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Comments on the 2006 Draft of the ICRP Recommendations

Statement of the German Commission on Radiological Protection (Strahlenschutzkommsion - SSK)

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1 General comment

ICRP continues to develop its basic recommendations within the well established and successful system of limitation, justification and optimisation under the assumption of a no-threshold risk. ICRP recommendations should represent the scientific approach to radiological protection and should provide guidance to regulatory bodies which have to transform the recommendations into regulations taking into account social, economic, political and other aspects. Consequently, national and international regulations are results of compromises between the scientific and other aspects related to radiation protection.

ICRP should restrict itself to formulating the scientific basis as clearly as possible and describe the principles how radiological protection should ideally be. ICRP should not take into consideration the other aspects mentioned above and should not search for excuses for deviations from its recommendations in actual regulations. It is not the task of the ICRP to make recommendations which represent just that part of radiological protection which is accepted by everybody as a minimum consensus.

We suppose that all individuals whose mother tongue is not English would highly appreciate a simpler phrasing of the Recommendations.

2 Specific comments (listed according to the ICRP paragraphs)

(15) These consolidated Recommendations are supported by a series of foundation documents and supporting documents termed 'building blocks', which elaborate on important aspects of the Commission's policy. The foundation documents address the following topics: …The concept and use of reference animals and plants for the purposes of radiological protection (Publication YY, ICRP, 200Y) …The scope of radiological protection: exemption and exclusion (Publication WW, ICRP, 200W)

The problem is that some Foundation Documents are still under discussion and that the short paragraphs in the draft recommendation can be completely changed in their meaning by the foundation documents. This is particularly the case for the foundation document *The Scope of Radiological Protection* (ICRP, 2006).

(28-33) Structure of the System of radiological protection

(The following comment refers primarily to the Foundation document *The Scope of Radiological Protection, Executive Summary (e))*

The SSK welcomes the emphasis put on the clear formulation of the system of radiological protection which is based on the three principles of justification, optimization and limitation. The SSK supports the assumption of a no-threshold risk and concludes – as ICRP does – that any radiation exposure, –large or small –, of any origin, – artificial or natural –, are within the scope of radiological protection regulations. The SSK agrees that „*regulations should control coherently and consistently any exposure regardless its origin taking also into account the amenability of control and social and economic factors*".

However, the SSK is of the opinion that the ICRP recommendation should not use "*the concerns of those affected by the different exposure situations*" as a justification for the "*dichotomous approaches to control radiation exposure*" in natural and artificial radiation exposures. The different degrees, to which natural and artificial exposures are amenable to control, provide in combination with social and economic factors the only meaningful justification for deviating standards in radiological protection for natural and artificial radionuclides.

Given the assumption of a no-threshold risk, ICRP should exclusively promote a coherent and consistent system of radiological protection, even if a success in this respect is highly unlikely on short time scales. ICRP should not use the argument of „*different public expectations under different circumstances of exposure*".

(47) Some generic exemption criteria have been established by intergovernmental organisations in order to promote international consistency. For example, international exemption levels have been adopted for apparatuses and devices that emit adventitious (or unintended) radiation of low energy (or low intensity) and for radioactivity in a variety of substances, such as radioactivity in commodities that are not consumed and in some foodstuffs (refs to FAO, WHO, IAEA). Detailed guidance on exclusion and exemptions is provided in the foundation document The Scope of Radiological Protection Regulations (ICRP, 2006).

(Again, the following comments refer primarily to the Foundation document *The Scope of Radiological Protection*)

"Scope" Chapter 6.2 (88) The SSK strongly supports the recommendations of the EURADOS Working Group WG5 ISOTC85SC2WG21:

As far as the aircrew exposure issue is concerned, a deep change appeared in the committee's approach compared to its publication 60, i.e. "exposure to cosmic rays at altitudes above ground level may be considered as a candidate for either exclusion from legislation or generic exemption from most regulatory requirements, depending on the legislative system and national arrangements in place". This approach is not correct for the following reasons:

– The effective dose received by aircraft crews is between 1 and 6 mSv per year for long haul flights. It is clearly above the dose limit for the general public and comparable or even higher than doses received by the great majority of nuclear workers. So, why, for categories exposed to the same or a higher magnitude of risk, are there different ways to manage this risk? Further, can we accept to definitively say that this source of human exposure is "unamenable to control by any reasonable means" whereas the means of assessing the individual doses exist?
– For the most exposed crew members (routes at high latitude), the dose can be used to manage the activity.
– There is the situation of the pregnant women even if specific dispositions may already be taken for aircraft crew members.
– A lot of civil aviation companies (especially in Europe) have already taken dispositions to evaluate and record the individual doses aboard aircraft. So, we may fear that a change in the rules in an opposite way will cause a negative perception of radiation protection management in general.

– More than 50% of exposed persons are women in reproductive age and the radiation protection aspect will be correctly taken into account only in case of an appropriate survey.
– More than 50 % of the effective dose is received from radiation with high LET. This is unique among the professional exposure and leads to keep a specific dose assessment.
– The case of a heavy GLE should be named, even if the probability of such an event is very low, that aircraft crews may be exposed in the order of mSv during a single flight.

In conclusion, while it is justified to exclude doses from cosmic radiation at ground level from the scope of radiation protection regulations, the exemption of human activities such as civil aviation which result in increased doses to a large global workforce is unacceptable.

"Scope" Chapter 6.4.5. (115) The exemption of radon concentrations of 200 Bq m^{-3} in dwellings and of 500 Bq m^{-3} at workplaces would exempt radiation exposures with effective doses of 4 mSv a^{-1} respectively 3 mSv a^{-1}. This is not in agreement with the *de minimis* criterion for natural exposures. Considering recent epidemiological findings (e.g. Darby et al. 2005 BMJ, 2006 Scand.J Work Environ Health) which are neither mentioned nor discussed in the ICRP draft, one has to assume an increase of the relative risk of deadly lung cancer of about 10% per 100 Bq m^{-3} radon concentration.

In the judgement of SSK there is no other environmental carcinogen for which the epidemiological database is as comprehensive and unambiguous as in the case of radon. Therefore, the SSK does not agree with the exemption of radon in dwellings and at workplaces. The discussion about levels of radon concentrations which can be exempted from control is up to now neither nationally nor internationally finally discussed. The proposal by ICRP is not sufficient because of the lack of scientific foundation.

