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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

October 18, 2006

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

ATTENTION: Rulemakings and Adjudication Staff
SUBJECT: Requirements for Expanded Definition of Byproduct Material
(RIN 3150-AH84)

PROJECT NUMBER: 689

Dear Ms. Vietti-Cook:

The Nuclear Energy Institute (NEI)¹ is submitting the following comments on the "Requirements for Expanded Definition of Byproduct Material" (RIN 3150-AH84) that appeared in the July 28, 2006, *Federal Register*. NEI supports one regulator for all radioactive and nuclear materials. NEI supports the proposed rule as drafted. NEI, however, recommends the Nuclear Regulatory Commission (NRC) take into consideration implementation issues for the new rule.

The initial issue for implementation is the clarification of jurisdiction between the NRC and the Occupational Safety and Health Administration (OSHA). The NRC and OSHA have a Memorandum of Understanding (MOU) concerning industrial safety at NRC licensees however; as a result of the Energy Policy Act 2005 it is important for the NRC and OSHA to have an understanding on the jurisdiction of radioactive material which is located at non-NRC licensed facilities. This would include radioactive material which is an exempt quantity or concentration or within the facility as a Generally Licensed Device. The next issue is the regulation of PET isotopes and facilities. The proposed rule appropriately provides the requirements for the use of PET isotopes and facilities; however,

¹ NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

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in the area of decommissioning of facilities the NRC has not recognized that most PET facilities will not have any significant activation products. Therefore, NEI recommends the NRC consider a threshold such that the smaller (<18 MeV) cyclotrons designed for the production of PET are not subject to the financial surety requirements in 10 CFR 30.35.

Beyond the PET isotopes and facilities is the regulation of the operators. NEI supports the NRC taking a more aggressive approach. Rightfully, the NRC does not seek jurisdiction over the machine but does have jurisdiction over the isotopes, however to grandfather the operators is not appropriate. It is the operators who control the production, removal of targets, and initial processing of the isotopes therefore they should not be grandfathered from the rule but incorporated into the rule. The key reason NEI has been seeking one regulatory over radioactive materials is to address the inconsistencies between states in this area. Without capturing the operators under the rule will result in continued inconsistencies.

Dr. Michael Stabin at Vanderbilt University calculated 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, NEI 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	$1.4 \times 10^5 \text{ Bq/m}^3$ ($3.8 \times 10^{-6} \mu\text{Ci/mL}$)	$6.5 \times 10^2 \text{ Bq/m}^3$ ($1.8 \times 10^{-8} \mu\text{Ci/mL}$)
Oxygen-15	Submersion	$1.4 \times 10^5 \text{ Bq/m}^3$ ($3.8 \times 10^{-6} \mu\text{Ci/mL}$)	$6.5 \times 10^2 \text{ Bq/m}^3$ ($1.8 \times 10^{-8} \mu\text{Ci/mL}$)

Finally, NEI encourages the NRC to work closely with the states in the transition from state regulation to NRC regulation. In a number of facilities there will be dual regulations as the state will maintain its authority over the machine while the NRC establishes authority over the isotopes, this line must be clearly drawn. A number of operators are not fully aware or understand the changing regulations and the differences in authority. It would be most helpful if the NRC partnered in each state and conducted a workshop or training program to facilitate the bases of the change as well as the impact. It is important for this to be a joint effort.

NEI does not have any issues with the proposed rulemaking; however, we are concerned with implementation issues. We would be glad to discuss this with the NRC at its convenience.

Sincerely,



Felix M. Killar, Jr.

From: "KILLAR, Felix" <fmk@nei.org>
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Date: Wed, Oct 18, 2006 10:49 AM
Subject: NEI Comments on Requirements for Expanded Definition of Byproduct Material

Attached are NEI's comments on the proposed rule, we realize that the comment period closed on September 11, 2006. Our comments, however, address implementation issues vs. any changes in the proposed rule. In general we support the rule.

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