CORAR

Council on Radionuclides and Radiopharmaceuticals, Inc.

(19)

PR 20,30,31,32,33,35,50,61,62,72,110,150,170, and 171
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Henry H. Kramer, Ph.D., FACNP
Executive Director

September 8, 2006

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

Attention: Rulemaking and Adjudication Staff

RE: (RIN 3150-AH84) Proposed Rule – Requirements for Expanded Definition of Byproduct Material. Federal Register Vol. 71, No. 145, July 28, 2006.

These comments concerning the Proposed Rule are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR members include manufacturers and shippers 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. CORAR membership also includes manufacturers and operators of cyclotrons used to manufacture PET radionuclides and operators of cyclotrons in the commercial production of other radiopharmaceuticals. CORAR has an interest in ensuring that these products can be made available as needed for the delivery of quality patient treatment and care and the regulation of both byproduct and accelerator-produced radioactive material to ensure the safety of workers, patients and other members of the public.

In the past, CORAR had expressed that it is conditionally in favor of the expansion of NRC regulatory jurisdiction to include NARM. While CORAR maintains the position[1] that NRC need not continue nor expand its regulation of diagnostic and therapeutic use of radioactive materials, in general we view the Proposed Rule as a positive development in the domestic regulation of radioactive materials.

- NRC has done a good job closely following the Congressional intent in developing the proposed rule for NARM.
- NRC has taken many of the comments provided by the regulated community at previous workshops and the ACMUI meeting and worked them into the PRM making the rule much more practical and workable.
- The expansion of NRC's regulatory jurisdiction will streamline the regulatory framework in non-Agreement States. This is especially significant to CORAR whose companies distribute to customers in all states and have operations in most of them.
- We agree with the NRC's proposed approach to regulate radioactive material intentionally and

[1] CORAR comments submitted on January 28, 1998 to NRC Secretary concerning 10 CFR Part 35; Medical Use of Byproduct Material: Issues and Request for Public Input. Federal Register Vol. 62, No. 151, August 6, 1997.

Template = SECY-067

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incidentally produced by accelerators without regulating the actual possession or operation of the accelerator.

CORAR appreciates the effort that NRC has extended to meet the expectations of the congressional mandate for expedited rulemaking. We also appreciate that NRC has met their obligation under Section 651(e) of the EPAct to consider the impact of these regulations on the availability of radioactive drugs to physicians and patients. CORAR has reviewed the PR, considered the requests from NRC for additional comments on specific issues in the PR, and responds with the following specific comments.

1. Other Federal Agencies' Regulatory Jurisdiction Over NARM

1.1. The Occupational Safety and Health Administration published a Request for Information[2] in order to better understand what if any changes the agency needed to consider in its regulation of the use of ionizing radiation in the workplace. CORAR recommends that NRC pursue a memorandum of understanding with OSHA to assume regulatory jurisdiction over the occupational exposure to ionizing radiation in non-Agreement States, where, prior to the expansion of NRC's jurisdiction over NARM, OSHA had jurisdiction as the leading federal agency. NRC should take advantage of this opportunity to work actively with OSHA to streamline the regulatory landscape and eliminate the needless duplication of authority over the use of NARM in non-Agreement States.

2. Particle Accelerators

2.1. CORAR has always found the decommissioning financial assurance funding triggers in Part 30.35 to be appropriate. The PR states that it is considering how to assure the safe decommissioning of particle accelerators buildings and facilities, including the removal and disposal of activated building materials to assure that the dose limits to members of the public are not exceeded. Our experience is that the decommissioning of a commercial production cyclotron facility is a very complicated task and it is costly to demonstrate the level of activation in concrete bunker walls and the cyclotron itself. This often requires making concrete borings into the bunker walls to extract and analyze core samples. CORAR believes that the financial surety requirements in 30.35 should be only applied to the larger (> 18 MeV), commercial production cyclotrons and their facilities, and this approach should be the standard in non-Agreement States where NRC will have jurisdiction. CORAR also requests that Agreement States be urged by NRC to adopt their current requirements for decommissioning where determined by the NRC Integrated Materials Performance Evaluation Program (IMPEP) for Agreement States.

