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Dose limits for occupational skin exposure to ionising radiation

Statement by the German Commission on Radiological Protection

Adopted at the 251st meeting of the German Commission on Radiological Protection on 25th October 2011

The German original of this English translation was published in 2011 by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety under the title:

Grenzwerte für die Strahlenexposition der Haut beim beruflichen Umgang mit ionisierender Strahlung

Stellungnahme der Strahlenschutzkommission

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1 Issue at hand

In a more recent analysis of the data on atomic bomb survivors (Preston et al. 2007), the excess relative risk (ERR) for the incidence of non-melanocytic skin cancer was evaluated. On the basis of this data, the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety asked whether the present limitation of the skin organ dose together with the limitation of the effective dose can still be considered sufficient protection against stochastic effects on the skin and which conclusions might or can be drawn with regard to protection against radiation exposure at the workplace.

2 Background

Dose limits for occupational skin exposure to ionising radiation are laid down in Article 55 of the Radiation Protection Ordinance 2001 (Strahlenschutzverordnung – StrlSchV 2001) and in Article 31 of the X-Ray Ordinance 2003 (Röntgenverordnung – RöV 2003).

For exposed persons the limit for the *organ dose* for the skin, hands, lower arms, feet and ankles is 500 mSv each for the calendar year (Article 55 (2) 2 of the StrSchV 2001 and Article 31a (2) 2 of the RöV 2003). This refers to the *local skin dose*, as a product of the averaged absorbed dose of a certain skin area, at a tissue depth of 0.07 mm and the radiation weighting factor w_R, represented by the value $H_p(0.07)$. The averaging area is always 1 cm², independent of the skin area exposed (StrSchV, Annex VI, Part B No. 1; RöV Article 2, 6d).

If only the skin is exposed, the *effective dose* is calculated solely by multiplying the averaged skin dose with the tissue weighting factor $w_T = 0.01$. Its limit is 20 mSv per calendar year in accordance with Article 55 (1) of the StrlSchV (2001), Article 31a (1) of the RöV (2003) and ICRP 103 (ICRP 2007). The calculation is based on the averaging of $H_p(0.07)$ over the whole skin area (StrlSchV 2001); the average adult skin area pursuant to ICRP 103 (ICRP 2007) is 1.9 m^2 for men and 1.66 m^2 for women. A local skin dose of 500 mSv (total exposed area 1cm^2) therefore equals only an effective dose of 0.26 µSv in case of a total skin area of 1.9 m^2. Even if the whole skin area were exposed to a dose of 500 mSv this would only equal an effective dose of 5 mSv.

The tissue weighting factors are based largely on data on atomic bomb survivors in Japan (Life Span Study) with regard to cancer mortality (Preston *et al.* 2003) and cancer incidence (Preston *et al.* 2007). The underlying dose values refer solely to neutron and gamma radiation with a high penetrating power. Radiation of low penetrating power is not taken into account in this context. Therefore applying tissue weighting factors derived from this requires an averaging over the whole skin area. In the context of occupational radiation exposure homogeneous radiation of the whole skin area in relation to the limit values almost never occurs.

The effects of radiation may be stochastic (e. g. tumour induction) or deterministic (e. g. dermatrophy). They only occur at exposed sites. The human skin is a large target organ in which significant dose inhomogeneities may occur due to its unregular shape and (partial) shielding by hair, clothes etc. In addition, several tumours can occur at different sites, a specific characteristic of the skin.

Skin cancer can be subdivided into malignant melanomas and the non-melanozytic forms, i.e. squamous cell carcinoma and basal cell carcinoma. While the malignant melanoma and the squamous cell carcinoma have a poor prognosis when diagnosed at a late stage, the basal cell carcinoma does not generally have any effects on life expectancy; with the latter the main

effect is restricted quality of life due to the destructive growth of this carcinoma, e. g. in the facial area.

Overall, skin cancer is among the most frequent tumour diseases, mainly induced by UV radiation. In Germany around 195 000 cases of one of the three types of skin cancer are newly diagnosed each year (www.krebsregister-sh.de); among them 24 000 malignant melanomas, 54 000 squamous cell carcinomas and 117 000 basal cell carcinomas.

3 Dose deposition in the skin in cases of occupational radiation exposure

In Germany the skin dose is rarely recorded separately. The report by the Federal Office for Radiation Protection (BfS) on occupational radiation exposure in Germany in 2007 (Frasch *et al.* 2009) only comprises 44 monitored persons, among them 22 exposed; the averaged local skin dose ($H_p(0.07)$) of the persons exposed was 6 mSv. As only very few data are available, data on the radiation exposure of the hands was also included, as this is also expressed in $H_p(0.07)$. With regard to hand exposure 19 724 persons were monitored, among them 5 923 exposed, with an average dose of the hands amounting to 15 mSv; in four cases the annual limit value of 500 mSv was exceeded. The report shows that the major part of the collective dose originates in the medical sphere, where it is mainly due to the handling of unshielded radioactive substances. One problem is that in most cases the dose was measured on the inner side of the fingers, with an average epidermis thickness of 0.3 mm (Konoshie and Yoshizawa, 1985). It is deduced from Cross *et al.* (1982), that the measuring unit $H_p(0.07)$ thus overestimates the real dose at the basal layer of the epidermis by a factor of 35.

