CORAR
Council on Radionuclides and Radiopharmaceuticals, Inc.
3911 Campolindo Drive
Moraga, CA 94556-1551
925-283-1850
FAX 925-283-1850
corar@silcon.com

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COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS POSITION PAPER ON SKIN DOSE LIMITS

EXECUTIVE SUMMARY

In recent years there has been considerable interest in the nuclear power industry concerning personnel skin exposure from "hot particles." The realization that microcurie (37k becquerel) quantities of beta-emitting radionuclides can deliver doses in the order of hundreds to thousands of rads (one to tens gray) to small areas of the basal layer of the skin without significant effect prompted the need to revise the dose limitation system. [(1)(2)]

It was also recognized that the dose limit for other sources of irradiation of small areas of skin such as contamination on skin or external exposure of small areas of skin by external radiation beams, could be similarly treated.

In the U.S. the National Council on Radiation Protection and Measurements (NCRP) reviewed these developments and recommended a revision to the skin dose limit [(3)] which was subsequently adopted by the U.S. Nuclear Regulatory Commission (NRC) and promulgated in revised regulations [(4)]. CORAR recommended to the International Commission on Radiological Protection (ICRP) [(5)] that the annual occupational skin dose limit should be 500 mSv averaged over 10 cm^2.

CORAR members include the major radiochemical and radiopharmaceutical manufacturers and distributors in the U.S. and Canada. Products are used for biomedical research, and medical diagnosis and therapy. CORAR members consequently have considerable experience in managing the safe use of radionuclides and have interest in assuring that occupational radiation protection is optimized.

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POSITION PAPER ON SKIN DOSE LIMITS

CURRENT ICRP RECOMMENDED SKIN DOSE LIMIT

The current ICRP recommended occupational dose limit for skin is the Annual Equivalent Dose Limit for Skin of 500 mSv averaged over 1 cm^2 area of skin regardless of the area exposed. [6]

This limit was well known to be over protective for stochastic effects. It is now understood that it is also over protective for unacceptable deterministic effects. Hence the ICRP skin dose limit is much more conservative than the recommended occupational limits for effective dose, lens of the eye and hands and feet. This imbalance between the recommended dose limits can prevent the optimization of radiation protection in certain occupational exposure conditions.

SKIN DOSE EFFECTS

The effects of ionizing radiation on skin are well known and include the induction of skin cancer, erythema, ulceration and late effects. For large-area uniform exposures at low doses, the risk of skin cancer is thought to be proportional to the area irradiated and to the average skin dose. The latent period for skin cancer is greater than 20 years and the mortality rate is very low. Hence, the risk of mortality from skin cancer due to irradiation with ionizing radiation is low compared with other tissues at risk in the body. For this reason, the ICRP assigns a conservative weighting factor, w_t, of 0.01 for total body skin irradiation [7]. This factor is conservative when mortality from skin cancer is the considered end point. A higher weighting factor may be necessary if the deterministic damage often produced in treating skin tumors is considered unacceptable and is to be avoided [8].

When an area of skin is irradiated non-uniformly or the area is much less than 100 cm^2, the risk of stochastic effects is significantly reduced. For very small areas of 1 cm^2 or less, stochastic effects are considered relatively unimportant and dose limitations are dominated by deterministic effects [8]. Furthermore, repeated high irradiation of small areas due to skin contamination is unlikely in practice and it should normally only be necessary to consider acute effects in single exposure events.

RECENT STUDIES ON THE EFFECTS OF SMALL AREA SKIN IRRADIATION

Recent studies on the irradiation of human and pig skin has greatly improved our understanding of acute effects [9] [10]. Irradiation of superficial epithelial cells with low energy betas such as from ^{147}Pm (maximum beta energy 225 keV) can result in erythema and transient moist desquamation in a few weeks. Irradiation of epithelial cells and the vascular system at the base of the dermis with more penetrating betas from $^{90}Sr/^{90}Y$ (maximum beta energy 2.27 MeV) results in erythema and transient moist desquamation initially and dermal necrosis 10-16 weeks after exposure. The thresholds for these acute effects considerably exceed 2,000 rad and depend on the depth of penetration and area irradiated [8]. The magnitude of these very high thresholds clearly indicates the need to review current regulatory practice. NCRP Report No.130 [11], published in 1999, summarizes the results of animal studies that provide additional information on the effects of low energy (i.e., maximum energy less than 500 keV) beta radiation on small areas of skin and the effects of low energy beta and gamma radiation. These studies imply that the 500 mSv averaged over 1 cm^2 skin dose limit is more conservatively protective against deterministic effects than is necessary. In NCRP 130, a new limit of 500 mGy averaged over 10 cm^2 is recommended for skin dose from single irradiation events due to hot particles. This limit was considered adequate to prevent the breakdown of the skin barrier and prevent subsequent infection.

NCRP STATEMENT No. 9 [3]

The NRC requested that the NCRP investigate the feasibility of establishing a skin dose limit that would be applicable to all skin dose geometries. The NCRP published the results of this investigation in Statement No. 9 on March 30, 2001. The NCRP recommended an annual limit of 0.5 Gy averaged over the most highly exposed 10 cm^2 of skin at a tissue depth of 70 μm.

This new recommended limit was applicable to radiation exposure from hot particles on the skin or on hair or clothing near the skin, small area skin contamination and exposure to small areas of skin by external radiation beams. This limit was also considered sufficient to prevent the breakdown of the skin barrier and subsequent infection.

