



Brugg, 4 June 2020

Comments on the ICRP draft « Radiation Detriment Calculation Methodology » [1]

1 General point about consistency of notation in the draft report [1]

The notation for lifetime risk is still confusing and mixed up in the draft report. Since the publication of ICRP 103 [2] we had been under the impression, that Lifetime Attributable Risk (LAR) was the risk measure used to calculate the nominal risks because it is clearly stated so on page 26 of ICRP 103 [2].

Only after reading the whole draft report, it finally becomes apparent that Risk of Exposure Induced Cancer (REIC) is the risk measure to be used to calculate nominal risks. However, Fig. 3.1 in the draft report still states that “lifetime attributable risk” was calculated and there are many confusing inconsistencies (some detailed below) throughout the draft report that need attention.

Generally, it would be important to point out the consequences of using REIC instead of LAR and to state that in the low-dose range the two risk assessment methods give the same results.

1.1 Lines starting at 166 and also lines 617- 618: They state, that risk of exposure-induced cancer incidence (REIC) is calculated – but ICRP 103 p. 26 states that lifetime attributable risk (LAR) was used: “The LAR was used in this report to estimate lifetime risks.” Is there an error in ICRP 103 [2]? According to lines 1435-1437 the main lifetime risk estimate was REIC, rather than ELR or LAR. Therefore, this should be stated more clearly somewhere, as it was for another error clearly indicated on line 752. Incidentally, a text search on “REIC” in ICRP 103 [2] does not yield any results at all.

1.2 Line 613, the heading states “Lifetime excess risk”, but for consistency of notation it should state “Risk of Exposure Induced Cancer” – particularly to avoid confusion with excess lifetime risk (ELR) considered in the sensitivity analysis later on in the draft report.

Lines 1070-1071: Here it is stated: “Although the lifetime risk calculations in Publication 103 [2] and this report were based on the risk of exposure induced cancer/death (REIC/REID),.....” – There are no REID calculations that we can recognize neither in [1] nor in [2].

1.3 Lines 470+: The diagram states that “lifetime attributable risk” was calculated – should this be “risk of exposure-induced cancer (incidence)” since line 166 states that REIC was used?

2 Leukaemia models in the draft report [1]

There is still a lot of confusion for a reader concerning which leukaemia models were applied. Lines 161-163: Here it is stated that ERR and EAR are modelled with modifying effects of sex, age at exposure, and attained age. Is time since exposure applied in the leukaemia model? On line 590 it is stated



that "...effect modification by sex, exposure age, and time following exposure....." was applied for leukaemia.

- 2.2** Lines 587-595: Here it is stated "However, the equations of the EAR-based and ERR-based models for leukaemia were not available" and then "The EAR-based model was similar to that derived from the LSS in 1994 (Preston et al., 1994), with a linear-quadratic dose response that allows for effect modification by sex, exposure age, and time following exposure". – How can you say that a model is similar to something if you don't have equations? The same question applies in line 625 where it is stated that REIC is calculated for leukaemia. How can you do this without equations?
- 2.3** Lines 590-593: This is similarly unclear as in comment 2.4 below.
- 2.4** Lines 750-755: This whole paragraph is not clear enough and therefore rather confusing – on the one hand it is stated that "equations of the EAR-based and ERR-based models were not available for leukaemia, calculations of lifetime risks of leukaemia are not presented in the rest of this report" – on the other hand it is stated that "The detriment computations used an average (50:50%) of the EAR and ERR transfer risk estimates" – If the models are not available, how can the transfer of risks be accomplished?

3 ICRP guidance

It would be really valuable to have comprehensive ICRP guidance about the types of exposure situations suitable for application of the nominal risks and detriments. It is perhaps illustrative to summarise all the ICRP 103 [2] and draft report advice given so far that we could find on this topic.

We could only find very limited guidance about applicability of the nominal risks and detriments in the draft report (lines 248:251): "High-dose exposures for which tissue reactions are of concern are strictly out of scope of this methodology, although it does not mean that stochastic effects do not occur at higher dose levels. It is also not recommended to use radiation detriment for assessing the health risk of acute exposures at intermediate dose ranges (e.g. a few hundred millisieverts)."

In ICRP 103 [2] there is also only very limited guidance (bold added):

Page 51:

(66) However, the Commission emphasises that whilst the LNT model remains a scientifically plausible element in its practical system of radiological protection, biological/ epidemiological information that would unambiguously verify the hypothesis that underpins the model is unlikely to be forthcoming (see also UNSCEAR, 2000, NCRP 2001). **Because of this uncertainty on health effects at low doses, the Commission judges that it is not appropriate, for the purposes of public health planning, to calculate the hypothetical number of cases of cancer or heritable disease that might be associated with very small radiation doses received by large numbers of people over very long periods of time (see also Sections 4.4.7 and 5.8).**

Page 76:

(161) Collective effective dose is an instrument for optimisation, for comparing radiological technologies and protection procedures. Collective effective dose is not intended as a tool for epidemiological studies, and it is inappropriate to use it in risk projections. This is because the assumptions implicit in the calculation of collective effective dose (e.g., when applying the LNT model) conceal large biological and statistical uncertainties. **Specifically, the computation of cancer deaths based on collective effective doses involving trivial exposures to large populations is not reasonable and**



Comments on the ICRP draft « Radiation Detriment Calculation Methodology »

4 June 2020

should be avoided. Such computations based on collective effective dose were never intended, are biologically and statistically very uncertain, presuppose a number of caveats that tend not to be repeated when estimates are quoted out of context, and are an incorrect use of this protection quantity.

