



DOCKET NUMBER
PROPOSED RULE PR 20
(66FR 36502)

2

Council on Radionuclides and Radiopharmaceuticals, Inc.

3911 Campolindo Drive
Moraga, CA 94556-1551
(925) 283-1850
Fax: (925) 283-1850
Email: corar@silcon.com

DOCKETED
USNRC

Henry H. Kramer, Ph.D., FACNP
Executive Director

September 21, 2001 (3:08PM)
OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

September 12, 2001

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

Attn: Rulemakings and Adjudication's Staff

Reference: NRC Proposed Rule on "Revision of the Skin Dose Limit". Federal Register, Vol. 66, No. 134, July 12, 2001

These comments on the above referenced proposed rulemaking are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR)¹.

CORAR members and their customers are NRC and Agreement State licensees who mostly use unsealed sources of radioactive materials where there is a potential for skin contamination. CORAR has been closely involved in the technical developments that form the basis for skin dose limits and is interested in this proposed rule.

CORAR fully supports the proposed rule to change the annual skin dose limit to 50 mrem averaged over the maximally exposed continuous 10cm². This proposed limit is fully protective and more compatible with current annual limits for deep dose, and lens of eye dose. Furthermore, CORAR agrees with the Nuclear Regulatory Commission (NRC) assessment that

¹ CORAR members include the major manufacturers and distributors of radiopharmaceuticals, radioactive sources and research radionuclides used in the U.S. for therapeutic and diagnostic medical applications and for industrial, environmental and biomedical research and quality control.

the proposed skin dose limit is applicable to all types of skin dose including dose caused by external radiation sources, skin contamination and discrete radioactive particles on or near the skin to both wide or small areas of skin.

CORAR appreciates these efforts to establish skin dose limits on a risk informed basis and that the proposal simplifies the regulation. Attached are specific comments which we hope will help licensees understand the proposed ruling.

We appreciate the opportunity to comment on this proposed rule and shall be glad to provide further information or clarification if needed.

Yours sincerely,

A handwritten signature in cursive script, appearing to read "L. R. Smith".

Leonard R. Smith
Chairperson CORAR Committee on Regulatory and
Legislative Issues

**CORAR COMMENTS ON NRC PROPOSED RULE: "REVISION OF THE SKIN DOSE
LIMIT"**

1. Page 36502, Col. 3, § 2

"A result of this rulemaking is to make the skin dose limit less restrictive when small areas of skin are irradiated and to address skin and extremity doses from all source geometries under a single limit".

- a. CORAR appreciates that the proposed rule will be less restrictive than the current skin dose limit for small area irradiation. This will have the beneficial result of allowing licensees to refocus attention and resources on minimizing large area skin dose, deep dose and lens of eye dose which will improve overall protection of the radiation worker.
- b. CORAR appreciates the simplification in the regulation in providing a single dose limit expressed in rem units.

2. Page 36503, Col. 2, § 2

"These contamination events [with high concentration radiopharmaceuticals] produce relatively large doses to very small areas of skin, resulting in an insignificant health detriment".

CORAR agrees with this assessment. This is also recommended by the National Council on Radiation Protection and Measurements supported by an extensive scientific literature referenced in NCRP Report No. 130 and Statement No. 9.

3. Page 36504, Col. 3, § 2

"...NCRP recommended that the absorbed radiation dose to skin at a depth of 70 μm ...from any source of irradiation be limited to 50 rads...averaged over the most highly exposed 10 cm^2 of skin".

- a. CORAR strongly supports the NRC's decision to adopt the above NCRP dose limit recommendation.
- b. This proposed skin dose limit is more compatible with deep dose and lens of eye dose limits than is the current skin dose limit.
- c. The proposed skin dose limit is still considerably more conservative than the deep and lens of eye dose limits. However, a certain amount of extra conservatism is appropriate because shallow dose exposure conditions can often be more difficult to control than deep dose exposure conditions.

