Written Testimony

of

Council on Radionuclides and Radiopharmaceuticals (CORAR)

Before the United States Senate
Committee on Energy and Natural Resources

December 3, 2009

CORAR[1] (Council on Radionuclides and Radiopharmaceuticals) supports H.R. 3276 and the provisions contained in the legislation. We believe this legislation will provide important funding, waste disposal and regulatory support to help establish reliable medical isotope production in the United States. The current medical isotope crisis has affected thousands of American patients who rely on these products every day for diagnosis, treatment planning and treatment. CORAR supports H.R. 3276 because it is an important step towards a stable source of these medical radionuclides for our patients and will contribute to enhancing supply well into the future.

As a supporter of H.R. 3276, CORAR would like to highlight a few issues for the committee's consideration to ensure that the bill will accomplish its goals and serve the medical needs of US patients:

- Assure DOE accepts radioactive waste generated as a result of medical isotope production at reasonable prices.
- Develop a regulatory framework in which the funding from the legislation can be distributed to worthwhile efforts without triggering duplicative regulatory reviews.
- Direct the Nuclear Regulatory Commission to develop a regulatory space to allow for the licensing of new medical isotope production reactors that do not have to be licensed as power reactors.
- Direct DOE to develop a process for the fair and technology-neutral administration of funds created in this legislation with appropriate input from industry.

CORAR would like to continue working with staff to determine the best way to address these concerns for the benefit of American patients.

[1] CORAR is comprised of companies which produce products utilizing many different radionuclides. CORAR members include the major manufacturers and distributors of radiopharmaceuticals, radioactive sources, and research radionuclides used in the U.S. for diagnostic and therapeutic medical applications and for industrial, environmental and biomedical research and quality control. Several of CORAR's members are the primary processors of Mo-99, or are manufacturers of Tc-99m generators which use Mo-99.

I. Introduction

Mo-99 and Tc-99m play an important role in healthcare. The use of medical radionuclides is very important today – these compounds help provide early detection and treatment of diseases which can reduce health care costs and improve quality of life. There are more than 100 different nuclear medicine procedures in use today, of which more than 16 million nuclear medicine procedures performed each year in the U.S. Of these, 41,000 use Tc-99m each day. Roughly 95% of the medical radionuclides used in nuclear medicine are produced using HEU targets in nuclear reactors. The majority of nuclear medicine procedures are for diagnostic imaging, but there are also many therapeutic nuclear medicine treatments including Non-Hodgkin's Lymphoma, Liver Cancer, and Thyroid Cancer and for bone pain palliation related to Prostate Cancer.

Over the last few decades more than 90% of the Mo-99, (Iodine) I-131, I-125 and (Xenon) Xe-133 that was used in the U.S. came primarily from just two government owned reactors. Those two reactors are the NRU reactor operated by AECL in Chalk River, Ontario, Canada and the HFR reactor operated by NRG on behalf of the European Union in Petten, The Netherlands. Until recently, these two reactors had been extremely reliable. However, NRU and HFR were commissioned in 1957 and 1961, respectively. The age of these reactors has led to age-related operating problems. NRU has been shut down since May while repairs are being made to the reactor vessel and is not expected to be back on-line until early 2010. HFR was recently shut down for a month for routine maintenance and is scheduled to be shut down again in early 2010 for several months while repairs are made to its cooling lines. These planned and unplanned shutdowns have created the current shortage of Mo-99. Both of these reactors operate with Low Enriched Uranium (LEU) fuel and HEU targets.

Currently, many efforts are underway to alleviate the Mo-99 shortage, which can reach crisis proportions when both reactors are out of service. These efforts are coming from governments, industry, and professional societies around the world. CORAR believes the primary focus of this new legislation should be to address the need for a longer term and sustainable solution to this problem. It should also provide a framework so that similar crises can be avoided in the future. CORAR has identified six needs that any long term solution should address or solve, including:

- Appropriate site security
- Reactor and isotope processing in proximity to each other
- Disposal path for the processing radioactive by-products must be defined and approved
- The manufacturing and processing sites should have good access to a well developed transportation network
- The reactor operation must use both LEU fuel and targets
- Knowledgeable and empathetic regulatory environment

II. Discussion of Specific Issues

CORAR is supportive of this legislation. We feel with some minor modifications and assistance from the Senate this bill can be extremely effective in creating additional medical isotope capacity. These issues are elaborated below.

DOE Disposal of Medical Isotope Waste

The production of medical isotopes generates Class A and Class B low level radioactive waste, and transuranic waste. Currently Mo-99 and other medical isotopes are being produced outside the U.S. and the local governments assist these facility operators in the disposal of that waste. For some radioactive waste in the U.S., there is currently no disposal pathway available. DOE has waste disposal facilities for all types of radioactive waste, but it is only available to the DOE. The legislation appropriately has a provision (Sec 3, (c)) for waste acceptance by the DOE. Our industry has worked with the DOE for many years, and as such we are aware of non-competitively high prices DOE charges for certain services and work performed for others. What we seek is an understanding that the DOE will accept radioactive waste at reasonable prices. We seek your guidance in assuring this happens, as unreasonable disposal charges would inhibit implementation of this legislation's goals.