It would be desirable to expand the ICRP guidance in this new draft report, to give more explicit and detailed guidance about what the practical (if approximate) quantitative limits are on the: “**very small radiation doses/trivial exposures**”, the “**large numbers of people**”, and “**very long periods of time**” for applications of nominal risks and detriments. A few, clear positive examples where the use of nominal risks is judged by the ICRP as appropriate within the model boundaries, could also be very helpful. This is urgently required because, for example, there are plenty of publications of all kinds often applying nominal risks and detriments to very small doses (~1 mSv) and very large populations (~1 million persons) to calculate large numbers of cancer deaths. How can this be avoided without a better risk communication and ICRP guidance?

4 Further comments and questions with regards to the draft report [1]

- 4.1 Line 203-208: In line 194 it is mentioned that the DDREF has a large impact on the cancer risk calculations and later in the lines 961-969 it is pointed out that the value of the DDREF is still under discussion. In order to provide a complete summary of the DDREF, it would be helpful to have additional information in this section mentioning the ongoing discussions.
- 4.2 Line 495: Why are the mortality rates for each cancer category required? How do they enter into the calculations?
- 4.3 Line 498+ and Fig 3.2: Were the survival curves only derived from the all-cause mortality rates, or were the survival curves calculated as the probability to survive cancer free. Cancer free survival curves need to be derived from the all-cause mortality rates and the all-cancer mortality rate and the all cancer incidence rate. It should be clarified here which types of survival curves are shown and applied in the calculations. Later on line 623 this becomes clear “ $S(a|e,d)$ is the cancer-free survival probability”. – so line 498+ and the figure 3.2 caption should be corrected so that reader knows exactly what they are looking at.
- 4.4 Line 509: It is not totally clear what “At beginning of risk” exactly means.
- 4.5 Line 514: “For most cancer sites, cumulative baseline risks are higher in males than in females (oesophagus, colon, lung, bladder, non-CLL leukaemia, and all solid cancers).” – This is true for lifetime baseline risks, but not for cumulative baseline risks as a function of age (as one can see in figure 3.2).
- 4.6 Line 511: “.... the sex-specific probability to be alive at age a for a person alive at age a_{min} ” - should this be “....probability to be alive and cancer free at age a”?
- 4.7 Line 649: “REIC at 1 Gy was computed as the REIC at 0.1 Gy multiplied by 10.” – It should be noted that this scaling is allowed, since REIC is almost linear in this dose range, but cannot be applied to higher dose ranges.
- 4.8 Lines 746-749: Lung cancer weighting of 30% ERR and 70% EAR – does this recommendation still apply in the light of the Cahoon et al Radiat. Res. vol 187, 2017, table 3 results for lung cancer incidence [3]?



Comments on the ICRP draft « Radiation Detriment Calculation Methodology »

4 June 2020

- 4.9** Lines 636-638: In the survival curve, it seems strange to adjust all-cancer incidence for the effects of radiation, but not the all-cancer mortality or all-cause mortality including acute effects – what is the reasoning behind this? Should the radiation dependent survival curve used in calculating REIC not adjust for radiation related all-cause mortality? By adjusting the survival curves to include the effects of radiation for all-cancer incidence, you are effectively including the cancer incidence radiation effect twice – please explain and justify why this was necessary for the ICRP calculations.
- 4.10** Line 788: What are these “strengths and limitations”? For the reader especially, the limitations are important to know and to understand.
- 4.11** Line 795: Does “applied” in this context mean added up? In general, a mathematical expression would help to understand how the different parameters are used in the calculations (also for DDREF, ERR and EAR weighting)
- 4.12** Table 3.6: It is not clear why the lethality fraction does not change when the whole population or the adult workers are considered. One would expect that if one omits the children and older people the lethality fractions would change. The same applies for the weights. Additionally some footnotes are missing (c, d, e). Further, the mathematical formula for the calculation of the detriment is first introduced in a footnote under this table. Since this calculation is the main subject of this draft report, the formula should be more prominent in the text and the notation should be equivalent to those used in ICRP 103 [2].
- 4.13** Line 855: “ q_{min} is a judgment-based parameter” - What does judgement-based parameter mean? Who provided the judgement and what was the judgement based on? The issue of traceability is crucial to establish confidence that expert judgement is used in a structured manner as needed. Application of expert judgement in the draft report should be addressed more explicitly. It would be beneficial to have clear mention of the method used and information about records availability.

References

- [1] ICRP, 20xx. Radiation detriment calculation methodology. ICRP Publication 1XX. Ann. ICRP xx(x), ICRP ref: 4829-8874-8978.
- [2] ICRP, 2007. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37(2–4). ISBN 978-0-7020-3048-2.
- [3] Cahoon, E. K., Preston, D. L., Pierce, D. A., Grant, E., Brenner, A. V., Mabuchi, K., Utada, M. and Ozasa, K. Lung, Laryngeal and Other Respiratory Cancer Incidence among Japanese Atomic Bomb Survivors: An Updated Analysis from 1958 through 2009. *Radiat. Res.* 187, 538–548 (2017).