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Comments on the “Draft for Consultation” of the 2005 Recommendations of the ICRP

Stellungnahme der Strahlenschutzkommission

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1 Preface

The German Commission on Radiological Protection (Strahlenschutzkommission, SSK) has followed the development of the 2005 Recommendations of the ICRP with great interest. Due to the highly commendable introduction of an almost public discussion during the process of this development, the SSK made already a number of suggestions in the past. As the 2005 recommendations nearly arrive at their goal, the SSK would like to make some additional remarks on this – presumably – final draft. Therefore, the SSK together with some representatives of the Federal Office for Radiation Protection (Bundesamt für Strahlenschutz, BfS) discussed the draft on its session on 25th of August. The following summarizes some of the essential points where further discussion and interpretation is seen to be necessary.

2 General Aspects

2.1 Topic: Basic Principles of Radiation Protection

In the draft, it is difficult to keep track of the basic principles of the radiation protection system. Thus, it might be a good idea to add a preamble to the Recommendations addressing the following aspects:

- A clear statement whether ICRP 100 is an addendum to ICRP 60 or a completely new version of recommendations replacing ICRP 60.
- A clear description of the basic principles.
- In particular, the role of “justification” seems to be unclear and, partly, contradictory. Even if “justification” is handed over to the government, there is a need to explain what is meant by “justification”. Otherwise, different governments will handle “justification” differently, a process that will result in very diverse regulations even in neighbouring countries.

In addition, the draft contains a lot of “declarations of intent” besides the recommendations. Perhaps, this will be changed in the final version, but a lot of possible misunderstandings can be avoided when the text is restricted to the recommendations.

2.2 Topic: Characterisation of the Individual

The characterisation of the individual, e.g. of members of the public, has always been a key issue in radiological protection. Moving from the utilitarian approach of the 'greatest good for the greatest number' to one with more concern for the 'individual' (6) the need for such a characterisation becomes even more important. It is unfortunate, that the indications in the draft report on how such a characterisation could be done are very vague.

For public exposure the application of the concept of the critical group (not the individual!) which has previously been proposed by ICRP is re-emphasised. There is, however, no general concept, which is accepted at international level, to define the critical group in various situations. It would be helpful if ICRP could give guidance on how to define the critical group.

In (173) an additional concept of using *age-averaged effective dose coefficients* and age-averaged habit data for the individual in the case of continuing exposures of the public is

mentioned. It is very unfortunate that the present draft of the 2005 recommendations does not give any details about this concept. It rather states: “*Methods to assess such doses will be addressed by a Task Group of ICRP Committee 4*”.

There is fundamental concern that the use of *age-averaged effective dose coefficients* and age-averaged habit data for the individual might not be suitable for practical application for the following reasons: the dose limits and dose constraints as defined by ICRP are fixed values and they are independent of the age of the individual. International legislation requires that the dose estimation has to be performed in 6 age-specific groups. The age groups ≤ 1 year and between >1 year and ≤ 2 year are of particular importance in this context because the age dependent dose coefficients vary by more than an order of magnitude over the lifetime with the highest values at young ages. For a given intake of certain radionuclides such as Pb-210 or I-131 the age-dependent values of the effective dose would be more than an order of magnitude higher for the age groups ≤ 1 year and between >1 year and ≤ 2 year than the values for adults. The application of *age-averaged effective dose coefficients* and age-averaged habit data would result in a substantial underestimation of the dose in these age groups. From a radiation protection point of view this can not be accepted.

2.3 Topic: DDREF

Para. (105) in combination with (38), (48), (101)

ICRP claims no good reasons to change its 1990 recommendations of a DDREF of 2. As pointed out, for a quantitative derivation of the DDREF the statistical precision of the data from cellular/animal studies as well as from dose-response relationships, particularly from LSS, is weak. This is true for the present, but even more for the past, where a DDREF in the order of 2 seemed to be justified. In the meantime, however, epidemiological data, mainly the incidence data from LSS, give much less justification, if any, for a DDREF >1 .

It is a matter of principle, whether good reasons are needed to *change* a consisting practice (if bearing shortcomings), or whether good reasons are needed to *retain* a practice, that bears inconsistencies due to deviances from a fundamental concept. DDREF >1 represents a conceptual deviance from the LNT-hypothesis, that is seen to be fundamental for the entire present radiation-protection philosophy (comments about LNT see below).

