



Council on Radionuclides and Radiopharmaceuticals, Inc.

3911 Campollindo Drive  
Moraga, CA 94556-1551  
(925) 283-1850  
Fax: (925) 283-1850  
E-mail: corar@silcon.com

Henry H. Kramer, Ph.D., FACNP  
Executive Director

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XSNM-3060

Chairman Richard Meserve  
U.S. Nuclear Regulatory Commission  
One White Flint North  
11555 Rockville Pike  
Rockville, Maryland 20582-2738

Dear Chairman Meserve:

As Chairman of the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR), I would like to strongly urge the Commission to fully consider the medical necessity for molybdenum-99 (Mo-99); the precarious and limited supply situation that confronts the radiopharmaceutical manufacturers; and the potentially adverse affect on physicians and patients who rely on life-saving procedures requiring radiopharmaceuticals produced from HEU should this supply be disrupted.

CORAR members include the major manufacturers and distributors of radiopharmaceuticals, radioactive sources and research radionuclides used in the U.S. for therapeutic and diagnostic medical applications and for industrial, environmental and biomedical research and quality control. CORAR members are the purchasers of the Mo-99 produced in Atomic Energy of Canada Limited's (AECL) NRU reactor, and Mallinckrodt Inc's Petten facility in The Netherlands. In the future, our members soon expect to purchase Mo-99 from AECL's MAPLE 1 and 2 reactors in Canada. CORAR member companies use the Mo-99 to manufacture Technetium-99m (Tc-99m) generators for use in nuclear medicine applications.

Our members support the NRC's decision last year to grant the export license and its findings that the Atomic Energy of Canada Limited (AECL) and MDS Nordion were in compliance with the Schumer Amendment provisions. By granting a five-year export license to MDS Nordion, the NRC ensured the manufacturers and physicians in this country of a reliable supply of radioisotopes. While CORAR supports the NRC in encouraging the development of low enriched uranium (LEU), it is concerned that a disruption in the supply of HEU to Canada and Europe caused by pressure to prematurely shift to Low Enriched Uranium (LEU) targets to produce Mo-99 could result in significant supply shortages of life-saving radiopharmaceuticals. Current LEU target technology is unproven to produce sufficient quantities of Mo-99 to meet the needs of North American nuclear medicine physicians and the patients that rely on these procedures.

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More than 80% of the approximately 14 million radiopharmaceutical medical procedures performed each year in the United States use Tc-99m. Many diagnostic procedures can be life-saving, such as determining the extent and spread of cancer and heart disease. Over sixty percent of the Tc-99m used in North America is produced in Canada by AECL and then processed and supplied to U.S. pharmaceutical manufacturers and our members by MDS Nordion. Radioisotopes are used to diagnose and treat a variety of diseases in thousands of patients every day in the United States.

We understand that while a meeting is not required as part of the approved export license that the NRC nevertheless plans to hold a briefing meeting on this matter on July 10<sup>th</sup>. The nuclear medicine community including radiopharmaceutical manufacturers, nuclear medicine physicians and manufacturers of nuclear isotopes is concerned about any possible change to the NRC's five year export licenses which is vital to the U.S. nuclear medicine community and its ability to offer life-saving nuclear diagnostic and therapeutic procedures to U.S. patients. Finally, we to urge the NRC to continue to maintain the export of HEU to Canada and not place any new requirements on the current five-year export license. Any such requirements could jeopardize the supply of radioisotopes to the United States and adversely affect patient care.

If you should have any questions please feel free to contact me at (314) 654-7914.

Yours sincerely,



Roy W. Brown  
Chairman

cc: Commissioner Diaz  
Commissioner Discus  
Commissioner McGaffigan  
Commissioner Merrifield