The global average of radon concentrations in dwellings is 40 Bq m^{-3} with a geometric mean of 30 Bq m^{-3} and a geometric standard deviation of 2.3 (UNSCEAR 1993). The global average of the radiation exposure due to radon in dwellings thus is about 1 mSv a^{-1}.

"Scope" Chapter 7.1(134) The exclusion of materials containing artificial radionuclides if the activity concentrations are below 1 Bq kg^{-1} for α-emitting radionuclides and below 10 Bq kg^{-1} for β- and γ- emitting radionuclides does not represent the state of scientifically founded generic model calculations of the expected radiation exposures of workers or members of the public if such materials are freely used as a consequence of their exclusion from the system of radiological protection. Further it is to emphasize, that the IAEA recommendation on the Application of the Concepts of Exclusion, Exemption and Clearance (IAEA, 2004) is internationally not finally accepted and still a controversy.

A value of 40 Bq m^{-3} for the exclusion of radon concentrations in ambient air, proposed by ICRP, appears rather conservative considering the large variability of radon concentrations. The SSK supports the recommendation to exclude radon in ambient air **not influenced by human activities**, but recommends excluding a high percentile, e.g. 95 %, depending on the geological and climatological conditions. Typical activity concentrations of Rn-222 and Rn-220 in ambient air range from 1 to 100 Bq m^{-3} with a global average of about 10 Bq m^{-3} (UNSCEAR 1993). For long-term averaged radon concentrations in ambient air of 10 Bq m^{-3} effective doses around 0.1 mSv a^{-1} are to be expected.

"Scope" Chapter 7.2(138) and "Recommendations (294) The exemption of materials containing natural radionuclides, if their activity concentrations are below 1,000 Bq kg^{-1} for Uranium and Thorium and below 10,000 Bq kg^{-1} for ^{40}K, are not consistent with the ICRP dose system for exemption.

The values recommended by ICRP regarding exclusion and exemption of radon and of materials containing natural and artificial radionuclides are particularly problematic since they are not coherent with the ICRP system of radiological protection and since they do not take into account the actual scientific approaches to derive generic exclusion and exemption levels.

Recommendations for exclusion, exemption and clearance levels by ICRP should mainly be **dose related** and not give explicit activity concentration levels which might or might not be meaningful under the viewpoint of scientific modelling.

(58) '...since the estimation of nominal cancer risk coefficients is based upon human epidemiological data, any contribution from these cellular phenomena (adaptive response, induced genomic instability, bystander signalling) would be included in that estimate…'

The SSK supports the view that risk coefficients derived from epidemiological data include the contribution from cellular phenomena like genetic predisposition, induced genomic instability or bystander effects. These risk coefficients, however, apply primarily to the dose range for which the corresponding epidemiological study gives significant results. For lower doses the cellular phenomena might result in different risk coefficients. Some of the biological mechanisms mentioned above might also play a role in the medium to high dose range, when risk on an individual level is estimated.

It is proposed either to delete the cited sentence or to mention explicitly the low dose range and individual risk.

(60) '...for a number of organs/tissues there are indications of differences in radiation risk estimates among the various data sets, with the LSS estimates being generally higher…'.

It should be clarified, whether this statement relates to the relative or to the absolute risk. Assuming that it relates to the relative risk, it should be noted that there is a number of epidemiological studies, in which the estimate of the relative risk is higher than in the LSS study. A few of these counter-examples among larger epidemiological studies (cited from UNSCEAR draft R.658) are given in Table 1.

Slightly more than half of the results cited in Table 1 relate to the Canadian National Dose Registry. Although there might be a bias in the dose estimations of a subset of the Canadian National Dose Registry, the results of this study should not be totally abandoned at this stage.

The SSK recommends deleting the words *'... with the LSS estimates being generally higher'*.

Table 1. Examples for larger epidemiological studies with larger risk coefficients than the corresponding values in the LSS data (UNSCEAR report 2006, to be published)

Cancer site incidence or mortality	LSS	Other study
All solid cancer incidence	Age at exposure: 20-40 Observed cases: 3093 Mean dose: 0.21 Sv ERR at 1 Sv: 0.50 (0.39; 0.61)	Canada National Dose Registry Observed cases: 2031 Mean dose: 0.07 Sv ERR at 1 Sv: 2.5 (1.1; 4.2)
All solid cancer incidence	Age at exposure: 20-40 Observed cases: 3093 Mean dose: 0.21 Sv ERR at 1 Sv: 0.50 (0.39; 0.61)	UK Chapelcross workers Observed cases: 157 Mean dose: 0.08 Sv ERR at 1 Sv: 1.3 (-0.4; 3.8)
All solid cancer incidence	Age at exposure: 20-40 Observed cases: 3093 Mean dose: 0.21 Sv ERR at 1 Sv: 0.50 (0.39; 0.61)	UK Springfield uranium workers Observed cases: 901 Mean dose: 0.03 Sv ERR at 1 Sv: 1.8 (-0.06; 4.0)
Colon cancer incidence	Age at exposure > 20 Observed cases: 191 Mean dose: 0.22 Sv ERR at 1 Sv: 0.22	Canada National Dose Registry Observed cases: 315 Mean dose: 0.07 Sv ERR at 1 Sv: 3.0 (0.5; 6.8)
Leukaemia incidence	Age at exposure < 20 Observed cases: 46 Mean dose: 0.26 Sv ERR at 1 Sv: 8.3 (5.0; 13.7)	Chernobyl-related childhood exp. Observed cases: 421 Mean dose: 0.006 Sv ERR at 1 Sv: 32.4 (9.8; 84.0)
Lung cancer incidence	Age at exposure > 20 Observed cases: 426 Mean dose: 0.24 Sv ERR at 1 Sv: 1.06	Canada National Dose Registry Observed cases: 476 Mean dose: 0.06 Sv ERR at 1 Sv: 3.6 (0.4; 6.9)
Lung cancer mortality	Males Observed cases: 403 Mean dose: 0.21 Sv ERR at 1 Sv: 0.56 (0.29; 0.89)	Canada National Dose Registry Observed cases: 386 Mean dose: 0.07 Sv ERR at 1 Sv: 2.6 (<0; 8.0)

