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CORAR

Council on Radionuclides and Radiopharmaceuticals, Inc.

3911 Campolindo 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

September 25, 2008

Ms. Annette L. Vietti-Cook, Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

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Subject: Docket No. PRM–50–90; NRC–2008–0279
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Natural Resources Defense Council;
Receipt of Petition for Rulemaking

The Council on Radionuclides and Radiopharmaceuticals (CORAR)[1] members are involved in production of Mo-99 and the manufacturer of Tc-99m generators which use Mo-99. The above referenced Petition for Rulemaking has a direct impact on several CORAR member companies.

There are more than 100 different nuclear medicine procedures in use today. There are more than 15 million nuclear medicine procedures preformed each year in the U.S., or 41,000 per day. Greater than 80% of these procedures utilize Tc-99m produced using HEU targets. The majority of nuclear medicine procedures are diagnostic, but there are also a number of therapeutic nuclear medicine treatments including bone pain palliation related to Prostate Cancer, Non-Hodgkin's Lymphoma, Liver Cancer and Thyroid Cancer. Meeting patient needs is paramount to CORAR member companies, and the reliability of medical isotope supply must not be compromised.

Production of Mo-99 and other medical radionuclide production from the fission of U-235 dates back to the 1970's. At that time the production of Mo-99 and other medical radionuclides was developed around the use of HEU targets. The use of HEU material in reactor targets was, and continues to be, a cost effective and environmentally responsible method for large scale, commercial production of Mo-99. Prior to the 1970's there was a relatively small quantity of Mo-99 used in medical applications, so the majority of Mo-99 and other medical radionuclides were produced utilizing neutron activation.

[1] 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.

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SECY-02

The production of Mo-99 from HEU has been proven and demonstrated for large scale production for over 35 years. Production techniques and regulatory filings with the U.S. Food & Drug Administration (FDA) were based on these HEU-produced techniques. Changes in the production methodology of radioisotopes from HEU to other avenues (including LEU) might impact the quality of source materials and final pharmaceutical products. So after conversion to LEU production, resulting pharmaceuticals will have to undergo review and approval by the FDA

CORAR supports the conversion of HEU to LEU. This is evident by the conversion of reactor fuel from HEU to LEU that has taken place in the last several years. We share in the goals of the NRDC to remove the use of HEU from medical radionuclide production. However, the conversion must be done in a manner not to interrupt the supply of medical radionuclides and radiopharmaceuticals to our patient, and not to put an undue cost burden on those patients. Meeting patients' needs is a paramount concern to CORAR member companies.

The Department of Energy's National Nuclear Security Agency conducted a workshop on the LEU production of Mo-99 in Sydney, Australia December 5-7, 2007[2]. That workshop examined the current methods of Mo-99 production, new and emerging technologies for the production fop Mo-99 using LEU, and the production of Mo-99 in developing countries using LEU. One of the conclusions at the workshop was that large scale production on Mo-99 utilizing LEU is technically feasible and had been demonstrated, but it had not yet been proven commercially viable. The workshop also identified that there are technical, economic and political and lead time obstacles that need to be overcome in order to convert to LEU production of medical isotopes. It should also be noted that additional technical obstacles for conversion of large scale existing processes must be resolved and addressed without interrupting supply to patients. These existing sources of supply provide more than 95% of these critical life saving isotopes every day.

We cannot support the Petition for Rulemaking submitted by the NRDC for several reasons. Although we support the conversion to LEU, we do not feel the path to that conversion proposed by the NRDC can be done without jeopardizing the supply of radionuclides to nuclear medicine patients and without significantly increasing the cost of nuclear medicine procedures to those patients. We have several specific comments to their Petition for Rulemaking. These are summarized below.

