

Report to the Nuclear Science Advisory Committee

**Annual Assessment of the NNSA- Material Management and Minimization
(M³) ⁹⁹Mo Program**

July 30, 2015

Report of the NSAC ⁹⁹Mo Sub-Committee

Executive Summary

The Nuclear Science Advisory Committee (NSAC) ⁹⁹Molybdenum (⁹⁹Mo) Subcommittee met May 7-8 to address the charge to NSAC requesting that a second annual review of the National Nuclear Security Administration (NNSA) ⁹⁹Mo program be performed. The Subcommittee found that the NNSA has worked diligently and proactively over the course of the program based on the specific American Medical Isotopes Production Act of 2012 (AMIPA) requirements, especially considering the many complex factors outside their direct control. They conducted peer reviews of initial proposals based on well-defined criteria flowing from AMIPA; they have made good use of the national laboratories to support their cooperative agreement partners; and they have been responsive in managing the projects they awarded. In addition, they have effectively partnered with other parts of the Department of Energy (DOE) where it is needed to advance the ⁹⁹Mo program, e.g. working on the development of the Uranium Lease and Take Back program. Still, the program faces difficult issues.

The international context for ⁹⁹Mo availability has changed in some significant ways since the last review. The Organization for Economic Cooperation and Development's Nuclear Energy Agency (OECD-NEA) has updated its assessment of the ⁹⁹Mo global supply chain movement toward full cost recovery. The Canadian government has announced the possibility of providing ⁹⁹Mo during the period 2016-2018 should a worldwide shortage develop.

The Subcommittee found that NNSA had considered its previous recommendations, but that they had not increased funding based on our recommendation to consider increasing funding available to Cooperative Agreement (CA) projects. Since the last review in 2014, all CA projects have incurred delays ranging from one to two years in the projected dates for first ⁹⁹Mo commercial production. It is likely that one or more of the NNSA supported projects will enter the market eventually, though likely not with sufficient capacity initially to mitigate potential shortages in the period 2016-2018. The Subcommittee finds that the likelihood of a shortage of ⁹⁹Mo in the period 2016-2018 has increased substantially since the last review.

The NNSA has worked within funding limitations that are consistent with the principles of full cost recovery. However, the international community of ⁹⁹Mo producers has not made adequate progress toward full cost recovery according to the OECD-NEA. The \$25M limit, coupled with the 50/50 cost share being applied to all phases of the projects, are proving to be a serious impediment to projects that do not take advantage of significant existing infrastructure, even preventing them from spending up to the present \$25M limit. One partner stated explicitly that the delays in the last year were due to difficulty in obtaining funds. The CA project that anticipates producing ⁹⁹Mo in the near term relies heavily on

existing infrastructure at the Missouri University Research Reactor (MURR) that has been operating since 1966. If the terms and amount of funding available through the M³ program is not changed, it is likely the only new production in the U.S. will rely on the MURR reactor.

Based on these findings, the Subcommittee has four recommendations:

Recommendation #1: DOE should increase funds available to individual Cooperative Agreement projects sufficient to significantly accelerate their ability to rapidly establish domestic production. This could be accomplished, for example, by increasing the \$25M cap or increasing the NNSA cost share fraction during the R&D phase of projects.

Recommendation #2: DOE must support NNSA in their continued efforts to advocate for the timely establishment of the Uranium Lease and Take Back (ULTB) Program. The publication of a draft of the ULTB model contracts is an urgent need and NNSA has taken very credible actions to move the program definition by the DOE intra-agency working group forward. However, high-level agency engagement will be essential in reducing the risk caused by delays in projects resulting from lack of ULTB model contracts by ensuring model contracts are finalized as soon as possible.

Recommendation #3: NNSA should document a contingency plan to ensure a supply of ⁹⁹Mo from Canada within a few months if a significant shortage of ⁹⁹Mo appears imminent during the period 2016-2018. This plan should include details on working within the U.S. government and with the Canadian producers/government to address the definition of a trigger mechanism for ⁹⁹Mo production at NRU and ensure that valid import and export licenses for HEU are in place prior to the need for them. This contingency plan document should be available by the next NSAC review.