Cancer site incidence or mortality	LSS	Other study
Stomach cancer incidence	Females Observed cases: 1011 Mean dose: 0.21 Sv ERR at 1 Sv: 0.51 (0.33; 0.72)	Cervical cancer case-control Observed cases: 348 Mean dose: 2 Sv ERR at 1 Sv: 0.54 (0.05; 1.5)
Thyroid cancer incidence	All Observed cases: 132 Mean dose: 0.26 Sv ERR at 1 Sv: 1.5 (0.5; 2.1)	Canada National Dose Registry Observed cases: 129 Mean dose: 0.07 Sv ERR at 1 Sv: 5.9 (2.5; 9.9)
Cancer of urinary bladder, incidence	Males Observed cases: 76 Mean dose: 0.23 Sv ERR at 1 Sv: 0.35	Canada National Dose Registry Observed cases: 139 Mean dose: 0.12 Sv ERR at 1 Sv: 1.4 (<0; 8.2)

(64) '…the Commission finds no compelling reason to change its 1990 recommendations of a DDREF of 2…'.

The essential point of the position of the SSK is here that strong evidence is needed for assuming a lower risk per unit dose at low or protracted exposures than for high acute doses. The SSK considers this demand stronger than the demand that strong evidence is needed for a change of a DDREF. Since the SSK does not see any strong evidence for a lower risk coefficient in the low dose range, it is recommended to abolish the DDREF.

Recently, several large epidemiological studies have been published on cancer risk after exposures to low doses or medium doses with low dose rates of low-LET radiation (see Table 2). In two of ten observations the excess risk was not significant. In the eight other observations the best estimate of the relative risk is higher than the corresponding value of the LSS study. Due to the large uncertainty ranges of the results, it can of course not be concluded that the DDREF is smaller than one. However, the results of these studies weaken the support of radiobiological studies for assuming a DDREF value larger than one for humans.

All epidemiological studies have some shortcomings. Arguments against the studies are readily established. If, however, a number of epidemiological studies gives consistent results, as it is here the case, then the studies should not be neglected.

Table 2: Recent larger epidemiological studies on cancer mortality risk after low-LET exposures with low doses or dose rates.

Cancer site	LSS	Other study
All solid cancer	Cardis et al, BMJ 2005 Males, age at exposure: 20-60 Observed cases: 3246 Mean dose: 0.21 Sv ERR at 1 Sv: 0.32 (0.01; 0.50)	Cardis et al, BMJ 2005 15 countries nuclear workers Observed cases: 2031 Mean dose: 0.02 Sv ERR per dose: 0.9 (0.03; 1.9) Sv^{-1}
All solid cancer	Preston et al, Radiat Res 2004 All survivors Observed cases: 10 127 ERR at 1 Sv: 0.43 (0.33; 0.53)	Krestinina et al, Radiat Res 2005 Techa River population Observed cases: 1842 ERR per dose: 0.9 (0.2; 1.7) Sv^{-1}
All solid cancer	Cardis et al, BMJ 2005 Males, age at exposure: 20-60 Observed cases: 3246 Mean dose: 0.21 Sv ERR at 1 Sv: 0.32 (0.01; 0.50)	Wing et al, Occup Env Med 2006 Hanford workers Observed cases: 2265 Mean dose: 0.03 Sv ERR per dose: 3.2 (0.8; 6.2) Sv^{-1}
Leukaemia excluding CLL	UNSCEAR 2000 All survivors Observed cases: 141 ERR at 1 Sv: 4.4 (3.2; 5.6)	Krestinina et al, Radiat Res 2005 Techa River population Observed cases: 49 ERR per dose: 6.5 (1.8; 24) Sv^{-1}
Leukaemia excluding CLL	Cardis et al, BMJ 2005 Males, age at exposure: 20-60 Observed cases: 196 Mean dose: 0.26 Sv ERR/dose[a]: 1.5 (-1.1; 5.3) Sv^{-1}	Cardis et al, BMJ 2005 15 countries nuclear workers Observed cases: 83 Mean dose: 0.02 Sv 1.9 (<0; 8.5) Sv^{-1}
Leukaemia excluding CLL	Cardis et al, BMJ 2005 Males, age at exposure: 20-60 Observed cases: 196 Mean dose: 0.26 Sv ERR/dose[a]: 1.5 (-1.1; 5.3) Sv^{-1}	Wing et al, Occup Env Med 2006 Hanford workers No association
Leukaemia	UNSCEAR 2006 Age at exposure 20-40 Observed cases: 66 ERR at 1 Sv: 3.1 (1.8; 4.9)	Kubale et al. Radiat Res 2005 Portsmouth shipyard, case-control Observed cases: 115 ERR per dose: 8 (1; 16) Sv^{-1}

Cancer site	LSS	Other study
Leukaemia	UNSCEAR 2006 Age at exposure 20-40 Observed cases: 66 ERR at 1 Sv: 3.1 (1.8; 4.9)	Yiin et al. Radiat Res 2005 Portsmouth shipyard, cohort Observed cases: 34 ERR per dose: 11 (-0.9; 39)
Lung cancer	UNSCEAR, 2000 Males, age at exposure: > 40 Observed cases: 182 Mean dose: 0.23 Sv ERR at 1Sv: 0.5(-0.1; 1.1) Sv^{-1}	Wing et al, Occup Env Med 2006 Hanford workers Observed cases: 666 Mean dose: 0.03 Sv ERR per dose[b]: 9.1 (3.0; 18) Sv^{-1}
Lung cancer	UNSCEAR, 2000 Males, age at exposure: > 40 Observed cases: 182 Mean dose: 0.23 Sv ERR at 1Sv: 0.5(-0.1; 1.1) Sv^{-1}	Yiin et al, Radiat Res 2006 Portsmouth shipyard cohort Observed cases: 411 No association

[a]: linear term of LQ model
[b]: For dose accrued at age 55 and above

As it is somewhat unlikely that the ICRP will refrain from using the DDREF of 2, it is recommended that ICRP states, at least, that the DDREF of 2 is a matter of **judgment** based upon scientific data, but that these data are not sufficient to give compelling evidence that a DDREF of 2 is definitely correct and that a DDREF of 1 cannot be excluded with certainty.