Therefore, it is believed, that at present the scientific basis in favour of retaining a DDREF = 2 is weak and changes are justified. In particular, there are no evidences with respect to solid cancers (rather to leukaemia) and with respect to acute low doses (rather to low dose rates). This is based on the LSS incidence-studies, which still represent the main source of quantitative risk estimates.

In the case of retaining DDREF = 2, Para. (105) one should at least refer to three additional aspects:

- DDREF is applied for doses below 0.2 Gy, and for dose rates below 0.1 Gy/h.
- DDREF is not applied for high-LET radiation.
- The nominal risk coefficients (Tab. 6 and A1) that are derived on the basis of DDREF = 2 are considerable lower than in ICRP 60. Although this is not due to the

DDREF (the hereby implications, however, would be diminished if DDREF is rejected) an urgent need for discussion of the reasons and the consequences is seen.

2.4 Topic: LNT-hypothesis

Para. (38), (48), (101)

The question about the features of the dose-effect relationship in the low dose range is fundamental for conceptual radiation protection. It is not clear, however, whether the ICRP supports the LNT-Hypothesis in its "pure" form or in any kind of modification.

In (48) it is said, that *"the averaging of absorbed dose ... is only possible under the assumption of ... LNT. All protection quantities rely on these hypotheses."* This refers to the "pure" LNT. In (101) it is said *"... up to a few tens of mSv, it is scientifically reasonable to assume ... cancer risk will rise in direct proportion to absorbed dose"*. This implies a deviation from linearity above some tens of mSv. How does this deviation look like? Clarification in the same way should be achieved in (38) where it *"... is assumed that ... any increment of exposure above the natural background produces a linear increment of risk."* Furthermore, natural background: Does it refer to dose rate (~1mSv/a), or to annual dose (~1mSv), or to lifetime dose (~100mSv)?

2.5 Topic: The Nominal Probability Coefficients

Para. (112), (113), Annex A

The recommended nominal probability coefficients represent a weighting of the incidence probabilities with lethality and with quality-of-life detriment. This procedure has a number of advantages and yields considerable improvements to ICRP 60. First of all, the coefficients are based on incidence data being more reliable than former mortality data. Furthermore, improved healing methods, different prognoses for various cancer sites, and other developments that involve the relationship of mortality and incidence are considered and integrated appropriately.

However, the procedure of determination of the probability coefficient is not fully clear: In Tab. 6 (113) the nominal probability coefficients for the detriment (e.g. 6.5 %/Sv for the whole population) are compared to the corresponding values from ICRP 60 (7.3 %/Sv). This can be understood from Tab. A1 and Annex A. In (112) the corresponding quantities for cancer mortality, i.e. 4.4 %/Sv and 5 %/Sv, respectively, are given. These calculations, however, can not be retraced from Tab. A1a. The lethality factor for total tissue is not given, but can be recalculated by means of the function given in the footnote on p. 72: With skin cancer and gonads excluded the unweighted nominal risk coefficient is 792/10,000 per Sv (total value in the 2nd column of Tab. A1a) and the lethality adjusted nominal risk is 615/10,000 per Sv (total value in the 4th column). Using the function in the footnote with $q_{\min} = 0.1$ (from A31) this leads to a lethality factor of about 0.5. With this factor the risk coefficient for cancer mortality is 4.0 %/Sv (not 4.4 %/Sv as cited in (112)). The reduction compared to ICRP 60 is therefore not 10 % but 20 %. This deviation is of considerable relevance, since the advertency -the scientific as well as the public- towards this sensible and well known quantity is very pronounced.

2.6 Topic: Optimisation in Medicine

In section 9 (Medical Exposure) it seems that “optimisation” is not a very crucial aspect in medicine. In section 9.3, for example, it is stated *“The medical procedures causing patient exposures are clearly justified and are usually for the direct benefit of the exposed individual and consequently somewhat less attention has been given to optimisation of protection in medical exposures than in other applications of radiation sources.”*

There should be a clear statement of ICRP that, although from a historical perspective the sentences cited above might be correct, there definitely is a need of optimisation also in the medical field, both technically and organisationally. Actually today, there exists the danger that physicians do not even think about the possibilities of optimisation, because they argue that the adopted radiological procedure is justified. It is necessary to sharpen the awareness that the net benefit of the patient can be dramatically increased by optimisation measures.