To ensure that the NCRP recommendation was sufficiently protective, the NRC sponsored reviews of potential health implications that confirmed that stochastic effects on the skin were negligible and deterministic effects in worst-case scenarios were slight and acceptable. [12] [4]

NRC REVISION OF SKIN DOSE LIMIT REGULATION. [4]

On April 5, 2002, the NRC published a revision of the regulatory annual dose limit, specifying it as a shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole-body or the skin of any extremity. [4]

The assigned shallow-dose equivalent is defined in the regulation as the dose equivalent at a tissue depth of 0.007 cm ($7 mg/cm^3$) averaged over the contiguous 10 cm^2 of skin of the whole-body or extremity receiving the highest external exposure.

This new annual limit is elegantly applicable to both large area and small area skin irradiation and is also compatible with the extremity dose limit, simplifying compliance.

The NRC requirement to determine the dose equivalent at a tissue depth of 0.007 cm is different from regulatory requirements in other countries. For example, in the UK and Canada it is permissible to determine the dose at the applicable affected tissue depth.

SKIN EXPOSURE CONSIDERATIONS

In the 1980's radiation protection staff in the U.S. nuclear power industry had the following concerns about skin exposure to "hot particles":

a. There was a need to timely detect "hot particles" to enable them to be promptly removed to minimize exposure.

b. There was a need to determine the skin dose to demonstrate compliance with the regulatory limit.

c. The time taken to prevent, detect, remove and assess hot particles in the presence of ambient penetrating radiation caused an increase in whole body dose to the operators and radiation protection staff or to operators when leaving and reentering the radiation area to monitor.

d. It was perceived that efforts to minimize the dose from hot particles were resulting in more serious risk of stochastic effects due to increased whole body effective dose.

"Hot particle" control was primarily a concern of the fuel-cycle industry in the U.S.. However, it was recognized that similar, if less common, conditions of non-uniform skin exposure occur in other occupations in the U.S.. These conditions include:

a. Small area skin contamination due to the transfer of beta-emitting radionuclides through undetected pin-holes in gloves or the penetration of gloves when handling equipment with rough surfaces. These conditions are commonly encountered in nuclear medicine, nuclear pharmacy, radiopharmaceutical manufacturing, radiochemical manufacturing and biomedical research operations.

b. Leakage radiation from shielded syringes used to dispense gamma, x-ray and/or beta-emitting radionuclides in nuclear pharmacy, biomedical research and radiopharmaceutical manufacturing quality control operations.

c. Occupational non-uniform radiation encountered during medical procedures including computerized tomography, brachytherapy and fluoroscopy.

In the above exposure conditions the radiation worker is subject to both non-uniform skin dose, mostly to the hands, and a lower amount of whole-body exposure. To minimize the skin dose it may be necessary to frequently monitor to allow prompt detection and dose avoidance. However, like monitoring for "hot particles", this may cause an increase in effective whole body dose.

In the U.S. the annual number of medical procedures using ionizing radiation is increasing about 5 to 10% each year. Furthermore, new medical technologies often involve greater exposure. This trend increases the occupational exposure of physicians, medical support staff, and radiopharmaceutical dispensing technologists. These workers are emerging as the highest exposed group in the U.S.. This is the main reason that it is impractical in the U.S. to implement an occupational annual effective dose limit of 20 mSv. The ICRP should consider trends in other countries and the need to revise the skin dose limit to facilitate the optimization of protection.

Although most significant cases of skin contamination involve the irradiation of very small areas of skin, it is recognized that there are other less frequent situations that should be treated differently. Uniform wide area contamination should involve a more restrictive dose limit than non-uniform localized contamination. This also applies to cases of contaminated clothing that may have moved during activities and consequently caused a wide area of skin to be irradiated. Certain labelled compounds, especially halogenated acids and other compounds that readily complex with proteins, will penetrate protective clothing and skin and then prove difficult to remove unless harsh decontamination methods are used. Normally, emissions from low energy beta-emitters, such as ^{14}C, ^{35}S and ^{3}H, deposited on the surface of thick skin cannot penetrate the skin to reach live tissue. If, however, the radionuclide is absorbed into the skin, the close proximity of these beta-emitters to live tissue can result in prolonged significant irradiation. These, less common, skin contamination situations can result in a wide range of doses according to the specific circumstances. They might require careful study to derive a correct dose assessment. Generally, it is not difficult to identify these special situations. Although dose assessment may be complex in certain rare situations, the dose-effect relationships are similar.

Strategies to minimize exposure include: automating dispensing operations, improving the efficiency of procedures, using a team approach to reduce the exposure of critical individuals and maintain accurate occupational dosimetry that is not over-conservative. For example, the use of robotic dispensing systems has greatly reduced exposure from ^{32}P radiochemical processing in the manufacturing industry. However, these controls are often harder to deploy in the hospital.

CORAR RECOMMENDATIONS

CORAR recommends that the ICRP considers adopting an annual skin dose limit of 500 mSv averaged over 10 cm^2. This recommended limit should provide a similar level of protection as the ICRP's other occupational limits and would therefore be more compatible with them.

CORAR recommends that skin dose should be assessed at the applicable affected tissue depth, particularly when occupational dose approaches or exceeds the recommended skin dose limit. This practice is necessary to ensure that the significance of skin dose is properly evaluated with respect to the significance of dose to other tissues. This practice is also preferred because it directly produces a skin dose record that more accurately documents the actual dose to the relevant tissue that must be protected. However, CORAR recognizes that, when evaluating past exposure and planning future exposure, the potential for exposing different areas of skin with different applicable tissue depths should be comprehensively considered and appropriate operational controls implemented to accommodate the likely exposure conditions. CORAR recommends that the ICRP should consider promoting the use of a default value for the skin tissue depth of 70 μm when exposure conditions are uncertain or impractical to evaluate to the necessary level of detail.

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