4. **Page 36504, Col. 3, § 3**

"...skin exposures at the dose limit of 50 rem ... of SDE averaged over 10 cm² could result in stochastic risks...confirming that stochastic risks at the proposed limit are small."

It would be useful to licensees if this statement was clarified by specifying the skin exposure risks to be estimated for one year or for an occupational lifetime.

5. **Page 36505, Col. 1, § 5**

"...the only dose limit for the extremities is a SDE limit on the dose delivered at a depth of 0.007 cm...not a deep dose limit".

- a. CORAR understands that the proposed shallow dose limit applies to both the skin of the whole body and the skin of the extremity and is not a deep dose limit.
- b. It is not clear what deep dose limit applies to the extremity. CORAR believes that the regulatory intent since 1988 has been to limit deep dose to the extremities to 50 rem per year. However, the definitions in 10 CFR 20.1003 imply that the 5 rem deep dose limit for irradiation from external sources applies to any part of the body without excluding the extremities.
- c. It would be helpful if this could be clarified by defining the Total Effective Dose Equivalent to include "deep dose equivalent (for external exposures)" to correspond only to the "whole body", which is defined to exclude the extremities.
- d. While CORAR supports the shallow dose limit to be specified for tissues at a depth of 0.007 cm as a default value, the NRC should also allow licensees to estimate doses for the actual skin thickness involved. The licensee would have to be able to show that thinner skin was not at risk. There are a considerable class of operations common to research uses of radiochemicals where only the palmar surfaces of the hands are at risk. It is important to allow licensees to demonstrate compliance using the thicker skin of the palmar surfaces (400 μm) because this will encourage the use of ³⁵S and ³³P instead of ³²P. ³⁵S and ³³P are usually significantly less hazardous to work with than ³²P.
- e. It would be useful to explain the above considerations in a Reg. Guide or Information Notice.

6. **Page 36505, Col. 1, § 6**

"...the assigned SDE must be the dose averaged over the 10 contiguous square centimeters of skin receiving the highest exposure".

- a. The National Council on Radiation Protection and Measurements recommends that multiple small area skin exposures in a calendar year only be summed when the exposed areas overlap. While CORAR recognizes that multiple small area exposures in a calendar year are very unlikely it would be useful to licensees if this were clarified in a Reg. Guide or Information Notice and also in a preamble to the final rule.
- b. It would also be useful to clarify in a Reg Guide or Information Notice that the maximally exposed 10 cm² include total shallow dose equivalent from all sources of external exposure.

7. **Page 36506, Col. 2, § 3**

"The commission believes that the less restrictive limit on skin dose to small areas that might permit more observable, transient, deterministic effects will also result in a less hazardous work place and reduced whole-body occupational dose. The Commission considers this tradeoff to represent a substantial increase in worker protection. This represents a shift in emphasis toward a risk-informed approach that would possibly permit more frequent deterministic effects in order to avoid the physical stress and whole-body doses associated with monitoring workers and the use of protective measures".

- a. CORAR agrees with the above statement particularly with respect to controlling discrete particles in a radiation area.
- b. CORAR members and their customers are licensees who are more likely to be concerned with skin contamination from radiochemical solutions rather than discrete particles. For CORAR operations, the main benefit would be increase in worker protection due to shifting emphasis from small area skin contamination to control of deep and lens of eye dose.

8. **Page 36507, Col. 1, § 2**

"The proposed modifications to §§ 20.1003 and 20.1201, ..., are designated compatibility Category A".

CORAR strongly agrees with the NRC that the proposed rule should be adopted identically by Agreement States and should therefore be designated Category A.

9. **Page 36508, Col. 3, § 8**

"(ii) A shallow-dose equivalent of 50 rem.. to the skin of the whole body or to the skin of any extremity".

This rule could be simplified by deleting the end of the sentence starting "of the whole..." However, if this is done the intent of skin to include both the "whole body" and the "extremities" should be fully explained in the definition or in some other place in the regulations.