2.2. CORAR does not believe smaller (<18 MeV) cyclotrons designed for the production of PET radionuclides are capable of producing activation products that will trigger the financial assurance requirements in 10 CFR 30.35. Self-shielded PET cyclotrons reduce incidental activation even more. CORAR strongly recommends a categorical exemption for PET cyclotrons from 10 CFR 30.35 financial surety regulations. In support of this, CORAR could provide data on incidental activation resulting from a 16.5 MeV cyclotron running at maximum beam current at maximum duty cycle to the NRC staff.

2.3. NRC states that the EPAct does not give NRC the authority to regulate the possession or operation of particle accelerators. It is then difficult to understand how NRC plans to regulate both the intentionally and incidentally produced radioactive materials, and the decommissioning of facilities under 10 CFR Part 30. In other words, since the requirements in NRC regulations (including 30.35) generally apply to licensees, what will be the process for NRC to commence regulatory oversight of an accelerator facility in a non-Agreement State if NRC authority (which conventionally is established by an NRC-approved license) does not apply to

[2] Occupational Safety and Health Administration. Occupational Exposure to Ionizing Radiation – Request for Information. Docket No. H-016. Federal Register Vol. 70, Page 22828. May 3, 2005.

the owner and operator? At what point and with what regulatory mechanism will the NRC assume oversight of the radioactive material produced by an accelerator in a non-Agreement State? There are some states that currently have no requirements for a license to operate an accelerator or for the material that is produced so it cannot simply be assumed in all cases that a state license will transition to the NRC. NRC will need to establish and communicate a practical process for obtaining NRC authority to produce material by an accelerator prior to operating the machine.

3. Consideration of SSRs in the NRC's Regulatory Approach

3.1. CORAR agrees, as NRC has stated in the PR, with the "general agreement among the States" that accelerator-produced materials should be regulated in a manner consistent with regulation of byproduct material. If this agreement is reflected in the SSRs, then CORAR strongly recommends that these be used as a model for better consistency to be achieved between different Agreement States. While this is an issue that CORAR needs to address with organizations such as Conference of Radiation Control Program Directors (CRCPD) and the Organization of Agreement States, we urge the NRC to work more closely and effectively with the states to ensure that they adopt NRC requirements consistently and as recommended as a result of IMPEP reviews.

4. Regulatory Framework for Accelerator-Produced Radioactive Material Used in Medical Activities

4.1. CORAR agrees with NRC's proposal that facilities authorized by a state to produce PET radionuclides for non-commercial distribution be allowed to do so without a medical distribution license.

4.2. As discussed in 2.2, above, NRC should categorically exempt small cyclotrons (<18 MeV) that produce PET radionuclides from the decommissioning financial surety requirements in 10 CFR 30.35.

4.3. CORAR continues to be concerned about the grandfathering of PET cyclotron operators and engineers. The preamble of the proposed rule discusses including the grandfathering of these types of professionals as Authorized Users in Part 30. CORAR expected to see an expanded definition in Part 30 to include these jobs. However, CORAR was not able to find such a modified definition in proposed Part 30. We would like to see this grandfathering codified in the final rule to assure these individuals are covered as Authorized Users.

5. Consideration of NARM in 10 CFR Part 20, Appendix B

5.1. CORAR had originally planned to file a Petition for Rulemaking to suggest new DACs for O-15 & N-13. CORAR had believed the values in the proposed rule would be unreasonably low. Since that time CORAR has solicited the help of Dr. Michael Stabin at Vanderbilt University to calculate new DACs for O-15 & N-13 using ICRP 30 and EPA Federal Guidance Report #12 methodology. We found the default DACs for these two radionuclides in the PRM were precisely what that accepted methodology yielded. Based on this, CORAR will not file a Petition for Rulemaking, but recommends these specific DACs for O-15 and N-13 be added to 10 CFR 20 Appendix B as follows:

