



Advancing Molecular Imaging and Therapy

PRM-50-90
(73FR30321)

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September 24, 2008

DOCKETED
USNRC

Submitted Electronically: rulemaking.comments@nrc.gov

September 24, 2008 (1:30pm)

Secretary
US Nuclear Regulatory Commission
Washington, DC 20555-0001
Attn: Rulemakings and Adjudications Staff

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

**RE: Docket No. PRM-50-90; NRC-2008-0279
Natural Resources Defense Council, Petition for Rulemaking**

Dear NRC Rulemakings and Adjudications Staff:

The Society of Nuclear Medicine (SNM)—an international professional organization representing more than 16,000 members dedicated to promoting the science, technology, and practical application of molecular imaging and therapy—appreciates the opportunity to comment on the Natural Resources Defense Council's (NRDC) Petition for Rulemaking (PRM-50-90, *Federal Register*, May 27, 2008) regarding the civilian use of highly enriched uranium (HEU).

In its petition, the NRDC is requesting that the Nuclear Regulatory Commission (NRC) amend the regulations that govern domestic licensing of production and utilization facilities, and special nuclear material to establish a date when the NRC will no longer license the use or export of highly enriched uranium (HEU) except for restricted use by a few specialized facilities. The NRDC asserts that the amendment is needed to protect the public from potential exposure to an improvised nuclear explosive device made with HEU and used by terrorists.

The SNM recommends that the NRDC's petition be denied for the following reasons:

Forcing a change from HEU to low enriched uranium (LEU) will, first and foremost, put patients at risk because of the inevitable delay in production of much needed radionuclides, such as Technetium-99m (Tc-99m) which is made from molybdenum-99 (Mo-99). Tc-99m is used in more than 85,000 nuclear medicine procedures each day around the world. Such procedures include: detection and staging of cancer; detection of heart disease; detection of thyroid disease; study of brain and kidney function; imaging of stress fractures. Currently, no large scale, commercial processes using LEU targets for medical isotopes have been developed and implemented. The technology must first be proven, robust and reliable, and requires a transition period to demonstrate this. Furthermore, the system must be able to provide commercial quantities of Mo-99 (thousands of curies per week, every week). Otherwise patients—the ultimate consumers of Tc-99m—will be put at risk.

Second, the financial impact of forcing a change from HEU to LEU has been underestimated by the NRDC. Although it is technically feasible to produce Mo-99 from LEU, it would not be commercially viable without substantial federal subsidies. In addition to structural and technological changes that must be made, approval will have to be obtained from the Food and Drug Administration (FDA). Any new technology will not be considered complete until it receives both FDA and NRC approval, which is expensive both in terms of time, and the expected fees associated with the application process. It has been estimated that the cost of verifying and generating approval for a different process will be in the millions of dollars.

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SECY-02

Third, the environmental impact such a switch would cause has also been underestimated by the NRDC. A switch to LEU will not only increase the amount of plutonium produced due to the increase in U-238 in the target which will capture neutrons during Mo-99 production, but will also increase the amount of radioactive waste produced. Both the plutonium and the radioactive waste will have to be disposed of properly, further increasing costs, which will ultimately be passed on to the patient.

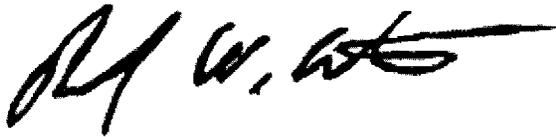
Fourth, the NRDC has based its petition on an article they wrote, which was more opinion than fact, to defend their argument. The fact that they have not cited other technical and scientific literature to defend their petition is evident of its lack of merit.

Finally, the SNM recommends that the NRC possibly re-open the comment period and also delay its decision until there has been time to fully assess the recommendations put forth in the National Academy of Sciences' (NAS) report on "Medical Isotope Production Without Highly Enriched Uranium", due to be released this fall.

An uninterrupted, reliable supply of medical isotopes is essential; any change from HEU to LEU must ensure that patient needs are not compromised.

The SNM appreciates the opportunity to comment on this issue, and is ready to discuss these comments with the NRC. Please contact Hugh Cannon, Director of Health Policy and Regulatory Affairs at hcannon@snm.org, or 703.708.9000, ext. 1322.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert Atcher". The signature is stylized and includes a long horizontal flourish extending to the right.

Robert Atcher, Ph.D., MBA
SNM President

Rulemaking Comments

From: Tomlinson Cindy [CTomlinson@snm.org]
Sent: Wednesday, September 24, 2008 10:56 AM
To: Rulemaking Comments
Subject: Docket No. PRM-50-90; NRC-2008-0279
Attachments: SNM Comments PRM-50-90.pdf

Please find attached SNM's comments on PRM 50-90; NRC 2008-0279.

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Received: from mail2.nrc.gov (148.184.176.43) by OWMS01.nrc.gov
(148.184.100.43) with Microsoft SMTP Server id 8.0.751.0; Wed, 24 Sep 2008
10:54:03 -0400

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24 Sep 2008 10:54:02 -0400

X-MimeOLE: Produced By Microsoft Exchange V6.5

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Date: Wed, 24 Sep 2008 10:56:11 -0400

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X-MS-Has-Attach: yes

X-MS-TNEF-Correlator:

Thread-Topic: Docket No. PRM-50-90; NRC-2008-0279

Thread-Index: AckeVa6NphMDG9xXR4G6q5T036aobQ==

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