1. **HEU Currently in Use by the Medical Community is handled in a safe and secure manner.**

   We believe the threat for the using HEU for the production of medical isotopes in terrorist activities is being overstated by the NRDC. Security arrangements for the delivery and storage of HEU for medical isotope production are highly regulated with significant government oversight. Member companies consistently meet or exceed security requirements for the industry mandated by governments. For example, transfer of HEU from the U.S. to Canada involves interaction with and

[2] Global Initiative to Combat Nuclear Terrorism Workshop on the Production of Mo-99 Using Low Enriched Uranium, Sydney, Australia, December 2-7, 2007

oversight by the Nuclear Regulatory Commission, the International Atomic Energy Agency, the U.S. Department of State, the U.S. Department of Energy, the U.S. Department of Homeland Security, the U.S. Customs & Border Protection, the U.S. Department of Transportation, the Canadian Nuclear Safety Commission, the Canada Border Services Agency, and Transport Canada. Further, the actual transport of HEU is conducted by the U.S. Military. Furthermore, once in Canada, the HEU is stored at a secure government site that is regulated by the Canadian Nuclear Safety Commission.

HEU has been routinely transferred to Canada for peaceful uses of isotope production for the last 55 years. All of that HEU has been accounted for and there has never been a security incident with those transfers. That HEU has been used to provide for well over 250 million nuclear medicine procedures for patients in the U.S. The benefit of the medical diagnostic information collected in those nuclear medicine studies has saved countless lives and has provided important information on the staging of cancer patients, the extent of heart disease and functional information on the organ systems of these patients. The medical information derived from these studies far outweighs the risk associated with the transfer of this HEU. However, CORAR still supports the conversion to LEU produced medical isotopes as soon as it is economically, technically and commercially feasible.

2. CORAR is supportive of the Conversion from HEU to LEU.

There are several issues that need to be addressed before conversion can be successful. These issues include technical feasibility, economic feasibility, and environmental stewardship. The technical issue must address changes that would be required in the LEU target that consistently and reliably provides high isotope output. Once the new target is developed it would have to be qualified and licensed in the reactor. New process development would need to be done because the technical composition of the LEU target will be different from that of its HEU counterpart. The new process will also generate a new waste stream that needs to be characterized and properly disposed of. Mo-99 removal efficiency in this new process is a key consideration. Quality assurance and product specifications will also need to be developed for the new targets and processes. In addition, conversion of existing facilities is further complicated by the requirement to produce material while developing new technologies and ensuring the transition to LEU does not interrupt supply.

The ultimate customer for the medical isotopes produced using this technology is the nuclear medicine patient. The new LEU target developed will have to be done in a manner that does not significantly impact the cost of the medical isotope production. Any cost increase caused by the conversion has to be passed on to the final customer. For that reason the isotope manufacturers want to develop an LEU target in which Mo-99 and other medical isotopes can be extracted without a significant cost increase. The current manufacturers are studying the cost impact and are trying to look at conversion to LEU in a cost efficient manner so as not to negatively impact the cost of production, and ultimately the price paid by reimbursement for nuclear medicine patients.

The environmental stewardship aspects of a new target and process need to be developed carefully. Since a new 20% enriched LEU target has roughly $1/5^{th}$ the quantity of Uranium in the target compared to 93.75% enriched HEU target, the waste stream of the new process will be much different. Before these new processing procedures could be implemented, waste minimization efforts would be undertaken to limit the increase of low level waste generated as a result of the conversion. This is discussed further in Point #4 below. Impact of the process changes on worker safety and the environmental impact of gaseous effluents also need to be examined before a major process change such as this is undertaken.

3. Reliability and Continuity of Isotope Supply

There are over 15 million nuclear procedures performed each year in the U.S. for over 100 diagnostic and therapeutic indications. The worldwide number is roughly double that figure. More than 95% of these products use HEU produced medical radionuclides. As stated earlier, CORAR is supportive of the conversion to LEU, but it must be done in a manner than will not impact the reliability or continuity of these isotopes.