4 Epidemiological studies

For many types of cancer, the Life Span Study - relating to the population in Japan - showed clear associations between radiation dose and cancer incidence. Due to its diligent data collection including the implementation of cancer registries and comparisons with mortality tables the Life Span Study represents a globally unique data basis. Its key results are scientifically valid and consistent.

In a more recent analysis of the data on atomic bomb survivors in 2007, Preston and his co-authors examined the excess relative risk (ERR) for the incidence of non-melanocytic skin cancer. They based their work on two different models: a linear dependency on the dose and an increase in the slope of the dose-effect-relationship at 1Gy. Depending on the model applied, the resulting ERR at 1Gy (ERR_{1Gy})[a] was 0.58 (linear dose-effect-relationship) and 0.17/Gy for doses <1 Gy and 1.2/Gy (90 %-CI: 0.57–2.3) for doses >1 Gy (change of the slope) respectively, with the latter model describing the data significantly better. Histologically speaking, there was a strong association between radiation exposure and the incidence of basal cell carcinomas (ERR_{1Gy}=0.57, 90 %-CI: 0.18–1.38) for the linear dependency and 0.48 (90 %-CI: 0.12–1.3) and 2.64 (90 %-CI: 2.2–3.0) for doses </>1 Gy, with a change of the slope.

In earlier analyses of the Life Span Study (Ron *et al.* 1998) an ERR_{1Sv}[b] of 0.62 (90 %-CI: 0.23–1.30) resulted for all types of non-melanocytic skin cancer and of 1.8 (90 %-CI: 0.83–3.30) for basal cell carcinoma. A later analysis (Kishikawa *et al.* 2005) resulted in an ERR per dose of 1.9 per Sv (95 %-CI: 0.8–3.9) for basal cell carcinomas.

[a] [b]The dose given here (weighted skin dose, shielded kerna in Gy (Preston et al. 2007) or Sv, respectively (Run et

Overall, the results with regard to the non-melanocytic skin cancer from the Life Span Study can be considered conclusive. It can be assumed that there is a connection between radiation dose and incidence of the basal cell carcinoma. However, no statistically significant connection between the radiation dose and the incidence of squamous cell carcinoma could be found in the Life Span Study. The Life Span Study is not suitable for assessing the incidence of malignant melanomas depending on the radiation dose, as only 17 incidences occurred during the follow-up observation period of approximately 40 years.

In the modelling of the dose dependency of basal cell carcinoma by Preston *et al.* (2007) the ERR for doses <1 Gy is 0.17/Gy and thus clearly below that for higher doses (>1 Gy ERR 1.2/Gy). This directly affects the assessment of the *attributable fraction* (i.e. the estimated share of tumours which are attributable to radiation exposure). With radiation doses <0,1 Gy only up to 3 % of basal cell carcinoma are to be attributed to radiation exposure; with doses between 0.1 and <1 Gy the attributable fraction is 10 to 18%. With radiation doses >1 Gy the attributable fraction increases to more than 50%.

If applying the results of the Preston Study (Preston *et al.* 2007) to risk assessment, the limited transferability of the results regarding specific types of skin cancer to European conditions must be discussed. The malignant melanoma has an age-standardised annual incidence rate (calculated for Germany pursuant to the world standard) of 11.9 per 100 000 men and 12.6 per 100 000 women (Globocan 2008); however, the incidence rate in Japan is very low (M: 0.5 per 100 000; F: 0.6 pro 100 000). Due to insufficient international data collection no valid incidence data for non-melanocytic skin cancer are available; however, differences between German and Japan should be similar.

5 Expert statement

The SSK therefore concludes:

- The new analysis of the data of the Life Span Study cohort results in valid risk assessments with regard to a homogeneous skin exposure to ionising radiation.
- The new analyses by Preston *et al.* (2007) basically confirm the former results of the Life Span Study. Therefore it does not seem to be necessary to modify the limits for the skin organ dose together with the limitation of the effective dose.

Persons with an occupational exposure to radiation generally experience dose inhomogeneities and varying exposures for sites of different epidermis thickness. However, this is not the case with the cohort in the Life Span Study. Dose inhomogeneities should be taken into account if the results of the Life Span Study are to be applied to occupational exposure to radiation.

Applying the surface personal dose $Hp(0.07)$ to describe the local skin dose at the hands is not an ideal approach. A new concept which, for example, would take into account the varying skin thickness at different sites and the related dose reduction depending on the radiation energy needs to be discussed on the international level.

As yet there is only very limited conclusive data on occupational skin exposure to ionising radiation in Germany. Such a data collection would be desirable as a basis for epidemiological analyses.

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