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

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Attention: Rulemakings and Adjudications Staff

Reference: NRC notice of "Collection, Reporting, or Posting Information; Availability of Draft Rule Language". Federal Register, Vol. 69, No. 36, February 24, 2004

These comments on the above referenced draft rule language are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR)¹. CORAR members and their customers are NRC and Agreement State licensees and are, therefore, interested in the first, third and fourth sections of the draft rule that affect material licensees.

CORAR supports most of the proposed changes in this draft rule and indicates others to be reconsidered in the attached comments. 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,

Leonard R. Smith
CORAR Committee on Regulatory and Legislative Issues

¹CORAR 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 for industrial, environmental and biomedical research and quality control.

Template = SECY-067

SECY-02

CORAR COMMENTS ON NRC DRAFT RULE ON COLLECTION REPORTING OR POSTING OF INFORMATION

1. **Page 8351, col. 1, paragraph 1.**
“...licensees would continue the current [annual] reporting [to workers] for workers who receive more than 2 percent of the limits specified in 10CFR20.1201 (...100 millirem in one year)”.
 - a. 10CFR10.1502 only requires licensees to monitor worker external exposure when there is a reasonable expectation that the worker could exceed 500 mrem in a year. CORAR recommends that licensees should not therefore be required to inform workers unless their annual exposure exceeds 10 percent of the limits.
 - b. Licensees often provide dosimeters to workers, who enter Restricted Areas, but who are unlikely to receive more than 500 mrem in a year. This is a convenient way to document their low exposure. Licensees should not be required to report these doses to workers when they exceed 2% of the limits.
 - c. It would be useful if the NRC clarified why it believes it is necessary to require licensees to report annual dose to workers who receive less than 500 mrem in a year.

2. **Page 8351, col. 1, paragraph 3 and col. 2, paragraph 1**
“(1) Does the language being considered appropriately balance the intent of the Federal Government’s guidance and regulations...in...avoiding burdensome requirements...while adequately providing...information.

CORAR agrees that the language being considered satisfies both federal requirements for providing information to occupationally exposed workers and reducing regulatory burden.

3. **Page 8351, col. 2, paragraph 2**
“(2)...is “exceeds 2 percent of the dose limit...or the worker makes a request for a report of their dose” a reasonable threshold)?”
 - a. CORAR agrees that there should be a dose threshold for reporting annual dose to occupationally exposed individuals.
 - b. CORAR considers a more appropriate threshold to be 500 mrem because there may be numerous unmonitored individuals who receive between 100 and 500 mrem in a year.
 - c. CORAR would appreciate the NRC explaining why licensees who monitor employees that receive less than 500 mrem should receive reports when others who are similarly exposed are not monitored and cannot, therefore, receive reports.
 - d. CORAR agrees that the licensee should be required to provide an annual and termination report on exposure when workers request.

4. **Page 8351, col. 2, paragraph 3**
“(3) Would the change...result in cost savings...”
- a. The suggested changes should reduce the quantity of reports and should result in cost savings to most licensees.
 - b. The total cost savings to all licensees in the country could be substantive. Cost savings to individual licensees should vary considerably according to how automated the report process is. Some licensees may continue to provide dose reports even if not required by the changed regulation, and therefore, will not be significantly affected.
 - c. For a manufacturing license, with 300 employees who are monitored for radiation exposure and where the data is managed electronically, savings due to the NRC proposal may be only \$100 per year. If a 500 mrem threshold was used, the savings would be greater than \$300 per year. However, a license where the data is managed manually may realize substantially larger cost savings from the changes under consideration.
5. **Page 8351, col. 2, paragraph 4**
“(4) Should licensees be required to notify workers periodically of their right to request their dose report...”
- a. Current requirements to inform workers of their right to request their dose report when they register in a dosimeter or bioassay program should be continued.
 - b. The NRC should also update NRC Form 2 “Notice to Employees” to reflect the proposed changes.
6. **Page 8351, col. 2, paragraph 5**
“(5) Does the possible consolidation of required reports...into 10CFR20.2205 and the deletion of 10CFR 19.13(d) clarify the regulations and could there be a significant cost associated with implementing this possible change’.
- a. The proposed change clarifies the regulations.
 - b. Agreement States should be required to adopt strictly compatible reporting requirements to facilitate uniform understanding of the regulations.
 - c. The cost of this change should be minimal for licensees. Regulatory agencies would need to update their regulations, but this would be a one time cost with small, but long term cost savings benefits.

7. Page 8351, col. 3, paragraph 1

“...require that licensees obtain the records of cumulative occupational radiation dose only for those individuals being authorized to receive a planned special exposure”.

- a. CORAR agrees with the NRC proposal to delete the requirement to obtain records of exposure in previous years unless a planned special exposure is intended.
- b. Most material licensees do not provide for planned special exposures and, therefore, do not need records of exposure in previous years.
- c. Some licensees may still need to obtain records of prior exposure since they perceive that these records can be used to support liability protection.
- d. The NRC should emphasize in the proposed regulations the requirement that licensees must still provide cumulative dose records when requested by a worker.
- e. Licensees will still need to obtain dose records for the current year to be able to ensure compliance with 10CFR20.1201.

8. Page 8351, col. 3, paragraph 3

“(1) would the change,...ensure adequate protection of radiation workers?”

The change should not affect the protection of radiation workers.

9. Page 8351, col. 3, paragraph 4

“(2) would the change,...result in cost savings to licensees?...”

- a. The change should reduce the number of requests for records and follow-ups when there are delays in responding to the request. The cost savings, however, will be small because the licensee hiring the worker may still need to request dose records for the current year.
- b. In manufacturing industry most new hires do not have prior dose records. For example in one manufacturer with 250 radiation workers only three requests for records were made in 2003. In this case the savings would be about \$30 per year.

10. Page 8352, col. 1, paragraph 4

“(3) Should the rule address approvals by Agreement States of dosimetry methods for using effective dose equivalent when external exposure is determined by measurement.”

CORAR recommends that if the NRC redefines Total Effect Dose Equivalent the new definition must also be adopted by the Agreement States.