(67) …. In the light of further knowledge the Commission judges that many of the underlying assumptions in such calculations are no longer sustainable….

The marked reduction in the nominal risk coefficient for hereditary effects is described as the most significant change *viz* ICRP Publication 60 (see (72)). In the same paragraph (72) it is noted that the main reason for this is the choice of the commission to express such risks up to the second generation and not at a theoretical equilibrium (the theory of which actually underlies the use of the doubling dose method - which has been retained). Given the importance of this change and the likely discussion it may generate, the SSK strongly recommends to include a more thorough discussion of this choice not only in Annex A but also in the main text.

The wording will be critical, because the assumptions to which the current text (in italics above) refers (see page 110, Annex A) appear to have been somewhat unrealistic and certainly untestable also in 1990. Therefore a new judgment declaring them as no longer sustainable now can be seen as implying poor judgment in 1990 or a change from the precautionary approach adopted in 1990.

(74) '...In this respect the nominal risk coefficient given will tend to be an over-estimate of risks in the future.'

Due to the assumed DDREF of 2, it cannot be excluded that the nominal risk coefficients underestimate the risk per unit dose at low doses or low dose rates. It is therefore not guaranteed that the risk coefficients will tend to over-estimate the risk per unit dose in future.

It is proposed to delete the sentence.

(81) In utero exposure

In the context of "1 mSv during the remainder of the pregnancy" the statement "the Commission recommends that in utero exposure should not be a specific protection case in prolonged exposure situations where the dose is well below about 100 mSv" looks very strange. It is particularly strange, because this statement is made in the context of cancer risk.

(108) '....from inhaled radon progeny or ingested alpha-emitting radionuclides such as isotopes of plutonium...'

The main pathway at working places with plutonium exposure is inhalation and not ingestion.

(112) Effective dose E

The denomination "effective dose *E* " is misleading. The new definition of the effective dose *E* contains new w_T and w_R values, a new summation on organs and tissues, and averaging over new gender specific reference persons (voxel phantoms). This means that the variation of *E* with energy and angle in radiation fields will in general be different from the former *E*. **The new *E* is a new quantity and should be given a new name and symbol.** Who will decide in the future which definition of *E* was relevant at what time? There may be changes of more than 50 % in the values of the new *E* (e.g. for neutron and proton radiation and due to the revised tissue weighting factors of the gonads and the breast).

(114)

Proposal on a revised first sentence:

"The w_T for the remainder tissues (0.12) applies to 14 organs and tissues listed in the footnote in table 4 and is used for the dose averaging of the organs and tissues of the remainder of the male and female (see section 4.3.5). This leads to a mean w_T of the gender averaged remainder of 0.12. The so-called splitting .."

Add in the footnote in table 4 after Prostate "(in male)",
Add in the footnote in table 4 after Uterus/cervic "(in female)".

Table 4 is assumed to look clearer in the following form:

Table 4. Recommended tissue weighting factors

Tissue		w_T	Σw_T
Bone-marrow, Colon, Lung, Stomach, Breast		0.12	5 x 0.12
Gonads (ovaries in the female and testes in the male)		0.08	1 x 0.08
Bladder, Oesophagus, Liver, Thyroid		0.04	4 x 0.04
Bone surface, Brain, Salivary glands, Skin		0.01	4 x 0.01
Adrenals, Extrathoracic (ET) region, Gall bladder, Heart, Kidneys, Lymphatic nodes, Muscle, Oral mucosa, Pancreas, Small intestine, Spleen, Thymus	Remainder Tissues	0.12/13	12 x 0.12/13
Uterus/cervix in the female and Prostate in the male			1 x 0.12/13

For the calculation of the effective dose gender averaged values of the equivalent doses are used for the organs or tissues in rows 1, 3, 4 and 5. For the organs or tissues in rows 2 and 6 gender specific equivalent doses are determined in the male and female computational phantom. The mean values for the organs or tissues of these two rows are used for the effective dose calculation.

The sum of all the individual sums Σw_T in column 3 has to be one by definition.

(120)

Equation (4.6) defines the sum of doses and not an average as stated in the text.

Thus, the two equations (4.6) are incorrect. The sums over the 13 remainder tissues have to be multiplied by "(1/13)" to compute the arithmetic mean.

Last sentence of (120): Replace "(4.5)" by "(4.6)".

(133) Equation (4.10):

It should be noted that $H_p(10)$ is not a good approximation of E for exposures to low-energy photons or to electrons.

(135) '…The dose is not usually obtained by direct measurements…'.

After large scale environmental contaminations, e.g. after the Chernobyl accident, public exposure has been obtained by direct measurements (TLD measurements of external exposures and whole body measurements of internal exposures).

(145)

The unit '*man sievert'* is proposed to be changed in '*person sievert'*.

(241) ' ... However new data on radiosensitivity of the eye with regard to visual impairment are expected and the Commission will consider these data when they become available.´

New data on dose thresholds for cataract have been accumulating and point to a threshold much below the previously assumed 1.5 Sv. This includes e.g. studies among Chernobyl liquidators and most notably a reanalysis of atomic-bomb cataract data (Nakashima et al, 2006) where the threshold in dose response did not differ significantly from 0 Sv whereas point estimates were in the 0.6 - 0.7 Sv range. It would seem prudent to consider these new data and propose lower dose limits for the lens of the eye in the new recommendation text.

(269) Insurance companies may also require individuals to receive medical exposures. In these cases, the public constraints are not appropriate and national authorities should use higher values similar to those for helpers and carers of a few mSv per episode.

It should be pointed out that exposures due to medico-legal purposes, screening programs, or exposures due to "patients will" are not part of "medical exposures". They need a different justification by national legislative authorities. In these cases, there is not necessarily an "individual" indication involved, but an "assumed" benefit for a specified group, an economical advantage for a company or avoidance of risks for groups to which the exposed person even does not necessarily belong to.

