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Kevin D. Crowley, Ph.D.
Director, Nuclear and Radiation Studies Board
The National Academies of Sciences, Engineering, and Medicine
500 Fifth Street, NW
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Re: CORAR Comments on the Academies "Molybdenum-99 for Medical Imaging" Report

Dear Kevin:

On September 12th the National Academies of Science, Engineering, and Medicine (the Academies) released a prepublication copy of a report describing the current and projected future state of *Molybdenum-99 for Medical Imaging*.[1] This study was mandated by the American Medical Isotopes Production Act of 2012 (AMIPA) with a charge to conduct a study of the state of molybdenum-99 (Mo-99) production and utilization. Mo-99 is the parent isotope of technetium-99m (Tc 99m) which is used in 30 to 40 million nuclear medicine procedures worldwide every year.[2] In response to this Congressional mandate, the Academies constituted an ad hoc committee of technical and medical experts (the committee) with a charge to report their findings and recommendations to Congress in areas described in the Statement of Task.[3] **CORAR believes that the Academies' findings overstate the risk of Mo-99 shortages over the next five years. We elaborate below by discussing the many steps taken by Industry to continue providing reliable supply of Mo-99 after the Canadian Suppliers (National Research Universal (NRU) research reactor and the Nordion Mo-99 processing facility) stop regular Mo-99 production after October 31, 2016.**

One task of the Academies Mo-99 study was to evaluate "The adequacy of molybdenum-99 supplies to meet future domestic medical needs, particularly in 2016 and beyond." The committee interpreted "beyond" in the study charge to mean the next five years (i.e. until about

[1] National Academies of Sciences, Engineering, and Medicine *Molybdenum-99 for Medical Imaging* - http://www.nap.edu/23563.
[2] HLG-MR; 2016 Medical Isotope Supply Review: ^{99}Mo/^{99m}Tc Market Demand and Production Capacity Projection 2016-2021.
[3] Full Statement of Task described in "SIDEBAR S.1" of the report.

2021).[4] In the committees' findings, it was stated that "Global supplies of molybdenum-99 are adequate at present to meet domestic needs." The committee went on to acknowledge that Mo-99 supply capacity would be substantially reduced after October 31, 2016 when Canadian suppliers end routine production.

In Finding 4B of the Academies report, the committee judged that there is a substantial (>50 percent) likelihood of severe molybdenum-99/technetium-99m supply shortages after 2016, lasting at least until current global suppliers complete their planned capacity expansions. **As noted above, CORAR disagrees with this Finding**. However, to follow-up Finding 4B, the committees' Recommendation 4B encouraged the U.S. government to work with the Canadian government to ensure that there is emergency (contingency capacity) supply from Canada, if necessary. CORAR supports and welcomes all efforts designed to increase Mo-99 supply and to enhance the reliability of the Mo-99 supply chain. CORAR thus supports Recommendation 4B and believes it provides for an important ***emergency supply*** if a severe Mo-99 shortage should occur before March of 2018.

CORAR believes that the committee underestimated the impact of the significant work being done by the current Mo-99 producers to increase available supply capacity[5] in the next several years while new Mo-99 production facilities are projected to come on line to support a reliable and sustainable future supply. For example, in Chapter 3 of the Academies' report, it is mentioned that three current Mo-99 producers (ANSTO, Mallinckrodt, and NTP) have announced plans to expand their available supply capacities. According to the report, which is based on publicly-reported data and announcements, combining the plans from the three producers will provide approximately 4,400 6-day Ci per week[6] of increased Mo-99 available supply capacity by the end of 2017.[7] These plans to increase available supply capacity should substantially offset the loss of Mo-99 supply (and production)[8] capacity from the Canadian suppliers, which was reported at 4,680 6-day Ci per week in the Academies report.

In addition, work to maintain and increase capacity of the current fleet of research reactors, that irradiate targets for Mo-99 production, continues and is necessary to offset the ending of regular Mo-99 production by the Canadian suppliers on October 31st. For example, the Academies report referenced the refurbishment work recently completed on the BR-2 reactor (Belgium) and consideration by SCK•CEN (Belgian Research Centre, operator of BR-2) to expand the reactor's capacity for producing Mo-99 by increasing its irradiation schedule.[9] It appears that the Academies report failed to account for this potential for additional available production capacity. This further undermines the conclusion that there will be a severe shortage – particularly when combined with the supply capacity that is projected to be available from the three manufacturers identified above (ANSTO, Mallinckrodt, and NTP).

