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CORAR

Council on Radionuclides and Radiopharmaceuticals, Inc.

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

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

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

June 24, 2003

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555
Attention: Rulemaking an Adjudications Staff

RE: Rulemaking on Controlling the Disposition of Solid Materials: Scoping Process for Environmental Issues and Notice of Workshop. Federal Register Vol. 68, No. 40, p. 9595.

Gentlemen:

These comments concerning the rulemaking on controlling the disposition of solid materials are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR members include manufacturers of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals and sealed sources used in therapy, diagnostic imaging and calibration of instrumentation used in medical applications.

General

1. CORAR urges the NRC to proceed with rulemaking on the disposition of solid materials based on a dose standard.

2. We agree with NCRP's position (from Report No. 141) that in order to avoid the imposition of excessive cost and regulatory burden, there is a need to exclude certain practices and/or materials involving small amounts of radioactivity from the scope of regulation.

3. Any regulations established by NRC for release and disposal of solid materials should be a matter of compatibility with the Agreement States.

4. If the National Academies have determined that the current approach adequately protects public health and safety, then any new standard employed by NRC to control release or disposal of solid material should utilize methodology already in place to ensure practical application and reasonable, measurable performance expectations to facilitate demonstration of compliance.

5. The radiological criterion for releasing materials potentially contaminated with licensed radioactive material should be consistent with the dose-based limits established in ANSI/HPS N 13.12-1999 based on the public annual dose limit of 1 mrem/year, with a provision for doses up to 100 mrem/year on a case-by-case basis taking into account that members of a critical group could be exposed to multiple sources.

6. The NRC or NCRP should make a realistic assessment of the probability for multiple exposure sources to a critical group. In our industry experience it appears that the number of multiple sources that can expose a critical group to doses comparable with the public dose limit are typically one and very rarely two (i.e. not the four to six commonly assumed by NRC and NCRP to justify limits of 25 to 15 mrem/year for a single practice or pathway).

7. Contamination control guidelines are usually based on the assumption that infinite surface or volumes of material are contaminated at the limit. There needs to be recognition in the guidelines that contamination is not normally infinite but in well-controlled operations it is usually very limited in extent. For example, facility surface contamination is usually due to tracking small specks of contamination and the total quantity of radioactive material involved commonly in the nanocurie to microcurie range and therefore not sufficient to cause exposure that is a significant fraction of the exposure limits.

8. The NRC needs to differentiate between bulk and surface contaminated objects, short and long-lived radioactive material, uniformly and heterogeneously contaminated objects, and fixed and removable contamination when defining standards.

9. The NRC needs to differentiate between potential contamination and exposure risks for large sources and slightly contaminated materials where the radioactive material is distributed in the materials cleared for release.

Alternative 3 (Conditional Use) – Solid material could be released but its further use would be restricted to only certain authorized uses with limited public exposure environments.

1. Development of clearance standards needs to consider the NCRP position (NCRP Report 141, p. 63) that the primary goal in developing clearance criteria and procedures is to avoid unnecessary costs and the waste of resource materials that could have other beneficial uses within society.

2. The 1 mrem/year standard under consideration might be used as a screening standard but must not be a "limit for release." NCRP has established 1 mrem/year, as a "negligible individual dose" below which reduction of dose to the public is unwarranted. Release of materials resulting in doses above this level should be allowed if justified within a framework of regulatory constraints and the NCRP limit of 100 mrem/year to the public.

3. There needs to be a definition of clearance that excludes routine transfers of radioactive products, personnel and personal effects from restricted areas used to control contamination. For example: it would be unreasonable and impractical to subject individuals leaving a

radiologically restricted area to the same release criteria as solid materials.

4. Standards and guidelines on monitoring for clearance should be set such that current commonly available monitoring instruments have adequate sensitivity to unambiguously clear materials.

5. Detection capability of current and future monitoring technology raises the possibility of conflicts with risk-based release criteria.

6. There is a need for uniform clearance standards especially with regard to measurement of contamination levels. This is especially important where monitors are in use at locations such as landfills and scrap yards. The levels at which alarms are triggered need to be in line with any standards established for monitoring materials at the point of release.

7. Any NRC standard for release of materials should be able to be employed on a case-by-case basis by licensees as part of an established radiation safety program or license condition in terms of practical, measurable levels and the types of commercially available instruments typically used. Alternatively, NRC could use an approach similar to that used for release of patients administered radioactive materials where radionuclide-specific release criteria are based on activity or radiation level with a provision for calculation to justify release above certain quantities.

Alternative 4 – Solid material would be prohibited from general commerce by requiring it to be placed in an EPA-regulated landfill.

1. It is highly important from a waste minimization standpoint to ensure that we maintain currently acceptable procedures for monitoring short-lived radioactive materials in waste held for decay prior to disposal. This is especially true for low-level, short-lived radionuclides involved in manufacture and use of radiopharmaceuticals and other medical use material.

2. Radioactive waste materials placed in a disposal site should not be disposed such that they could become commingled with hazardous chemicals. Licensees do not want to become responsible for other wastes in the event of a disposal site failure. This is of particular concern since EPA inspection and enforcement practices are not as effective as those by the NRC and Agreement State Agencies.

3. Criteria for clearance for disposal should be based on the public annual dose limit of 100 mrem/year, with a provision for recognizing that members of a critical group could be exposed to multiple sources.

CORAR appreciates the intent of this request for comments on the scope of proposed rulemaking and the opportunity to express these comments. Please contact us if there should be any questions or if any additional information is needed concerning these comments.

Sincerely,

R. A. Smith FOR

Mark A. Doruff, CHP
Council on Radionuclides and Radiopharmaceuticals
Committee on Regulatory and Legislative Issues