(276) The recommendations do not explicitly state that urine should be stored or that patients should be hospitalised after therapy with high activities of radiopharmaceuticals. The public dose limits and dose constraints for other individuals should be observed. The decision to hospitalise or release a patient after therapy should be made on an individual basis considering several factors including residual activity in the patient, patient's wishes, family consideration particularly the presence of children and environmental factors.

One should add, that additional considerations for hospitalisation are the health status of the patient and the possibility to obtain information on the patient's dose through several measurements per day.

(281)

Cosmic radiation at flight levels is not mentioned. There is only a short remark on cosmic radiation at ground level (para (284)). Supplement necessary.

(282) ...Industries producing NORMs include: extractive industries for energy production; use of phosphate rock; and mining and milling of mineral sands.

and:

(288) ...Many industrially ***processed ores*** *are enriched in radionuclides in the thorium and uranium decay chains. The levels of these radionuclides are often* ***further elevated*** *in waste streams and by-products. ... New facilities for processing such materials, where radiological protection requirement can be considered during the design stage, are* ***planned situations****. The Commission's requirements for such situations should apply.*

ICRP should distinguish the terms NORM and TENORM to assign unchanged natural materials containing natural radioactive nuclides and those materials which contain those nuclides with enhanced concentrations as a consequence of technological changes.

ICRP should refrain from specifying certain industries and not mentioning others. ICRP should give a rationale based on dose criteria which industries should be included and which not.

It is not mentioned in the recommendation, but in paragraph (143) of the "Scope" document: deliberate dilution of NORM and TENORM materials.

"Scope" (143) Deliberate dilution of material (as opposed to the dilution that takes place in normal operations when radioactivity is not a consideration) to meet the recommended values of activity concentration given should not be permitted without the prior approval of the regulatory authorities. The Commission notes that while the recommended approach for management of radioactive waste is the treatment, reduction in volume and containment of radionuclides, for some types of waste, however, dilution may be the optimum regulatory option. For instance, dilution of waste from minerals processing operations, in which the only radionuclides in significant concentrations are ^{40}K *or those in the decay chains headed by* ^{238}U, ^{235}U *or* ^{232}Th, *may be permitted on the grounds that this is nothing more than re-establishing the original natural concentration of the ore.*

ICRP should not open the pathway for deliberate dilution of residues and wastes since what is meaningful for natural radionuclides could be equally meaningful for artificial ones.

(294) Many natural radiation sources are not amenable to control in that they are unavoidable or uncontrollable, at least without inordinate effort, or while theoretically controllable are not feasible to control. Examples of sources which should be excluded are cosmic rays at ground level, ^{40}K *in the human body and unmodified concentrations of naturally occurring radionuclides in most materials, except food stuffs, drinking water and animal feed, below* ***1000 Bq/kg for the heads of uranium and thorium series and 10,000 Bq/kg for*** ^{40}***K.*** *Due to the wide variations in residential radon concentrations between regions, exclusion levels should be set 40 Bq* m^{-3}, *i.e. the global mean indoor radon concentration The Commission recommends that such sources are excluded from the radiation protection system.*

These recommended values are not acceptable for the SSK since they cannot be derived from a de minimis concept and since it is not clear how they can be justified by lack of amenability of control or inefficiency of regulations. Without generic model calculations of the expected exposures in particular exposure scenarios such values cannot be justified. They merely appear to reflect minimum consensus numbers without radiological meaning.

The SSK has performed such model calculations for various exposure scenarios in the context of areas contaminated with natural radionuclides as a consequence of Uranium mining and milling (SSK 1992, Vol. 23). Using a dose criterion of 1 mSv per year, the SSK considers such areas only acceptable for general use taking into account the expected external and internal exposures of members of the public if the activity concentrations are less than 200 Bq kg^{-1}. The 5times higher exemption values proposed by ICRP do not fit into the dose system for exemption.

Actual model calculations by the SSK support this view. In figures 1 and 2 and tables 3 and 4, the results of such calculations are shown for large areas with materials containing 1,000 Bq kg^{-1} of uranium and thorium, respectively.

Table 3: Expected annual radiation exposures in mSv of members of the public living on soil with an activity concentration of 1,000 Bq kg^{-1} natural uranium in equilibrium with its decay products calculated on the basis of the Berechnungsgrundlagen Bergbau (http://www.bfs.de/www/extfs/ion/anthropg/fachinfo/berech_gl/ber_bgb.pdf). The model calculations do not take into account the exposures expected due to contamination of surface and ground water or the exposure due to inhalation of radon.

Age group	**≤1 a**	**>1 - ≤2 a**	**>2 - ≤7 a**	**>7 - ≤12 a**	**>12 - ≤17 a**	**>17 a**
external exposure	3.714	3.250	3.250	3.250	2.786	2.786
direct ingestion of soil		6.348	2.285	0.392	0.440	0.169
inhalation of dust	0.039	0.067	0.071	0.089	0.100	0.103
milk, milk products	0.251	0.241	0.140	0.145	0.214	0.042
meat, meat products	0.160	0.137	0.268	0.216	0.186	0.136
fish	0.000	0.000	0.000	0.000	0.000	0.000
grain, grain products	1.225	1.019	1.477	1.289	1.407	0.624
fruit, fruit products	2.552	1.528	1.200	0.882	0.768	0.198
potatoes, root vegetables	3.062	1.358	0.831	0.746	0.704	0.312
leafy vegetables	0.306	0.204	0.129	0.122	0.141	0.074
vegetables	0.510	0.577	0.554	0.475	0.448	0.227
drinking water	-	-	-	-	-	-
mother´s milk	0.272					
total	12.092	14.729	10.204	7.606	7.193	4.670