Recommendation #4: NNSA should develop a contingency plan to adapt the program should OECD-NEA continue to determine that the global community is not making adequate progress toward full cost recovery in order for domestic production to be economically feasible. This should be available by the next NSAC review.

On the present path, there is substantial risk of shortages in ⁹⁹Mo available in the United States in the next few years, with potential for negative impact on the health of the population. The recommendations above are meant to improve the outlook relative to this substantial risk. Implementation of these mitigation measures reduces but does not remove this risk. Further, a domestic producer that does succeed in entering the market might ultimately fail because they are not able to compete in the (*still*) subsidized international market. The relative priority of competing national goals of domestic availability, enabling domestic

producers, nuclear non-proliferation, and full cost recovery in the international market may need to be re-visited. This may be beyond the scope of the NNSA ⁹⁹Mo program and is beyond the scope of this NSAC review.

Introduction

The Nuclear Science Advisory Committee (NSAC) ⁹⁹Molybdenum (⁹⁹Mo) Subcommittee was originally formed in response to a charge letter dated December 5, 2013. This letter was motivated by the legislation “American Medical Isotopes Production Act of 2012” (AMIPA) that was contained in the National Defense Authorization Act for Fiscal Year 2013. This act requires the Secretary of Energy to establish a technology-neutral program to provide assistance to commercial entities to accelerate production of ⁹⁹Mo (aimed at ensuring a reliable domestic supply of the isotope ⁹⁹Mo) used to supply the medical diagnostic ^{99m}Tc in the United States, without the use of Highly Enriched Uranium (HEU). The entity responsible for development of this program in 2014 was the National Nuclear Security Administration (NNSA) Global Threat Reduction Initiative (GTRI). This act also called for an annual review of the NNSA GTRI program by the NSAC. The program responsible is now the NNSA Material Management and Minimization (NNSA-M³) program.

NSAC set up a Subcommittee to perform this review in 2014. A new charge was delivered to NSAC April 3, 2015 (*Appendix 1*) requesting the second in the series of annual reviews called for in the AMIPA Act. The 2015 Subcommittee membership and relevant experience is given in *Appendix 2*.

The Subcommittee met May 7-8, 2015 in Gaithersburg, MD and built on the extensive work of the first review. At this meeting the Subcommittee was briefed by NNSA on details of the program, and received input from representatives of the Organization for Economic Co-operation and Development-Nuclear Energy Agency’s (OECD-NEA) High Level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) and the National Academy of Sciences’ (NAS) Committee on State of Molybdenum-99 Production and Utilization and Progress toward Eliminating Use of Highly Enriched Uranium. The Subcommittee invited input from both current cooperative agreement (CA) partners and both presented briefings. The Subcommittee also invited representatives of a prospective cooperative agreement partner to present. Finally, the Subcommittee solicited feedback from a broad set of ⁹⁹Mo stakeholders, devoting a session to all stakeholders who requested time to make a presentation in person. A number of other stakeholders submitted written input to the Subcommittee. Appendix 3 contains the agenda of the Subcommittee meeting.

Considerable information on ⁹⁹Mo production and the events leading to the AMIPA legislation were presented in the previous NSAC report. The reader is directed to this report science.energy.gov/~media/np/nsac/pdf/docs/2014/Mo-99_report-8-may-2014-submitted.pdf for additional background information.

Changes in the International Landscape Since the 2014 Report

The commitment to full cost recovery is laid out in the OECD-NEA's joint declaration (<https://www.oecd-nea.org/med-radio/jointdeclaration.html> last reviewed 10 Feb 2015) which committed the signatories to *"Take the necessary actions described above by the end of December 2014 or as soon as technically and contractually feasible thereafter, aware of the need for early action to avoid potential shortages of medical radioisotopes that could arise from 2016"*. These goals are not being met as rapidly as expected or needed and this impacts the economic competitiveness of all CA partners. This fact was recognized by NNSA and is supported by the 2014 report of the OECD-NEA: The Supply of Medical Radioisotopes: Results from the Second Self-assessment of the Global ⁹⁹Mo/^{99m}Tc Supply Chain [Ref. 3]. This report states: *"Progress towards implementing full-cost recovery by reactor operators and processors has been slow since the first self-assessment" and "Although reduced, government subsidies continue to be a barrier to efforts to implement full-cost recovery everywhere. This sends a negative signal to the rest of the market and slows down full implementation. Also, planned new reactor and processor infrastructure is being built with public funds, which further undermines the progress towards economic sustainability."*

