the radiation protection purpose of the concept of detriment." Note that this is stated well in lines 891-892. We suggest using that language here as well.

P15 L497

3.1.1.3. The explanation of the survival functions is unclear. It appears to be the general percent of population alive as a function of age, but the text describes it as being derived from mortality rates associated with cancer. Please clarify.

P16 L505

3.1.1.4 (or summary). An explanation for using a maximum age of 90 years would help. It appears that risk is being accumulated to this age, but this age is dramatically above life expectancy. Is this a conservative estimate of the life expectancy, thereby providing a conservative risk estimate, or has the risk model incorporated the survival function and therefore this accounts for risk to people up to 90 years old (with the assumption that risks beyond that contribute negligibly)? More clarity seems appropriate given that 90 years old is mentioned several times.

P16 L506

If LBR is the same as cumulative baseline risk, why not stick with one standard usage?

P16 LL507-8

The calculation of LBR is supposed to be cancer risk in the absence of radiation exposure, but it is not clear from the variable defs below the integral whether radiation exposure is eliminated in the estimate of mu. (Whereas, this is explicitly mentioned in the definitions of similar parameters below the integral on p. 23.)

P18 LL544-5

Where is the parameter beta defined? It is defined in Table 3.2, but that's pretty far away from this equation. We suggest incorporating that definition here.

P18 LL549

Footnote 2: The explanation there discusses dose in Gy that is arrived at by a weighted sum involving a neutron quality factor. Does this mean that the dose is in Sv, not Gy?

P23 L615

"Several types of lifetime risk estimates..." Please include references to the other types.

P23 L619 of exposed

P25 L694

For Figures 3.8-3.11 please note in the figure caption that no DDREF has been taken into account at these steps, as stated in the preceding text.

P30 LL765-6

Several reviews of the DDREF question have been performed and should certainly be referenced here (Ruhm2015/2016;Shore2017;andalsoinclude-Hoel2018https://www.tandfonline.com/doi/abs/10.1080/09553002.2018.1437483?journalCode=irab20

P33 LL836-9

Were they given greater weight or is that actually what the lethality adjustment accomplished? We suggest starting this sentence with 'In this manner, high..."

P38 L928

General comment: This section does NOT describe a sensitivity analysis, but rather selected sensitivity based on some selected alternative parameter values. This should be emphasized as one expects a full analysis based on the wording present in the draft.

P38 L928

Lethality fraction in Section 4. The sensitivity analysis provides important perspective for the risk model and for the most part, we found this reasonable. For some cases, the variation was well defined (e.g., DDREF, which was argued in the literature to vary between 1 and 2, and this was the range evaluated). For other parameters it was not easy to objectively establish a range over which to test the sensitivity (e.g., qmin), but a wide range was studied and minimal effect was seen. Again, no problem. However, the lethality fraction was identified as having a "large impact", but this was based on the consideration of all cancers being fatal as compared to when realistic lethality was used. This is a dramatic assumption, but it does not realistically span the range of this parameter's value (i.e., it is unrealistic to imagine all thyroid, breast, etc. cancers to be fatal). While the authors acknowledge the limitations of this sensitivity analysis, medical professionals could provide a reasonable range for this estimate to better capture the true sensitivity of this model to this parameter. Given that realistic estimates are achievable, it is a shame that more realistic handling of this parameter was not done given that it is now listed as one of the most important parameters when it is unclear if that is really true.

P38 L932

Use "selected sensitivity analysis" or other language throughout as not the whole range of possible values were evaluated.

P38 L948

DDREF of 1 was chosen. Why not bound the ultimate choice of 2? ICRP Publication 99 had addressed a range of possible DDREF values, why not evaluate that range. Note higher DDREF values will of course result in lower risk estimates. Choosing only DDREF of 1 for 'selected sensitivity analysis' appears to influence the conclusions. Suggest an unbiased broader full range of analyses instead.

P45 L1096 Vary among organs and tissues

PP48-9 LL1172-3

"the issue is not limited to the choice of DDREF, but is related to the shape of the dose-response curve." Use of extreme values of a parameter for a sensitivity analysis seems a bit crude, particularly when a derivative (or in this case, a slope) could be calculated, and the product of that taken with, say, a standard deviation of the parameter in question.

P53 L1328 Weighting factors, wT, was determined

P53 L1355

There should be a comment about linear extrapolation up to 1 Gy from 0.1 Gy and the appropriateness of that methodological choice added to the report.

P54 L1366

We suggest including reference to NCRP Commentary #27 on LNT that also addressed epi evidence for circulatory disease.

P54 L1382

Since DDREF was identified as one of the most important factors, we would have expected many more suggestions on future improvement on the understanding of DDREF, worker population studies, etc.

P54 L1399

The sentence ending in "...deteriorated health condition" is unclear. Please edit for clarification.

P56 LL1445-8

Note that similarly if the DDREF is set to 4, it halves the radiation detriment...

P57 L1459 Provide a reference for the progress in diagnostic techniques and treatments.

P61 L1617 Gy: gray

P61 L1624 LQ is listed, but not LNT?

P62 L1652 Haematopoietic

P62 L1654 exposure

P63 L1685 Since HT is obtained by summing over R, should a summation appear before wRDT,R?