Patients utilize Tc-99m and other HEU produced medical isotopes every day. The use of these products is also critically important in the hospital emergency rooms. Staging of cancer and the technetium for heart disease is extremely time sensitive. Recent minor interruptions experienced in the delivery of bulk Mo-99 in the U.S. has demonstrated the critical nature of receiving bulk shipments on time and consistently. If the industry is pushed to convert to LEU before all of the conversion factors discussed in Point #2 above are addressed, we risk interruption of supply. It is very likely that when the conversion to LEU targets is ready to commercialize, the HEU and LEU processes will run in tandem operation for some period of time to assure the reliability of the new technology. In that manner the industry will ensure there is no interruption in the supply of medical isotopes. It is for this reason that CORAR does not support a mandatory conversion date. The current supplies of Mo-99 and other medical isotopes have an excellent record of reliability and working together when infrequent supply issues have arisen.

4. Conversion to MEU

CORAR closely reviewed the NRDC suggestion to consider conversion to Moderately Enriched Uranium (MEU) targets. To the best of our understanding, the concept of MEU has not been accepted by the non-proliferation experts and policy makers as meeting the threshold requirements for non bomb grade material. Until that takes place, it seems that the concept is somewhat moot. Unless MEU gains acceptance as an international standard, CORAR does not feel it should be considered a viable option.

However, were it an acceptable concept, from the isotope production perspective, there may be some advantages of using MEU targets over LEU targets. For example, there could be less production of waste using MEU targets which would

be attractive from a cost and environmental impact. It must be noted, however, that the production processes would have to be developed to prove these hypotheses.

The quantity of solid waste generated in the processing of LEU versus HEU will increase roughly five times. The amount of plutonium produced with the LEU target will also be increased. The increase in waste volumes and plutonium (Pu) component will change the characterization of the waste and lead to higher disposal costs. MEU target processing would reduce the quantity of Pu produced (over LEU targets) and the quantity of solid waste generated. If the final goal were to achieve the use of MEU rather than HEU this appears to be an attractive alternative. However, we believe it will take the same effort to develop an MEU conversion as an LEU conversion.

However, to convert from an MEU target to an LEU target would require resolution of another set of conversion issues as discussed in Point #3 above. If total conversion to LEU is the ultimate goal, CORAR believes it would make technical and economic sense to convert directly from HEU to LEU. Beside the waste disposal issues previously discussed, we believe the conversion to MEU or LEU would be approximately the same cost. The anticipated FDA regulatory oversight of a conversion from HEU to MEU, or HEU to LEU would be the same. Furthermore, if converting to MEU is only a step along the way to convert to LEU, the development and approval, of new processes, the construction of new production facilities would have to be repeated for each step. This would render the conversion cost prohibitive.

5. Timeline for Conversion

The NNSA workshop[3] in Sydney examined four pathways to an LEU conversion. Those four pathways included: (1) Scale-up of available technology to large-scale (>1000 6-day Ci/week) production facilities designed from the very beginning to use LEU fuel and LEU targets; (2) Expansion of LEU research reactors to add Mo-99 production capacity using LEU targets; (3) Conversion of existing large-scale production facilities ("brownfields") now using HEU to LEU fuel and LEU targets; and, (4) New entrants using ("greenfields") LEU technology. Each of those pathways represents a different approach that would take varying amounts of time to complete. As we have seen from the OPAL project in Australia and the MAPLE project in Canada, new facility start-up can be difficult.

The NNSA workshop estimated that it would take eight years or longer to complete a successful conversion. CORAR member companies have extensively studied various conversion pathways and have estimated the time for conversion could take ten years or more. Conversion is also facility specific and times can vary greatly from one facility to another. CORAR's estimate includes the regulatory approvals from NRC and FDA that would be necessary to complete the conversion and begin using the LEU produced medical isotopes. Regulatory approvals can be lengthy.

[3] Global Initiative to Combat Nuclear Terrorism Workshop on the Production of Mo-99 Using Low Enriched Uranium, Sydney, Australia, December 2-7, 2007

CORAR is committed to the conversion to LEU but feels it is important to complete the conversion while maintaining reliable and continuous supply of medical isotopes. For that reason we are not supportive of a fixed target date for the conversion. Any forced conversion timetable to eliminate the use of HEU for the industry before they were ready would jeopardize the reliable supply or terminate it all together until the conversion can be completed.