The Canadian government continues to have a firm October 2016 deadline to stop routine production of ⁹⁹Mo. They have recently announced [Ref. 1] that the National Research Universal reactor (NRU) will run through March 2018 (pending extension of license) but will not produce ⁹⁹Mo except on an emergency basis in the case of an extreme shortage. At present, the trigger for this emergency production has not been announced and the availability and timeline for emergency procurement of HEU targets (which would need to come from the U.S.) is unknown.

Developments in the NNSA Program

The NNSA efforts to establish reliable domestic supplies of ⁹⁹Mo have been reorganized since last year. Those efforts are now part of the Material Management and Minimization (M³) program. The M³ program has three pillars:

1. The Convert pillar works to convert research reactors and isotope production facilities to non-weapons-usable nuclear material both domestically and abroad;
2. The Remove pillar works to remove or confirm the disposition of excess weapons-useable nuclear material at civilian facilities across the globe and consolidate those materials that remain; and
3. The Dispose pillar works to dispose of and manage excess weapons-useable nuclear material, from both domestic stockpiles and material returned from abroad and implement the Plutonium Management Disposition Agreement (PMDA) with Russia. The ⁹⁹Mo production program now lies within the Convert pillar.

The objectives of the M³ ⁹⁹Mo program remain the same: to achieve HEU minimization and to assist in establishing reliable domestic supplies of ⁹⁹Mo produced without HEU. The M³ program seeks to achieve these objectives through assisting global ⁹⁹Mo production facilities to convert to the use of low-enriched uranium (LEU) targets and accelerating the establishment of commercial non-HEU-based ⁹⁹Mo production in the United States. It is the latter of these that was the main concern of this review.

The problem of improving the reliability of the domestic isotope supply is a complex one and many of the complicating factors lie outside the direct control of the NNSA, or of the U.S. government. NNSA has identified several strategies to address weaknesses in the current ⁹⁹Mo supply chain (Figure 1 reproduces a slide from NNSA illustrating the overall supply chain).