2.7 Topic: Limitation of Dose

Further clarification and explanation is needed to avoid misinterpretation.

2.7.1 The co-existence of limits and constraints

The most fundamental level of protection is the restriction on individual dose related to a single source by a dose constraint (S5). The level of protection for an individual from all sources within a class of exposure (in normal situations only) is defined by the dose limit (S8). Some additional explanation in the following way would be helpful: In a multiple source situation the numerical value of any constraint would always be lower than the value of the corresponding limit (e.g. for example (164): 1 mSv/year for a single source and 0.3 mSv/year for multiple dominant sources).

2.7.2 Numerical values of limits and constraints

ICRP continues to recommend the numerical values of dose limits of ICRP 60. From a regulator's point of view this is very positive!

In Table 7 ICRP defines numerical values of maximum constraints for 3 classes of situations where they apply and a minimum value of any constraint of 0.01 mSv. Table 7 requires further explanation and some clarification:

- It is not clear whether the figures of Table 7 are meant to represent values of the effective dose (mSv) and/or of the dose per year. This is important for situations with dose values that are time dependent, e.g. emergency situations.
- The statement *“national values of constraints normally will be lower than the maximum value recommended by the Commission, but probably not by as much as a factor of ten (§S7)”* needs explanation and justification. It is not evident, that a generic factor of ten is applicable for all situations mentioned in the Table.
- For Radon and old contaminated sites where there is no *“direct benefit for the exposed individuals”* the appropriate constraint would be 1 mSv rather than 20 mSv (Table 7 and (164)).

- For the constraint of 0.01 the verbal contradiction between the characterisation of the figure (“maximum” constraint) and of the characteristic of the “situation to which it applies” (“minimum” value of any constraint) has to be resolved.
- The terms “constraint” and “limit” are used in Sec. 9 (Medical exposure, (225)). It is not clear from the text of (225) whether this use of the term constraint is consistent with the definition of the constraint used in the rest of the document and whether there is a need to use the term constraint in this context at all.

2.8 Topic: In Utero Exposure

In (118) it is mentioned: *“Finally, for the reasons given in Publication 82 (ICRP; 1999a), the Commission suggests that in utero exposure should not be a specific protection case in common prolonged exposure situations where the prolonged dose is well below about 100 mSv.”*

There are several problems with this sentence:

- In ICRP Publication 82 the last part of the sentence reads: “.. the annual prolonged dose is ..”. Why has the adjective “annual” been omitted? In the context of a prolonged exposure this means a one fourth increase in dose for the nine months duration of a pregnancy.
- What is meant by “well below”? People will have very different opinions. For some, for example, 50% lower is “well below”; that means that there is no need for protection measures at an expected dose of 50 mSv for the fetus?! This leads us to another problem:
- If values of, let’s say, 30, 40 or 50 mSv are “well below”, then this means, that the most radiosensitive stage of human life must not be considered to be “a specific protection case” at these doses, whereas ICRP sees the necessity to limit exposure of adult individuals at 20 mSv per year. This is hard to understand and to justify. It is even more difficult to understand, when one takes into consideration that there is evidence of a statistically significant increase in risk of childhood cancer after 10 mGy during pregnancy (R. Doll and R. Wakeford. *Risk of childhood cancer from fetal irradiation. Brit.J.Radiol. 70:130-139, 1997*), a level of statistical significance about 5 to 10fold lower than that for the survivors of Hiroshima and Nagasaki.

ICRP should reconsider its recommendation given in ICRP 82. Against the background of dose limits like 1 mSv for the general population, it is incomprehensible that doses of “well below 100 mSv” for the fetus are not “a specific protection case”.

2.9 Topic: Exclusion

2.9.1 Artificial radionuclides

In the draft the internationally established system of exemption, clearance and exclusion is reduced to the term “exclusion” (e.g. [1, 2]). Exclusion levels are taken from the report IAEA DS 161, but are given only for two groups of radionuclides – alpha-emitters and beta/gamma-emitters.

The exclusion of sources from the scope of the recommendations is justifiable when the expected dose is below the range of 10 $\mu\text{Sv/y}$. The reduction of all the artificial radionuclides to the two groups results in the same exclusion level for radionuclides of extremely different radiological importance (e.g. H-3 and Sr-90). The exclusion value is related to the most restrictive radionuclide, so that this recommendation would result in potential dose restrictions orders of magnitude below 10 $\mu\text{Sv/y}$ for lots of radionuclides.