6. Government subsidies to convert to LEU

Large scale production of Mo-99 is currently being done by the NRU reactor in Canada, the HFR reactor in The Netherlands, the BR-2 reactor in Belgium and the SAFARI reactor in South Africa. All of these reactors receive some sort of government subsidy. It is not known to what extent, if any, this subsidy figures into the economics of Mo-99 and other isotope production.

However, the elimination of HEU for civilian uses is a U.S. government policy. There will be significant cost associated with this conversion. The cost associated with this conversion and the possibility of government subsidies to assist manufacturers with conversion was discussed at the NNSA meeting in Sydney. The cost to convert to LEU targets for the production of medical isotopes will have to be passed on to patients unless the cost can be underwritten by a government subsidy. We would reiterate that the exports of HEU for medical isotope production are highly regulated with extensive security measures in place to ensure these transactions are safe and secure. The view of CORAR is that if the government is driving this policy as part of their threat reduction platform, then the government should provide funding to facilitate this conversion to achieve their objective CORAR would be supportive of any initiative that would provide funding for such a conversion.

Although government subsidies could assist in the conversion efforts the ongoing operating costs would need to be passed on to patients. To date there isn't an LEU based technology that has been demonstrated that can provide isotopes at the same or reduced cost of the current efficient HEU processes. Furthermore, there would be an incremental cost increase during the time when the new process was running in parallel to the old process. This would be part of the cost to transition from HEU to LEU.

7. Conversion of Research Reactors fuel to LEU

The NRDC proposed the conversion of all research reactors in the U.S. to LEU fuel in their Petition. This has been the mission of DOE's Reduced Enrichment for Research and Test Reactors (RERTR) program for many years. CORAR has been supportive of the RERTR program, and its conversion efforts. We are also

supportive of this provision of NRDC's Petition. At least one of the research reactors in the U.S. is used to produce medical isotopes for the nuclear medicine community. We have an interest in ensuring that this supply of medial isotopes is also not interrupted. We would like to assure that the conversion of these research reactors is done in such a way as to not interrupt the supply of these isotopes.

CORAR is committed to support, encourage and advocate for a viable solution to produce medical isotopes using LEU technology. However, a reliable and consistent supply of these important products to our patients and their physicians is of paramount concern. Interruption of supply could result in inadequate patient care. The use of HEU is required until feasible alternatives are developed, approved and implemented. Before this conversion can take place, LEU based isotope production needs to be proven and demonstrated to be reliable. CORAR is not supportive of this Petition by the NRDC for these reasons.

CORAR would like to thank the NRC for the opportunity to comment on the NRDC Petition for Rulemaking. We believe we share the same conversion goals as the NRDC. However, we are asking for a more structured and deliberate conversion to LEU fuel and targets so as not to jeopardize the production of critically important medical isotopes for patients in the U.S.

Sincerely,

Roy W. Brown
Senior Director, Federal Affairs

Rulemaking Comments

From: roywbrown@sbcglobal.net
Sent: Thursday, September 25, 2008 11:46 AM
To: Rulemaking Comments
Cc: Michael Lesar
Subject: Comments on Docket No. PRM-50-90
Attachments: CORAR Comments on NRDC Petition.pdf

Please find comments from the Council on Radionuclides and Radiopharmaceuticals (CORAR) on the NRDC Petition for Rulemaking. If you have any questions you may contact me at the e-mail below or at (314) 795-6166. Thank you for the opportunity to comment on this Petition for Rulemaking.

Roy

Roy W. Brown
Senior Director, Federal Affairs
CORAR
roywbrown@sbcglobal.net

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From: <roywbrown@sbcglobal.net>
To: <rulemaking.comments@nrc.gov>
CC: "'Michael Lesar'" <Michael.Lesar@nrc.gov>
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