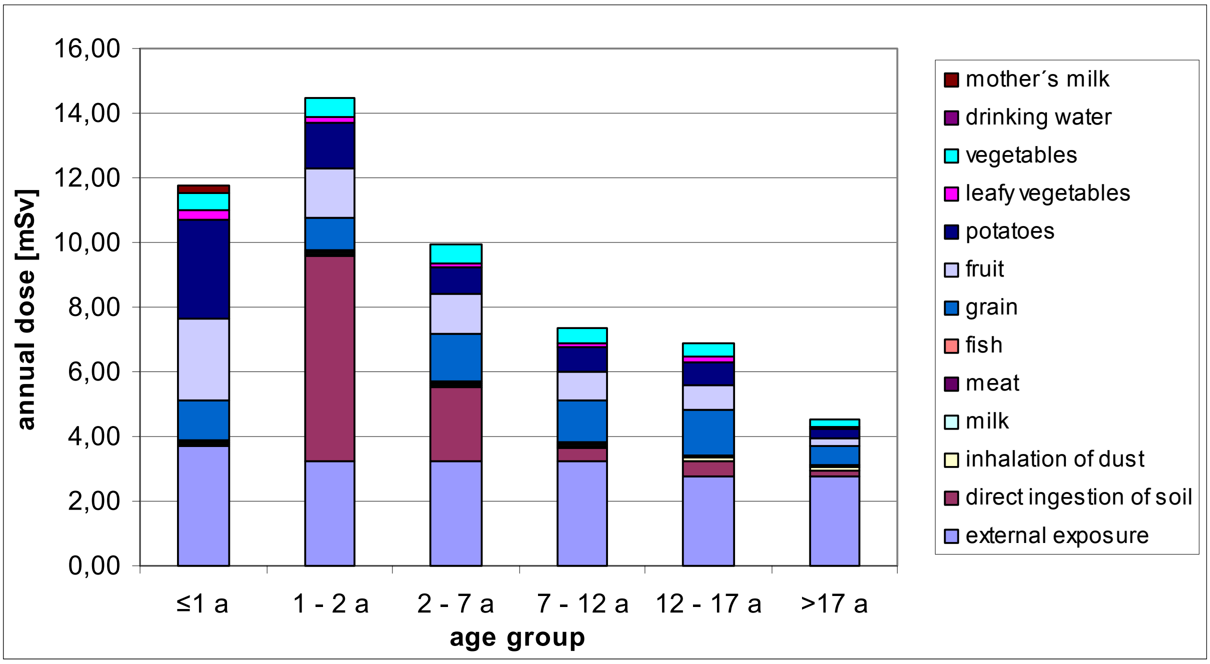

Figure 1: Expected annual radiation exposures in mSv of members of the public living on soil with an activity concentration of 1,000 Bq kg^{-1} natural uranium in equilibrium with its decay products calculated on the basis of the Berechnungsgrundlagen Bergbau (http://www.bfs.de/www/extfs/ion/anthropg/fachinfo/berech_gl/ber_bgb.pdf). The model calculations do not take into account the exposures expected due to contamination of surface and ground water or the exposure due to inhalation of radon.

Table 4: Expected annual radiation exposures in mSv of members of the public living on soil with an activity concentration of 1,000 Bq kg^{-1} Thorium in equilibrium with its decay products calculated on the basis of the Berechnungsgrundlagen Bergbau (http://www.bfs.de/www/extfs/ion/anthropg/fachinfo/berech_gl/ber_bgb.pdf). The model calculations do not take into account the exposures expected due to contamination of surface and ground water or the exposure due to inhalation of radon.

Age group	**≤1 a**	**>1 - ≤2 a**	**>2 - ≤7 a**	**>7 - ≤12 a**	**>12 - ≤17 a**	**>17 a**
external exposure	3.714	3.250	3.250	3.250	2.786	2.786
direct ingestion of soil		5.712	2.087	0.456	0.593	0.104
inhalation of dust	0.048	0.073	0.079	0.096	0.112	0.110
milk, milk products	1.024	0.656	0.391	0.465	0.619	0.067
meat, meat products	0.035	0.016	0.037	0.054	0.088	0.014
fish	0.000	0.000	0.000	0.000	0.000	0.000

Age group	**≤1 a**	**>1 - ≤2 a**	**>2 - ≤7 a**	**>7 - ≤12 a**	**>12 - ≤17 a**	**>17 a**
grain, grain products	1.039	0.462	0.738	0.976	1.497	0.222
fruit, fruit products	2.164	0.693	0.600	0.668	0.817	0.071
potatoes, root vegetables	2.597	0.616	0.415	0.565	0.749	0.111
leafy vegetables	0.260	0.092	0.065	0.092	0.150	0.026
vegetables	0.433	0.262	0.277	0.359	0.476	0.081
drinking water	-	-	-	-	-	-
baby food	0.782					
total	12.094	11.832	7.938	6.981	7.886	3.592

