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OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

November 17, 2006

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

Secretary,  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

Attention: Rulemakings and Adjudications Staff

Reference: NRC proposed rule "Occupational Dose Records; Labeling Containers and the Total Effective Dose Equivalent."  
Federal Register, Vol 71, No. 184  
September 22, 2006.

Subject: Comments on proposed rule  
RIN 3150-AH40.

These comments on the above referenced proposed rule are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR)<sup>1</sup>. CORAR members and their customers are NRC and Agreement State licensees and are, therefore, interested in the first, third and fourth proposed amendments to the regulations that affect material licenses.

On April 6, 2004 CORAR submitted comments on Draft Rule Language on the same topics published in the Federal Register on February 24, 2004. In these attached comments to the proposed rule, CORAR continues to support NRC proposal and provides more extensive justification for preferring a requirement to notify radiation workers above 10% of the occupational limits as opposed to above the NRC's proposed 100 mrem.

CORAR appreciates the NRC's intent to reduce regulatory burden. CORAR also appreciates the opportunity to comment and would be glad to provide clarification or further comments as needed.

Yours Sincerely

A handwritten signature in black ink, appearing to read 'L.R. Smith'.

Leonard R. Smith, CHP  
CORAR Manufacturing Quality and Safety Committee.

1. CORAR is a North American trade association that includes members who are the major manufacturers and distributors of radiopharmaceuticals, radioactive sources and research radiochemicals used for therapeutic and diagnostic medical applications and for industrial environmental and biomedical research and quality control.

**CORAR COMMENTS ON NRC PROPOSED RULE ON OCCUPATIONAL DOSE RECORDS, LABELING CONTAINERS, AND THE TOTAL EFFECTIVE DOSE EQUIVALENT.**

**1. Page 55383, column 3, paragraph 3.**

**“The NRC is proposing a change to the notification requirement in 10 CFR 19.13 (b) so that licensees would provide reports to occupationally exposed individuals whose annual dose exceeds 1 millisievert (mSv) (100 millirem (mrem)) TEDE or 1mSv (100 mrem) to any individual organ or tissue in the preceding year....**

**The criterion of 1 mSv(100mrem) was selected because it corresponds to the occupational dose threshold for requiring instruction to workers under 10 CFR 19.12.”**

- a. CORAR has previously recommended to the NRC that licenses should not be required to report occupational dose to workers when their annual dose is less than 10% of the applicable dose limits.
- b. If there is a substantive reason why a licensee should report lower doses to workers, this could be established as a license condition.
- c. Licensees who want to report lower doses to workers can do so.
- d. It is not clear why the NRC selected 1 mSv (100mrem) to be identical with the criterion for requiring instruction to workers under 10 CFR 19.12. We do not see any advantage in using the same criterion for notification and instruction. It would be helpful if the NRC explained the reason for selecting the same criterion for both requirements.
- e. The primary objection for using a 1mSv (100mrem) criterion for notification is that it results in different requirements for a facility where individuals are monitored and for a facility where individuals are not monitored. The proposed rule provides a strong incentive for a licensee to cease monitoring workers who might exceed 1mSv (100mrem) in a year but are unlikely to exceed 10% of the applicable limits. In an ambient economic climate where licensee managements are continuously seeking ways to minimize costs to be competitive, the proposed rule will make it difficult for a Radiation Safety Officer to justify assigning dosimeters to confirm the low doses that most workers receive. This will make it more difficult to demonstrate compliance.

- f. CORAR recommends that both the reporting requirements and the monitoring requirement use the same dose criteria so as to not compromise programs for using dosimeters to confirm compliance.
- g. CORAR also prefers that criteria are based on a percentage of the applicable limits. This preserves the graded approach to controlling exposure that the NRC promotes in risk informed regulations.
- h. Finally, 1mSv (100 mrem) per year is below the detection limit for TLD's that are used for dosimeter wear periods that are less than a month. Dose reports at this level would therefore be meaningless for extremity monitoring where TLD's are the preferred dosimeter and when short dosimeter wear periods are necessary.

**2. Page 55384, column 1, paragraph 1.**

**“This approach is simpler because there is one reporting threshold instead of three and results in the same reduction in burden.”**

- a. Different licensees are likely to have different opinions on whether the proposed approach is simpler. Some believe that having the 10% criterion for both reporting and monitoring is a more logical and simpler approach than different criteria for the two requirements.
- b. CORAR's recommendation allows licensees to choose either criteria or some optimal intermediate administrative criteria that best relates to the licensee's conditions and practices.

**3. Page 55384, column 1, paragraph 1 “...(i.e., 10mSv(1000rem)).**

The “1000 rem” should be “1000 mrem”.

**4. Page 55385, column 2, paragraph 3**

**“The fourth proposed amendment would remove the provision in 10 CFR 20. 2104 (a) (2) that requires licensees to attempt to obtain the records of cumulative occupational radiation dose for each worker requiring monitoring under 10 CFR 20. 1502.**

CORAR agrees that this requirement is redundant for most licensees who never need to have planned exposures exceeding annual limits.

5. Page 55386, column 1, paragraph 3

**“NUREG-0713, Volume 26, indicates that raising the threshold from the proposed value of 1 mSv (100mrem) would not significantly reduce administrative and information collection burdens on licensees.**

- a. This may be generally correct for all licensees collectively but some licensees will expect a significant difference in burden.
- b. If CORAR’s recommendation is accepted, those licensees who would not be affected by a different threshold would be able to select the NRC’s proposed 100 mrem threshold if they wanted.