Avoiding Duplicative Regulatory Review

For example, we are concerned the acceptance of money from DOE for the development of medical isotope capability under this legislation may trigger duplicative National Environmental Policy Act (NEPA) reviews. If NEPA is triggered and the DOE is required to complete Environmental Impact Statements (EIS) and/or Environmental Assessments (EA), it will cause significant delays in the development of these facilities which is counterproductive to the intent of the legislation. We feel the development of EAs and EISs is not necessary because of other regulatory controls these facilities will be under. Any new reactor funded under this legislation will be required to be licensed by the NRC. The NRC has a comprehensive regulatory framework for protection of the environment, workers and the public. This regulatory framework will adequately fulfill the intent of the NEPA and will protect the environment. Any new production facility receiving funding under this legislation will be licensed by the NRC or equivalent Agreement State agency. The NRC and the Agreement States also have the material program regulatory framework to protect the environment, workers and the public. Various aspects and operations of these facilities will also be regulated by the Food & Drug Administration, Department of Transportation and the Environmental Protection Agency, as well as state and local regulatory agencies. With these various levels of regulatory oversight, we do not believe the NEPA will offer any more protection of the environment. We would like to see a provision in the legislation for any federal money spent on the development of medical isotopes to be exempt from the requirements of NEPA.

NRC Licensing of New Isotope Production Reactors
Several groups are working on the development of new types of isotope production reactors which fall into a licensing gap at the NRC. These new types of reactors are being built in the U.S. and will utilize LEU fuel. These new reactors do not meet the definition of a research reactor under the language in Section 104 of the Atomic Energy Act (AEA), due to their production focus and lack of research being conducted. At the time the AEA was written, the use of these types of reactors for the production of medical isotopes was not envisioned. These types of reactors also do not have the inherent risk or security concerns of large commercial nuclear power reactors which are licensed under Section 103 of the AEA. Consequently, these types of reactors fall into a licensing gap for the NRC. CORAR would like to see H.R. 3276 either revise Section 104 of the AEA to recognize these types of reactors for the production of medical isotopes or direct the NRC to permit the licensing of these reactors under Section 104 of the AEA. If assistance of this type could be included in the legislation, it would help expedite the licensing of these new reactors and bring these new sources of Mo-99 to market more quickly.

Distribution of Funds Under this Legislation
CORAR believes NNSA at DOE is the logical administrator of funds identified in this legislation. NNSA has been closely involved in the development of LEU–based medical isotope production for many years. CORAR is aware of several promising efforts to develop new medical isotope capacity. We believe these efforts are worthy of funding from this legislation. We also feel the American public can best be served by developing several efforts concurrently rather than only backing one or two of these efforts. CORAR positively notes that the legislation does not limit the number of projects eligible for funding support provided the projects meet the legislation's criteria related to ability to meet the legislation's deadlines, capacity to fulfill domestic Mo-99 demand and cost. For example, given the legislation's intent to broadly serve American patients, funding should be directed to projects which stand a good chance of producing commercially meaningful quantities of medical isotopes. We also would like to see the process by which DOE awards development money, fully vetted through a rulemaking or some other process where our industry and other interested parties can review and comment on DOE's proposed decision-making process for these projects. The best process will be one that is technology-neutral and does not pre-judge these development efforts.

III. Other Important Medical Radionuclides

There are other medical radionuclides which are very important to nuclear medicine. Many of these radionuclides are used in therapeutic procedures for the treatment of cancer and other illnesses. Although their number of procedures do not come close to the annual usage of Tc-99m, they are also very important. These radionuclides can be produced in a fission reaction such as Mo-99, or they can be produced through neutron activation. The same reactors that produce Mo-99 also produce these other radionuclides including I-131, I-125, Xe-133. These radionuclides are used in diagnostic and therapeutic procedures and are being examined for use in exciting new products for

nuclear medicine. It is important to remember these other radionuclides play an important role in the practice of nuclear medicine and should be included in the overall approach to assuring a reliable supply for critical medical radioisotopes.

IV. Conclusion

The current worldwide shortage of Mo-99 has illustrated the fragility of supply and the need for additional medical radionuclide production. CORAR is supportive of H.R. 3276 and increasing the capacity for medical radionuclides in the U.S. We believe several key issues still need to be addressed in the legislation to assure it will provide the best environment to develop additional medical isotope production capacity.

By assuring DOE accepts all radioactive waste generated as a result of medical isotope production at reasonable rates, the new production facilities being developed will be economically viable.

Developing a regulatory framework in which the funding from this legislation can be distributed to worthwhile efforts without triggering duplicative regulatory reviews, such as National Environmental Policy Act (NEPA), will assure the new facilities will come on-line more quickly without compromising the environment or protection of workers or the public.

Directing the Nuclear Regulatory Commission to develop a regulatory space to allow for the licensing of new medical isotope production reactors that do not have to be licensed as power reactors will bring these facilities on-line more quickly, and at a lower cost. Reactors dedicated solely to medical isotope production were not envisioned when the Atomic Energy Act was first written in 1954.

Directing DOE to develop a process for technology-neutral administration of funds created in this legislation with appropriate input from industry will help assure the fair and most productive use of these funds. CORAR believes it is prudent to back several alternative technologies capable of producing significant quantities and multiple reactor sites in order to avoid a repeat of the current availability and capacity issues.

As H.R. 3276 moves forward, CORAR hopes to continue to work with the Committee and staff to ensure both a swift and long term solution to the medical isotope crisis. Thank you for the consideration of our perspective. CORAR looks forward to working with you toward the enactment of this legislation.