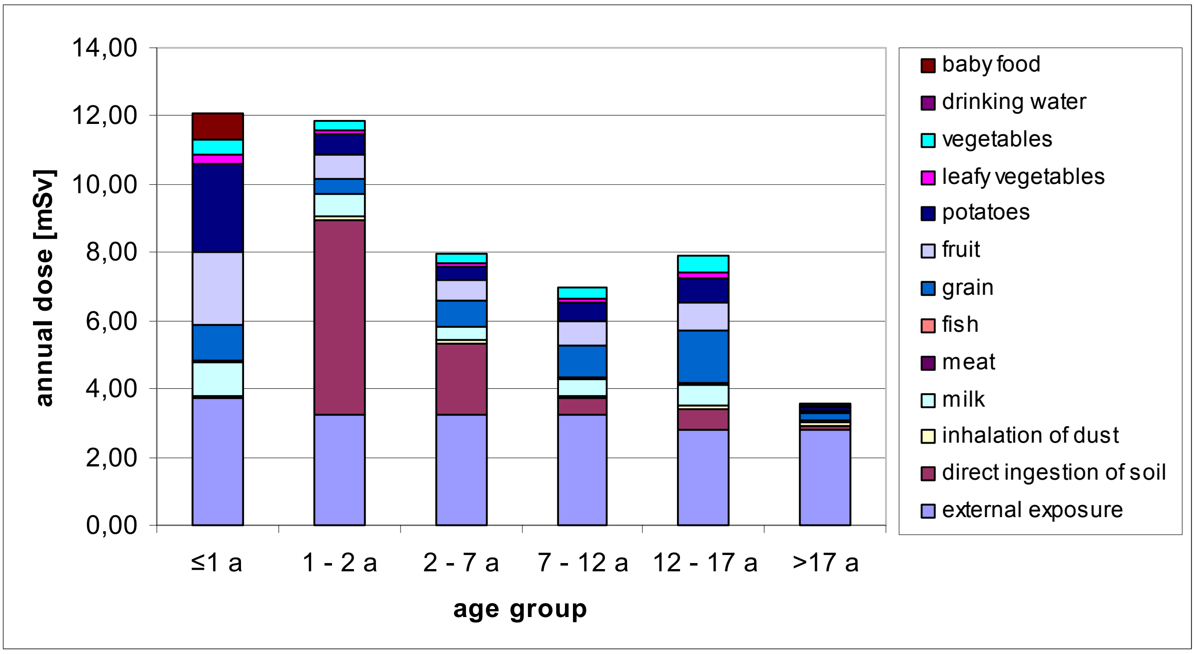

Figure 2: Expected annual radiation exposures in mSv of members of the public living on soil with an activity concentration of 1,000 Bq kg^{-1} Thorium in equilibrium with its decay products calculated on the basis of the Berechnungsgrundlagen Bergbau (http://www.bfs.de/www/extfs/ion/anthropg/fachinfo/berech_gl/ber_bgb.pdf). The model calculations do not take into account the exposures expected due to contamination of surface and ground water or the exposure due to inhalation of radon.

Also, the activity concentration proposed by ICRP for ^{40}K leads to radiation exposures which are not in compliance with the *de minimis* criterion. With a dose conversion coefficient for the external exposure according to (UNSCEAR 1993) of 0.0414 nGy h^{-1} per Bq kg^{-1} one expects for large areas with potassium-rich substances with 1,000 Bq kg^{-1} annual external exposures of nearly 4 mSv.

(301) ...the Commission reaffirms the basic principles for controlling radon exposure as set out in Publication 65 (ICRP, 1994a). Even though the nominal risk per Sv has changed slightly, the Commission, for the sake of continuity and practicality, retains the relationship between the constraint of 10 mSv given in Publication 65 and the recommended corresponding activity concentration. This means that the radon constraints remain at 1,500 Bq m^{-3} for workplaces and 600 Bq m^{-3} for homes (Table 6).

In the light of the European pooling study (Darby et al., 2005 BMJ, 2006 Scand.J Work Environ Health) it seems problematic to recommend such a high radon constraint for homes:

The ERR of 0.16 per 100 Bq m^{-3} found in that study means that in a country with an average radon concentration of 50 Bq m^{-3} the constraint of 600 Bq m^{-3} would almost correspond to a doubling of the RR.

Since the European pooling study shows a significantly elevated risk already in the range of 100-199 Bq m^{-3} it would be appropriate to consider this in the recommendation.

Furthermore, it should be taken into account that the radon concentration in most countries is close to lognormal. That means that the population attributable risk (PAR) for lung cancer due to radon at high concentrations is very small. Based on the European pooling study it has been calculated for Germany, that the total PAR is 5% and the PAR for concentrations above 100-199 Bq m^{-3} is 1% and above 600 Bq m^{-3} is only approximately 0.1 %. (Menzler S, Schaffrath-Rosario A, Wichmann HE, Kreienbrock L (2006) Estimation of the attributable lung cancer risk in Germany due to radon in homes. Report for the Federal Agency on Radiological Protection, in German). Therefore, for a relevant part of the population a constraint of 600 Bq m^{-3} would not be protective.

(302) It is the responsibility of the appropriate national authorities, as with other sources, to establish their own constraints ...

Here it should be added that the national constraint (or “guideline value” or “aim”) for radon in homes should try to be as close as possible to 100-199 Bq m^{-3} since at this concentration significant health effects have been found and the number of avoidable lung cancer cases is much higher if radon exposures are reduced to 100 Bq m^{-3} rather than to 600 Bq m^{-3}.

These suggestions are based on the recommendations of the SSK (SSK 2005: *Lung cancer risk due to radon exposure in homes,* Recommendation of the German Commission on Radiological Protection, http://www.ssk.de/werke/kurzinfo/2005/ssk0504.htm, SSK 2006: *Attributable lung cancer risk due to radon exposure in homes*, Recommendation of the German Commission on Radiological Protection, in German). It should be mentioned that WHO is currently preparing a guideline for radon in homes.

(309) The initial treatment of potential exposures should form part of the protection applied to planned or existing situations. It should be recognised that the exposures, if they occur,

may lead to actions both to reduce the probability of the events occurring, and limit and reduce the exposure (mitigation) if any event were to occur (ICRP, 1991; 1997).

The first "if they occur" should be omitted: in the planning stage actions are taken to reduce the probability of the event to occur.

(318) '…For occupational exposures, the Commission continues to recommend a generic risk constraint of 2 10^{-4}….'

Is this risk constraint meant per year or per life-time?

Using the nominal risk coefficient of 0.04 Sv^{-1}, a constraint for **life-time dose** of 5 mSv can be derived. It should be explained, how this value relates to the range for constraints for **annual dose** of 1-20 mSv, as given in Table 4 (actually Table 5 on page 61 of the draft).

(319)….The estimates of annual probabilities of initiating events much less than 10^{-6} must be treated with doubt because of the serious uncertainty of predicting the existence of all the unlikely initiating events.

As far as the annual probability of a specific initiating event is to be determined there seems to be no reason why values below 10^{-6} should not be sufficiently founded. For instance, that a plant is hit by a larger meteorite or a crash of a military jet. What ICRP wants to express is presumably that for situations where accidents can occur from a spectrum of initiating events one has to be cautious "because of the serious uncertainty of predicting the existence of all the unlikely initiating events" that could lead to an accident.

(353) The Commission has previously concerned itself with mankind's environment only with regard to the transfer of radionuclides through it, primarily in relation to planned exposure situations, because this directly affects the radiological protection of human beings. In such situations, it has been considered that the standards of environmental control needed to protect the general public would ensure that other species are not put at risk, ***and the Commission continues to believe that this is likely to be the case.*** *However, the Commission considers that it is now necessary to provide advice with regard to all exposure situations, including those that may arise as a result of accidents and emergencies, and those that exist but were not planned. It also believes that it is necessary to consider a wider range of environmental situations, irrespective of any human connection with them. The Commission notes that its recommended weighting factors for man, and effective dose as defined for man, are not intended for non-human species and cannot be utilised for such purposes. The Commission is also aware of the needs of some national authorities to demonstrate, directly and explicitly, that the environment is being protected, even under planned situations.*

It would be highly desirable if IRCP were more specific with respect to those situations in which it „*continues to believe that this is likely to be the case*". On the basis of recent literature, e.g. by A. Real, S. Sundell-Bergman, J.F. Knowles, D.S. Woodhead and I. Zinger, Effects of ionising radiation exposure on plants, fish and mammals: relevant data for environmental radiation protection, J. Radiol. Prot. 24 (2004) A123 – A137, it would be possible to give guidance up to which doses or dose rates this believe holds true in ecosystems where man receives doses below 1 mSv per year. This would be of outmost importance for practical aspects of radiological protection.