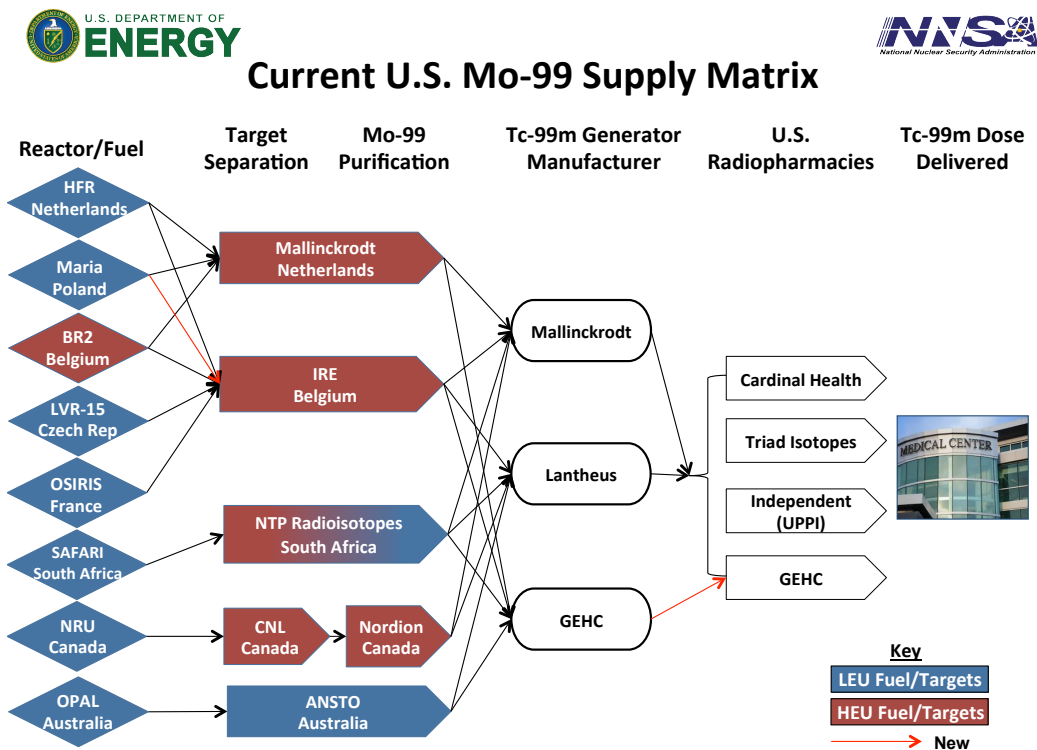


Figure 1: NNSA illustration on U.S. ⁹⁹Mo supply matrix. AECL has changed its name to Canadian Nuclear Laboratories (CNL)

New production capabilities at new and existing reactors (some using HEU fuel) have come on line (or are about to). Foreign governments are subsidizing these efforts. Additionally, the situation with respect to NRU/CNL/Nordion has changed. October 2016 is still a hard deadline for production of ^{99}Mo to cease in Canada. However, Canada has announced their intention to continue to run the NRU reactor through March 2018 [Ref. 1], allowing Canada to provide a supply of ^{99}Mo in the case of unexpected shortages. According to NNSA, before 2010, the NRU produced over 40 percent of global supply whereas today it supplies between 15 to 20 percent of the global market. The trigger mechanism for ^{99}Mo production has not yet been defined and therefore there is some uncertainty about the impact of this decision.

NNSA is continuing to work with the international community toward the establishment of a level playing field for competition in the ^{99}Mo market through implementation of full cost recovery principles. The NNSA said that progress toward full cost recovery is not proceeding as fast as planned or needed. The strategy has not been modified to adjust for this situation.

Sections 3173 (c) and (e) of the FY13 National Defense Authorization Act directs DOE to establish a Uranium Lease and Take Back (ULTB) program by January 2016 to make low enriched uranium available through lease contracts, for irradiation for the production of ^{99}Mo for medical uses. The Act also requires DOE to retain responsibility for the final disposition of spent nuclear fuel and to take title to and be responsible for the final disposition of radioactive waste for which the Secretary determines the producer does not have access to a disposal path, that is created by the irradiation, processing, or purification of the uranium leased. The Act also requires DOE to recover the costs associated with the ULTB Program.

This ULTB Program is coordinated between different organizations within DOE: the NNSA Production Office provides the management and leasing of LEU required for domestic fission-based ^{99}Mo production while the Office of Environmental Management (EM) manages the disposition of spent nuclear fuel and radioactive waste that does not have an existing disposal path, both of which may be generated by ^{99}Mo production. The cost recovery models DOE will utilize for the ULTB Program are of particular interest to potential ULTB users (including the CA partners of the ^{99}Mo program) because they need estimated program costs to assess and incorporate in their business case planning. NNSA has established an intra-agency working group to coordinate the completion of various activities in order to establish the ULTB program on schedule. A positive development in the last year has been the significant progress that M³ has made in completing its necessary scheduled items. However, there remain a number of important activities that will need to be completed but are not scheduled to be completed until late in the calendar year.

As required by AMIPA, the M³ program has continued to pursue several technologies to provide assistance to commercial entities to accelerate production of ⁹⁹Mo in the United States without the use of HEU. This program involves creating cooperative agreements with a set of commercial entities based on a 50/50 cost share between the government and the commercial entity. NNSA continues to operate using a total funding limitation of \$25M to each commercial project it supports; this is in accordance with the OECD-NEA guidelines on full cost recovery principles that government contribution remains less than 15% of the estimated project cost. NNSA supplied \$8.54M to CA partners in FY14, for a total expenditure of \$42.54M since the program started in FY09. In addition, NNSA also has sponsored research at the national labs that provide basic supporting information for the CA projects. The Congressional Budget Office estimates of the direct funding impact for the entire program in earlier proposed authorization legislation were on the order of \$150M.

