August 11, 2008

Ms. Annette L. Vietti-Cook  
Secretary of the Commission  
U.S. Nuclear Regulatory Commission  
Washington, DC 20550001

ATTN: Rulemakings and Adjudications Staff

SUBJECT: Natural Resources Defense Council; Receipt of Petition for Rulemaking [Docket No. PRM-50-90; NRC-2008-0279] [See 73 FR 30321 (May 27, 2008)].

Dear Ms. Vietti-Cook:

The American Association of Physicists in Medicine\(^1\) (AAPM) submits the following comments to the U.S. Nuclear Regulatory Commission (NRC) regarding the Natural Resources Defense Council; Receipt of Petition for Rulemaking [Docket No. PRM-50-90; See 73 FR 30321 (May 27, 2008)]. AAPM recommends that any decision to grant the Petition proceed with caution and ensure that if a date is set for terminating the exportation of highly enriched uranium (HEU), this date be established to ensure that the production of medical radionuclides will not be compromised in any manner.

Medical isotopes are used to diagnose potentially life-threatening conditions such as heart disease and to treat serious diseases such as cancer. Establishing a reliable supply of medical isotopes is an important issue for patients worldwide. Canada’s National Research Universal (NRU) reactor is one of only five\(^2\) reactors in the world with the capacity to produce isotopes for commercial use. NRU

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\(^1\) The American Association of Physicists in Medicine’s (AAPM) mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 6,700 medical physicists.

\(^2\) The other four reactors are located in South Africa, Belgium, France and the Netherlands.
supplies isotopes to MDS Nordion, who in turn processes them into medical isotopes that are then distributed to radiopharmaceutical companies worldwide, including licensees in the United States.

Continuity of medical isotope supply is critical, so the conversion to low enriched uranium (LEU) has to be technically and economically feasible to ensure medical isotope supply for patient care is not jeopardized or interrupted. To date, there is no demonstrated, qualified, large-scale commercial process for production of medical isotopes from LEU targets. It is important to note that Canada has already taken significant steps to use LEU. The NRU reactor has been converted to LEU fuel and irradiates HEU targets.

The ability of NRU to operate and produce medical isotopes is especially critical given the recent decision by Canada to terminate the MAPLE project. NRU produces approximately 50 per cent of the world’s medical isotopes, involving some 60,000 procedures per day worldwide.

The impact of shutting down the NRU was recently exemplified when, on November 21, 2007, MDS Nordion was informed that the NRU reactor would not restart after its regular maintenance schedule. This unexpected shut-down of the NRU reactor resulted in a worldwide shortage of medical isotopes, underlining the importance of long-term isotope supply. In fact, this action resulted in the passage of emergency legislation by the Canadian government (Bill C-38, on December 12, 2007) to permit the restarting of the NRU reactor. The NRU was returned to service on December 16, 2007. However the result of this unexpected shutdown resulted in an approximately 35 percent shortage in the global medical isotope supply. This demonstrated that vital medical procedures could not be performed during such a shutdown due to the limited access to imaging and therapeutic agents.

Currently, there is no alternative supplier in the U.S. that can supply medical isotopes in place of those produced by the NRU. A continuous and reliable supply of medical isotopes is essential, as they have a short shelf life and therefore cannot be inventoried. Such a supply would be compromised by granting this Petition (PRM-50-90).

Thank you for the opportunity to comment. Feel free to contact me at 720-854-7515 or via email: dpfeiffer@bch.org or Lynne Fairobent, Manager of Legislative and Regulatory Affairs at 301-209-3364 or via e-mail: lynne@aapm.org if you have questions.

Sincerely,

Douglas E. Pfeiffer, MS, DABR
Chair
AAPM’s Government and Regulatory Affairs Committee