(355) Reference animals and plants

The ICRP is developing a small set of Reference Animals and Plants, plus their relevant data bases, for a few types of organisms that are typical of the major environments. The SSK is convinced that there is no need to model doses of reference animals and plants in most cases where the protection of the environment has to be evaluated. There are relatively high dose rates which have been identified as thresholds for significant harm to animals and plants (results of research projects, e.g. FASSET). Priority should be given to identify such thresholds and to recommend their application, because this is of major interest in radiation protection practice.

The protection of soil, air and water is still not recommended by the ICRP. In other fields of environmental protection these nonliving 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.

Glossary

'Excess absolute risk '…The excess absolute risk is often expressed as the additive excess per Gy or per Sv'.

'Additive excess per Gy' is a mixture of a quantity (additive excess) and a unit (Gy). It is propose to replace the sentence by 'The excess absolute risk per unit dose has the unit (PY Gy)$^{-1}$ or (PY Sv)$^{-1}$

'Excess relative risk '…The excess relative risk is often expressed as the relative excess per Gy or per Sv'.

'Relative excess per Gy' is a mixture of a quantity (relative excess) and a unit (Gy). It is proposed to replace the sentence by 'The excess relative risk per unit dose has the unit Gy^{-1} or Sv^{-1}.

3 Comments to Annex B

Use of the quantity *N* in different context
Various quantities *N* are used in various contexts throughout Annex B:

Equation (2.1), N is "the product of all other modifying factors".
Equation (3.1), dN is "the number of particles incident upon a small sphere …"
Equation (5.1), dN is "the expectation value of the number of spontaneous nuclear transitions …", and
Equations (5.11) ff, dN is "the number of individuals who experience an effective dose …"

This should possibly be avoided. For "the product of all other modifying factors" it is proposed to choose a completely different name, whereas denominating "numbers of" something by the letter N seems quite logic. Here a distinction could be achieved by applying subscripts, e.g. N_p, N_t, and N_i for the number of particles, nuclear transitions, and individuals, respectively.

Eq. (3.17): this text is incompatible with the text in table 2 (note 3). The number of remainder tissues is 14, but only 13 are used for averaging over each gender. Add the factor “(1/13)” in the equations (3.17). Use the same symbols in the eq. (4.6) in the main text and (3.17) in the annex B.

Revise the notes of table 2 as follows:

Note 3: Add after Prostate “(for male)”,
Add after Uterus/cervic “(for female)”.

Note 4: Delete. This note is in contradiction to table 4 in the main part.

Table 4 in the main part and table 2 in the annex are inconsistent.

Remark: The equation (4.5) of the main text is missing completely in the Annex B.
The main text seems to be clearer understandable.

Figure 4: the masses of the reference persons given in the figure should be 73 kg and 60 kg instead of 70 kg and 58 kg (old values of ICRP Publication 89).

5.5.1, last paragraph: In cases of external exposure to low penetrating radiation, e.g. beta particle, very inhomogeneous irradiation of the body may occur. Even at effective doses below the limits high local skin doses could occur where tissue reactions are possible. For this reason the limit of skin dose (150 mSv per year for occupational exposure) corresponds to the local skin dose defined by the mean equivalent dose in 0.07 mm depth averaged over any 1 cm^2 of the skin.

”150 mSv” should be replaced by “500 mSv”, and after the last word “skin” it should be added: “and has to be estimated with suitable dosemeters”.

Chapter 5.5.2 should read: ”Any regulatory system will include guidance on the minimum requirements for keeping of dose records. The degree of detail and the retention period of dose records should be defined formally. It is, however, desirable to also retain records containing the supplementary information used in the interpretation of monitoring in the work place <u>and those obtained by the measurement of personal dose equivalent itself</u>. *As a general guide, and subject to regulatory requirements, dose records of individual workers should be stored for periods comparable with the expected lifetime of the individual; those containing the supplementary information should be retained for a period long enough to be available for any likely re-assessment of the dose record. Further advice on dose record keeping has been given by the International Atomic Energy Agency (IAEA, 1999)”.*

The underlined text should be added.

Chapter 3.5.1.3: The text after eq. (3.15) dealing with RBE values for neutrons with energies above 50 MeV should be supplemented with recent results.

R. Nolte, K.-H. Mühlbradt, J.P. Meulders, G. Stephan, M. Haney, E. Schmid: *RBE of quasi-monoenergetic 60 MeV neutron radiation for induction of dicentric chromosomes in human lymphocytes,* Radiat. Environ. Biophys. 44; 201-209 (2005)

R. Nolte, V. Dangendorf, A. Buffler, F.D. Brooks, J.P. Slabbert, F.D. Smit, M. Haney, E. Schmid, G. Stephan: *RBE of 200 MeV Neutron Radiation for the Induction of Chromosomal Aberrations in Human Lymphocytes,* submitted for publication in proceedings of "International Workshop on Fast Neutron Detectors and Applications" PoS (FNDA2006)

Chapter 5.5.1: Please, add the following (underlined) text after

For the assessment of effective dose in the special case of air crew exposure by cosmic radiation routine monitoring is not usually performed with individual personal dosemeters measuring $H_p(10)$*. In these cases exposure is assessed by determining the ambient dose equivalent,* $H^*(10)$*, and applying conversion coefficients.* Due to the complexity of the cosmic radiation at aviation and owing to the rather constant particle composition and particle fluences (except during energetic solar particle events, SPEs) at altitudes the calculation of the ambient dose equivalent is an accepted method for the dose assessment of aircrew members. This implicitly requires the validation of the software packages with real data which can only be done by well characterised dosemeter systems.