At the time of the present review there are three active CA projects with two different partners, SHINE Medical Technologies and NorthStar Medical Radioisotopes. This is unchanged since last year (NNSA's previous partnership with SHINE/MORGRIDGE has evolved to a partnership with only SHINE). In addition, NNSA is presently evaluating a proposal from General Atomics (GA). GA was selected as a result of the 2010 Funding Opportunity Announcement, but declined at the time following their own business evaluation. NNSA and GA agreed to re-engage on the project if GA's position changed. GA's position did change and they formally submitted a revised proposal to NNSA.

One active CA project (NorthStar) seeks to produce ⁹⁹Mo using a neutron-capture technology at the Missouri University Research Reactor (MURR) operating since 1966 using HEU as reactor fuel. In this case an isotope generator technology that differs from the existing isotope generator technology in the U.S. would be required. The partner is in the process of obtaining U.S. Food and Drug Administration (FDA) approval for a new generator system that will be used with this low specific activity material. They have previously made an initial New Drug Application (NDA) to the FDA for their RadioGenix ^{99m}Tc generating system and are now preparing a final amendment to be submitted to the FDA, answering previous questions. To achieve their ultimate production capacity, they will need to use enriched isotope ⁹⁸Mo targets that will require an amendment to their NDA. NorthStar completed a successful integrated production run that was announced on May 5, 2015. According to the Associated Press release, this test demonstrates the ability to produce, package and ship ⁹⁹Mo orders to customers. They have also completed a 50,000 sq. ft. facility that will house corporate headquarters, ISO 8 clean rooms supporting production needs, and recycling/building their Type A shipping vessels. The projected production of ⁹⁹Mo for the U.S. market is delayed by about one year from their timeline presented at the review a year ago. This is stated to be because the process of getting the FDA approval required for the new generator and the response to FDA feedback was taking longer than anticipated.

The second project of NorthStar is based on using electron accelerator technology to produce ^{99}Mo via photo-nuclear reactions on ^{100}Mo and will use the same new generator for low specific activity ^{99}Mo . Achieving 3,000 6-day Ci/week would require multiple (16) electron accelerators and irradiation target stations. This project will require significant funds to move forward and is viewed as a longer-term solution; therefore, most of the effort is being focused on the first project. NorthStar is working with national laboratory staff to optimize the accelerator production process. They have just completed a series of 24-hour runs at Argonne National Laboratory (ANL) and are preparing for a production simulation (6.5 day run) to be accomplished in fiscal year 2015. All of the runs at ANL are already utilizing enriched ^{100}Mo molybdenum targets, as is planned to be used in their production facility. The projected date of first production from this project is also delayed by about one year since the time of the 2014 review.

The third CA project (with SHINE) is pursuing fission-based production of ^{99}Mo , with the neutrons inducing fission originating from a D-T neutron generator instead of a reactor. The target is a sub-critical LEU aqueous solution. It surrounds a tritium gas cylinder irradiated with low energy deuterons. SHINE anticipates that the high specific activity ^{99}Mo produced with this technology will not require a new FDA NDA. If it meets the specifications of current reactor-produced high specific activity ^{99}Mo FDA approval should be greatly simplified. As high specific activity ^{99}Mo , it can be used as is by the current generator manufacturers. However, U.S. Nuclear Regulatory Commission (NRC) approval is needed both to begin construction and to operate the resulting facility of accelerators and sub-critical assemblies. First production from this project is delayed ~ 2 years since the 2014 review. Since the last review, this partner has signed supply agreements with two major generator manufacturers. In the last year they have produced and purified demonstration material meeting the purity specifications of the generator manufacturer. At present, progress of this project is hindered by the limited availability of investment funds

Finally, NNSA is in process of evaluating a proposal from General Atomics, as mentioned earlier. In this potential project ^{99}Mo would be produced from LEU targets using a selective gaseous extraction (SGE) process, which has been demonstrated in irradiation tests in MURR and in the TRIGA reactor at Texas A&M University. This potential project is based on the capabilities of the MURR reactor and seeks to develop the capability to produce a minimum of 3,000 6-day Ci of ^{99}Mo per week by the end of 2017, and to begin commercial production immediately thereafter. The ^{99}Mo produced by the SGE process has a high specific activity consistent with current $^{99\text{m}}\text{Tc}$ generator designs. In addition, the SGE technology also provides the capability to extract ^{99}Mo from the LEU targets in-situ while under irradiation. General Atomics has begun preliminary work but the full start of the project is awaiting a commitment from the DOE to establish a mechanism for lease and take back of the LEU required for the prototype target

assembly that will be fabricated and irradiated as part of the research and development portion of the program.

