CORAR

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CORAR comments submitted to The NNSA's Office of Global Threat Reduction (GTRI) "Call for Input Form" accessed through the http://mo99.ne.anl.gov/GTRI-seeking-input/ website.

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The Council on Radionuclides and Radiopharmaceuticals (CORAR) provides the following comments and recommendations to the Department of Energy in support of the implementation of the American Medical Isotopes Production Act of 2012 (AMIPA).

CORAR members are committed to working with all U.S. and international stakeholders to ensure a reliable, sufficient and sustainable supply of medical radioisotopes from non-HEU production sources, in particular due to nonproliferation and nuclear security risks arising from potential theft or diversion of highly enriched uranium (HEU) targets to unauthorized uses. At the same time, CORAR believes that efforts to promote the use of non-HEU produced molybdenum-99 (Mo-99) must be closely monitored to ensure that U.S. patients are not adversely impacted either by (1) supply shortages due to inadequate or unreliable supply sources, or (2) insufficient reimbursement for higher cost non-HEU Mo-99 including low enriched uranium (LEU).

CORAR is pleased to offer the following comments and suggestions to support effective implementation of AMIPA and to accelerate the conversion to non-HEU sourced Mo-99:

1. The cost sharing and research support that the National Nuclear Security Agency (NNSA) provides Cooperative Agreement Partners is helpful and an important first step towards supporting a domestic supply of Mo-99 from non-HEU sources. CORAR encourages the DOE to augment this support, where feasible, through the evaluation of additional opportunities to accelerate the progress of new domestic technology programs.

2. To support domestic isotope production, CORAR encourages the DOE to evaluate every feasible solution for waste disposal to support the lease and waste take back provisions of AMIPA. CORAR previously submitted comments to DOE on this issue in 2013 (CORAR letter to Deputy Assistant Secretary Marcinowski and Director Gelles; received October 9, 2013). We believe it would be helpful for Mo-99 producers that participate in a lease and waste-take-back program to dispose of waste using DOE approved disposal rates.

3. CORAR acknowledges that the supplemental payment for non-HEU sourced Mo-99 products under the Outpatient Prospective Payment System (OPPS) is an important first step in recognizing the higher costs of LEU sourced Mo-99. However, CORAR believes that the supplemental payment is insufficient to cover the higher costs and has significant workability barriers.


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For example, there is not a sufficient amount of LEU Mo-99 at this time to reliably supply the entire US market. The current policy requires manufacturers and nuclear pharmacies to manage a separate, potentially costly and inefficient supply chain with both HEU and LEU Mo-99 to produce products to providers.

Moreover, CORAR has commented on the two economic analysis studies conducted by the National Academy of Sciences and the Organization for Economic Cooperation and Development - High Level Group on Medical Radioisotopes (OECD HLG-MR). CORAR believes that both studies underestimate the cost of new Mo-99 production and conversion to LEU. These costs include the significant capital expense of building new reactors, retro-fitting current production facilities, and the long term investments necessary to develop new technology. In addition, other ancillary items, such as the cost for long-term storage of radioactive waste, need to be appropriately evaluated. CORAR requests that NNSA and CMS remain engaged with industry and stakeholders to evaluate additional options to ensure adequate payment of Mo-99 based products used in nuclear medicine.

4. CORAR recognizes the significant technical difficulties incurred by the current Mo-99 producers who are working to convert from HEU to LEU. In light of the technical challenges, CORAR anticipates delays in the total industry conversion to LEU past the 2015 timeline. Therefore, consistent with the American Medical Isotopes Production Act of 2012, CORAR believes there will be a need for additional US shipments of HEU beyond 2014 to avoid Mo-99 shortages in 2016 and 2017. This extension would avoid harm to patients by ensuring an adequate supply of Mo-99 past 2014.

5. Industry continues to invest significant resources to ensure reliable isotope supply today and plan for adequate Mo-99 supply in the future produced from non-HEU sources. However, the situation is complicated by the inadequate reimbursement support of the market and governments to fully cover the costs of conversion. Combined with the significant financial burden of LEU conversion, there is a real threat to industry's ability to meet the timelines necessary to ensure Mo-99 supply past 2016, when the NRU reactor in Canada is scheduled to end commercial medical isotope production. CORAR believes that it is necessary that policymakers work to provide the financial support necessary to create a stable industry that can continue to meet patient needs.

In conclusion, CORAR urges expansion of existing government and stakeholder collaboration to ensure that adequate supply of Mo-99 sourced products are available throughout the transition to non-HEU sources. Only with multilateral governmental engagement and support can we succeed in achieving a smooth conversion, without taking unacceptable risks of creating a Mo-99 shortage that would adversely affect patients in need.

CORAR appreciates the opportunity to submit these comments for DOE review. We would be happy to meet with DOE and NNSA representatives to discuss our comments and suggestions in more detail.

Respectively Yours,


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