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[4] See Study Charge 4 in Report Summary.
[5] The Academies report defines available supply capacity as the capacity of a target processing facility to process irradiated targets on a routine basis (Sidebar 3.1).
[6] Mo-99 production through the supply chain is calibrated at 6-days end of processing, The Supply of Medical Radioisotopes, OECD 2010, page 9.
[7] Increase of 4,4006-day Ci per week cited in Chapter 3, section 3.2.1 of report.
[8] The Academies report defines available production capacity as the capacity of a reactor to irradiate targets on a routine basis (Sidebar 3.1)
[9] National Academies of Sciences, Engineering, and Medicine *Molybdenum-99 for Medical Imaging* - http://www.nap.edu/23563.

Also, the Academies report reaffirms that the Canadian Mo-99 suppliers plan to maintain a hot-standby status to produce Mo-99, if a severe Mo-99 shortage were to occur between November 2016 through March 2018.

In contrast to the Academies report, the Organization for Economic Co-operation and Development's Nuclear Energy Agency High Level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) issued its latest report in June 2016 and reached a different conclusion.[10] In evaluating information from current and potential future Mo-99 producers, as part of its regular reviews of the global Mo-99 market demand and available production and supply capacity, the HLG-MR concluded in its June report that:

"Overall, the current irradiator and processor supply chain capacity should be sufficient and if well maintained, planned, and scheduled, be able to manage an unplanned outage of a reactor, or a processor throughout the whole period to 2021."

This conclusion is supported by the data referenced in the Academies report.

Looking to the future, current Mo-99 production will likely be further augmented by an additional number of companies that, according to publicly-reported information and plans, are moving towards fission and non-fission production technology to support U.S. domestic production of Mo-99. Several of these companies are CORAR members and the technologies they are pursuing include traditional fission (reactor) based approaches to irradiating LEU targets, using LEU targets with Selective Gaseous Extraction Technology, leveraging accelerator based technology utilizing LEU solution, and implementing non-fission technologies using Mo-99 and Mo-100 targets. Progress on these new domestic Mo-99 projects, as well as current projects, was presented at the recent Department of Energy Mo-99 Topical Meeting in St. Louis on September 11-14, 2016.[11]

In conclusion, the Academies and the HLG-MR received feedback from many of the same current industry reactor and Mo-99 producers (as well as potential future domestic producers) and evaluated much of the same data for their respective 2016 reports. However, the two reports provide different conclusions on the risk of severe Mo-99 shortages over the 2016-2021 time frame. Although it is impossible to totally eliminate the risk of Mo-99 shortages over the next five years, CORAR believes the risk of Mo-99 shortages is mitigated by the significant efforts of industry producers that are mentioned in both reports, and which include:

1. Current Mo-99 producers' planned increases in Mo-99 available supply capacity with potential increases in available production capacity by the end of 2017;
2. Ongoing maintenance and increases in production capacity of the research reactor fleet;
3. Contingency back-up Mo-99 supply from Canadian suppliers through March 2018, if necessary, and;
4. Potential new domestic Mo-99 producers pursuing conventional uranium fission technology as well as new non-fission technology to support supply of Mo-99 into the future.

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[10] HLG-MR; 2016 Medical Isotope Supply Review: ^{99}Mo/^{99m}Tc Market Demand and Production Capacity Projection 2016-2021.
[11] Mo-99 Topical Meeting information at http://mo99.ne.anl.gov/2016/.

Therefore, based upon the information contained in the Academies report, CORAR believes the conclusion of a substantial (>50 percent) likelihood of severe molybdenum-99/technetium-99m supply shortages in the 2016 – 2021 time period is overstated. **Given that the Academies' report has been released as a prepublication copy, CORAR encourages the Academies to reevaluate the available data and consider amending their report, and specifically the conclusion regarding the likelihood of severe Mo-99 shortages between 2016-2021, to more accurately represent the risk of severe Mo-99 shortages over the next five years.**

Respectfully submitted,

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Executive Director

cc:
Dr. Donald Geesaman Chair, DOE/NSF Nuclear Science Advisory Committee (NSAC)
Dr. Susan Seestrom, Chair ^{99}Mo Subcommittee, Los Alamos National Laboratory
Jeffrey Chamberlin, Director, Office of Conversion, National Nuclear Security Administration
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