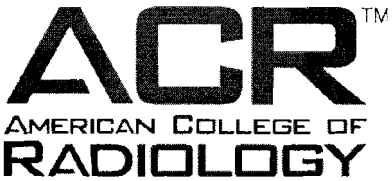
PRM-50-90
(73FR30321)



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USNRC

September 25, 2008 (10:19am)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

September 25, 2008

U.S. Nuclear Regulatory Commission
ATTN: Rulemaking and Adjudications Staff
Washington, DC 20555-0001

Subject: PRM-50-90

As a professional organization serving more than 32,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists, the American College of Radiology (ACR) appreciates the opportunity to comment on the petition for rulemaking (PRM-50-90) filed with the NRC by the Natural Resources Defense Council (NRDC). The petitioner requested the establishment of an end date for the civilian licensing of highly enriched uranium (HEU) used in several research reactors, including the National Research Universal (NRU) facility in Chalk River, Ontario. The ACR is deeply concerned that the policy advocated by the petitioner could seriously jeopardize the availability of medical isotopes relied upon by our patients; we urge against the adoption of such policies without careful consultation and collaboration with industry, review of the relevant NAS reports, and a thorough assessment of the impact any policy changes might have on the supply of medical isotopes. The ACR believes that preserving patients' access to medical isotopes, while simultaneously maintaining safety and security, should be the primary concern throughout the NRC's evaluation of the petition.

Uses of Isotopes in Medicine

Nuclear medicine is a subspecialty within the field of radiology that uses medical isotopes to diagnose or treat disease and other abnormalities within the body. Over 15 million nuclear medicine procedures are performed in the United States each year. According to the National Academies' 2007 report, *Advancing Nuclear Medicine Through Innovation,* more than 70% of all nuclear medicine procedures are based on technetium-99m, a short-lived medical isotope used in imaging the heart, brain, thyroid, lungs, bone, and other areas of the body. Technetium-99m is generated from molybdenum-99 produced at a small number of research reactors in the world, most notably the NRU facility in Canada. Almost all molybdenum-99 is produced using HEU.

Learning From the Past / Preserving Patient Access

The danger of a major research reactor shutdown and its impact on patient care is not theoretical. In November-December 2007, the medical community experienced a drastic isotope shortage of molybdenum-99 when the NRU reactor was unexpectedly shutdown for several weeks. Many North American patients in need of reactor-produced isotopes encountered severe delays in receiving diagnosis and treatment for cancer, heart disease, and other serious illnesses. A majority of physicians were forced to prioritize their patient lists to make efficient use of the available supplies, delaying all other patients or treating them with potentially less effective alternative procedures. The crisis was felt differently by health care providers depending on whether their primary supplier diversified its molybdenum-99 portfolio with non-NRU isotopes or if they had access to alternative suppliers. The situation became so dire that it quickly made international news and caused an unprecedented legislative intervention by the Parliament of Canada to override the Canadian Nuclear Safety Commission's regulatory authority and allow medical isotope production to resume at NRU.

Formalizing a timetable for the discontinuation of HEU without active collaboration with the medical isotope production community has the potential to cause a similar crisis, and perhaps for a longer period of time than in 2007. This is why it is important that the NRC work closely with industry to determine the

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safest path forward to convert research reactors to low enriched uranium (LEU) without negatively impacting patient care.

Cost to Patients and Their Families

A secondary consideration related to the patient access issue is the financial cost of medical isotopes. Notwithstanding the divergent opinions on the feasibility of HEU-to-LEU conversion, it can be reasonably assumed that major modifications at research reactor facilities would probably raise the cost of production. These costs would inevitably be borne by patients and their families.

Similarly, if activities at NRU or another medical isotope production facility were disrupted, the dramatic spike in demand for limited products from alternative suppliers could raise prices. In fact, the medical community reportedly experienced this problem with certain products during the molybdenum-99 shortage in 2007.

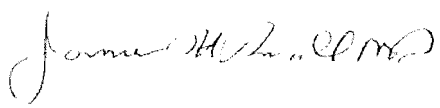
NAS Studies on Medical Isotope Production / Nuclear Medicine

It is important to note that the National Academy of Sciences (NAS) will soon complete a two-year study on the feasibility of medical isotope production without HEU. The final report from this study is expected to be publicly available in late 2008 or early 2009, though a formal publication date has not yet been determined. The NAS also published an earlier report on the state of the science in nuclear medicine, entitled *Advancing Nuclear Medicine Through Innovation*. This report discussed a variety of issues, including the status and challenges of medical isotope availability in the United States. The NRC should carefully review these and other resources that incorporate the findings of the medical community before taking any further action to address the petition.

The ACR believes it would be inappropriate for the NRC to initiate a rulemaking on this issue without careful consultation with industry and review of the relevant NAS reports. The dangerous and real possibility of unintended consequences in terms of a disruption to the medical isotope supply has already been demonstrated by recent events.

Thank you in advance for your consideration. Please contact Gloria Romanelli, ACR Senior Director, Legislative and Regulatory Relations, or Michael Peters, ACR Regulatory Affairs Specialist, at 202-223-1670 if you have questions or need additional information.

Sincerely,



James H. Thrall, MD, FACR
Chair, Board of Chancellors
American College of Radiology

Rulemaking Comments

From: Michael Peters [mpeters@acr.org]
Sent: Wednesday, September 24, 2008 9:16 PM
To: Rulemaking Comments
Cc: Gloria Romanelli
Subject: ACR comments re: NRC PRM-50-90
Attachments: acr-comments_nrc-prm-50-90_9-25-2008.pdf

Please see the attached comments from the American College of Radiology (ACR) addressing PRM-50-90. Thank you in advance for your time and consideration.

Sincerely,

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Regulatory Affairs Specialist
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American College of Radiology
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From: Michael Peters <mpeters@acr.org>
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CC: "Gloria Romanelli" <GRomanelli@acr.org>
Return-Path: mpeters@acr.org
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