For radiation protection in practice a set of several hundreds of exclusion levels is needed and they should also be given for different options (e.g. unrestricted reuse, disposal, reuse of buildings, reuse of sites). The ICRP should recommend the dose constraint for exclusion and should give advice for the modelling to derive nuclide specific exclusion levels (e.g. realistic approach, total masses) instead of presenting levels for two groups that are of no value in practice.

2.9.2 Natural radionuclides

Exclusion levels are also taken from the report IAEA DS 161, but reduced to only two groups. The exclusion levels of the IAEA report have not been – different from the ICRP statement in par. (210) – agreed internationally. The exclusion levels represent concentrations towards the higher end of the generally observed range and are not consistent with a dose constraint of 1 mSv/y or an effective dose of 0.2 mSv/y for individuals – different from the ICRP statement in par. (209).

2.10 Topic: Protection of the Environment

In Publication 60 the ICRP expressed the belief that the standards of environmental control needed to protect man will ensure that other species are not put at risk. In paragraph (242) of the draft recommendation the ICRP declares that “the Commission still believes that this judgement is correct in general terms”.

No scientific reasons are presented by the ICRP to support this statement. Current results of research projects, e.g. FASSET, are not evaluated and conclusions from this research are not drawn. Instead, a common approach for the radiological protection of humans and non-human organisms is recommended without giving reasons for any need of such a system.

In Annex B.3 the ICRP recommends to develop a small set of reference animals and plants plus their relevant databases to calculate doses according to the procedure to protect man. According to this recommendation a lot of (limited) resources would be exhausted to model doses of reference animals and plants. Therefore, this strategy should only be embarked if there is a need to do so, but the draft recommendations of the ICRP do not give any scientific basis for this approach on the one hand. On the other hand, the protection of soil, air and water is not recommended by the ICRP. In other fields of environmental protection these non-living parts of the environment must also be protected and sustainability is an important aspect of protection. Therefore, ICRP should indicate how this aspect should be considered, e.g. by limiting releases of Kr-85 and of long-living radionuclides (C-14, Cl-36, Mn-53, Tc-99, I-129, Cs-135, transuranium nuclides etc.) to the environment according to the state of the art and independent from potential doses to man or non-human beings.

3 Specific Aspects

- para (105): The last sentence states, that the DDREF has to be applied at low doses and low dose rates. It has to be made clear, that this is only the case when low LET radiation is considered.
- para (117): Have the findings by Hall et al. (BMJ 328 (2004) 19-23) been incorporated in this statement, namely, the second sentence?
- para (123): Probably, a hint to Chronic Radiation Diseases, as described in various parts of the former Soviet Union, could underpin the importance of considering non-cancer diseases.
- para (A12): Last but third line: delete “, and recently”.
- para (A13): It should be explained, why no Chernobyl data have been taken into account.
- para (A23): See (105)
- para (A26, A27): The terms ERR_{add} and ERR_{mult} should be introduced. Only after a second reading, it becomes clear what is meant.

There are several mistakes in Tab. A1 (p.72):

- Footnote: k_T instead of q (see p. 70(A30))
- 2nd columns of a) and b): Nominal Risk Coefficient : Caution: Cases per 10.000 Sv! Neither PY, nor per year. Even better would be normalization to 1 or to %: these quantities are lifetime probabilities.
- The lethality-adjusted nominal risk for thyroid is 5/10.000 per Sv instead of 7 (4th column of a)).
- “... values did not diverge ... by more than around two-fold. ... w_T value for the remainder tissues of 0.1 ...” This seems not to be true if compared with “Other solid” in Tab A1 with a relative detriment of 0.259.

Perhaps a “glossary of terms”, in which precise definitions are given, might be very helpful.

It is difficult to understand why new terms are intended to be introduced, although the definitions are not changed (e.g. “tissue reactions” instead of “deterministic effects”, “radiation weighted dose” instead of “equivalent dose”).

4 Final Remark

ICRP Recommendations, in particular, those addressing basic concepts are expected to be of an extremely high quality. Quality needs its time. Thus, please, do not publish these Recommendations under time pressure. Take your time!