Radionuclide	Class	Table 1, Column 3	Table 2, Column 1
		Inhalation DAC	Effluent Concentration – Air
Nitrogen-13	Submersion	1.4×10^5 Bq/m^3 (3.8×10^{-6} µCi/mL)	6.5×10^2 Bq/m^3 (1.8×10^{-8} µCi/mL)
Oxygen-15	Submersion	1.4×10^5 Bq/m^3 (3.8×10^{-6} µCi/mL)	6.5×10^2 Bq/m^3 (1.8×10^{-8} µCi/mL)

6. License Application and Annual Fees

6.1. There are CORAR members who will be required to obtain NRC licenses for the production of accelerator-produced radioactive materials. These licenses would supplant licenses currently issued by non-Agreement States for production, possession and distribution of accelerator-produced radionuclides. In many more locations, CORAR companies will be required to obtain NRC licenses for possession and distribution of accelerator-produced materials, principally radiopharmaceuticals. CORAR is not as much concerned about the need to obtain NRC licenses than it is about the fact that in many locations, non-Agreement States will likely not surrender their requirements for a license or registration to be maintained with license or maintenance fees associated with this. Some states have already indicated that they will require a NARM license regardless of whether an NRC license is required. This, with the addition of the proposed licensing of exempt quantities of accelerator-produced materials, indicates that the landscape of domestic radioactive materials licensing is expanding rather than becoming more streamlined which has been part of NRC's strategic plan, fully supported by CORAR in the past.

It is understood that since the NRC will not have jurisdiction over the possession and operation of accelerators, the States will continue to impose their requirements for licensing or registration of these radiation producing machines. However, NRC needs to be aware of our concern that some states will not surrender their current license requirements for accelerator-produced materials and address this in its transition plan as required in Section 651(e) of the EPAct.

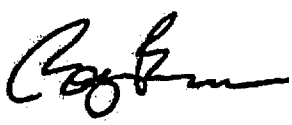
7. Transition Plan

7.1. Currently, some NRC licenses authorize the use of licensed material at temporary jobsites anywhere in the United States where NRC maintains jurisdiction for regulating the use of licensed material. CORAR would like NRC to confirm that upon the effective date of the rule, holders of such licenses will be able to amend them to add accelerator-produced radionuclides. CORAR would also like NRC to confirm that once such a license is amended, the licensee will be able to perform activities using accelerator-produced materials authorized in the license at temporary locations within non-Agreement States upon termination of the waiver period on August 8, 2009.

7.2. We urge the NRC to work very closely with the Organization of Agreement States and the CRCPD as well as the States themselves to address any licensing or transactional issues that may arise as a result of the transition of authority to ensure that our supply chain will not be disrupted.

Thank you for the opportunity to submit comments on this Proposed Rule. If, in consideration of these recommendations, you or your staff need additional information from CORAR or have any questions, please contact me at (314) 795-6166.

Sincerely,



Roy W. Brown
Senior Director, Federal Affairs
Council on Radionuclides and Radiopharmaceuticals

From: Carol Gallagher
To: SECY
Date: Mon, Sep 11, 2006 4:58 PM
Subject: Comment letter on Requirements for Expanded Definition of Byproduct Material

Attached for docketing is a comment letter on the above noted proposed rule from Roy W. Brown, Council on Radionuclides and Radiopharmaceuticals, Inc., that I received via the rulemaking website on 9/9/06.

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Thanks,
Carol

Mail Envelope Properties (4505CE0D.D21 : 5 : 35764)

Subject:	Comment letter on Requirements for Expanded Definition of Byproduct Material
Creation Date	Mon, Sep 11, 2006 4:58 PM
From:	Carol Gallagher
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MESSAGE	811	Monday, September 11, 2006 4:58 PM
TEXT.htm	723	
1646-0012.pdf	64845	Monday, September 11, 2006 4:34 PM

Options

Expiration Date:	None
Priority:	Standard
ReplyRequested:	No
Return Notification:	None
Concealed Subject:	No
Security:	Standard

Junk Mail Handling Evaluation Results
Message is not eligible for Junk Mail handling
Message is from an internal sender

Junk Mail settings when this message was delivered
Junk Mail handling disabled by User
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Junk List is not enabled
Junk Mail using personal address books is not enabled
Block List is not enabled