NNSA has been monitoring the impact of the \$10 per dose reimbursement for medical procedures using non-HEU produced ^{99m}Tc supplement that has been available since 2013 from the Centers for Medicare and Medicaid Services. NNSA presented data showing a steady increase in the number of units billed for the procedures using non-HEU produced ^{99m}Tc ; however, the number is very small (miniscule) compared to the total number of treatments nationwide. Reimbursements from private payers are not impacted.

Findings

The Subcommittee found that the NNSA has worked diligently and proactively over the course of the program based on the specific AMIPA requirements, especially considering the many complex factors outside their direct control. They conducted peer reviews of initial proposals based on well-defined criteria flowing from AMIPA; they have made good use of the national laboratories to support their cooperative agreement partners; and they have been responsive in managing the projects they awarded. In addition, they have effectively partnered with other parts of DOE where it is needed to advance the ^{99}Mo program, e.g. working on the establishment of a Uranium Lease and Take Back program.

NNSA has continued, and even improved, their efforts to coordinate with other organizations. In spite of these efforts, the Subcommittee finds that the possibility of a shortage of ^{99}Mo in the period 2016 -2018 has substantially increased since the last review. This conclusion is based on the delays in expected production from the domestic CA partners and the most recent estimates of capacity and demand from the OECD-NEA [Ref 2].

The ^{99}Mo program itself has concluded that commercial viability of domestic production depends on the global move toward full cost recovery. Progress is much slower than expected due to conditions outside of NNSA's control [Ref. 3]. This situation impacts the economic environment in which the CA partners must obtain funding. While different partners have divergent views on the need to change the funding limits and cost share parameters, the projects needing significant investment in facility construction (which may need licensing) are more disadvantaged in fundraising by the lack of global implementation of full cost recovery.

Significant quantities of ^{99}Mo produced outside the U.S. with LEU are being used in the U.S. There does not seem to be any issue, per se, with ^{99}Mo produced from LEU material being accepted in the U.S. market. The Subcommittee notes that two of the technologies being pursued by CA partners require the use of a completely new generator, which has a slower and more complicated elution process compared to current generators. This may cause some reluctance to

accept this technology in the market. There could be a window for higher acceptance of such new technology when the NRU stops producing material in 2016.

The subcommittee was informed that there are additional expenses to the patient and extra steps and records required of a hospital in order to get the additional \$10/dose supplemental reimbursement. Hence the demand for a certified pure LEU generator and claims for the additional \$10/dose supplement remain low.

In the next sub-sections the Subcommittee addresses the specific questions laid out in the NSAC charge.

What is the current status of implementing the goals of the NNSA-MMM ⁹⁹Mo Program? What progress has been made since the initial assessment?

The projected dates of production from the active CA projects have incurred delays ranging from 1-2 years since last year. The existing CA partners have nonetheless all made progress during the last year, with a number of important milestones. In addition, negotiations are in progress with a CA partner who previously declined an agreement that was offered. The possible activation of this CA is a positive development that could impact the domestic supply of ⁹⁹Mo in the longer term. However, the ⁹⁹Mo production technology involved in this approach is radically different from conventional dissolution methods and involves transport of volatilized radioactive materials. In another very positive development, NNSA has shown initiative in working to help in the establishment of the ULTB program

Is the strategy for continuing to implement the NNSA goals complete and feasible, within an international context?

The NNSA strategy does not appear to have been modified to take into account delays anticipated by present CA partners or the slowness in moving toward full cost recovery by the global producers. The strategy also has not been modified to account for the possibility that NRU/Nordion could serve as an emergency supplier in the October 2016 to March 2018 period. Although there has been progress in defining the ULTB program, in part because of NNSA's efforts, the uncertainty in the ULTB program remains an issue for the CA partners.

In the last report, the Subcommittee concluded that the strategy was reasonable but not complete, as it does not address all possible risks in the program; these recent developments reinforce this conclusion. There are many factors outside NNSA's direct control. There is an inherent conflict between the NNSA goal of achieving full cost recovery for new U.S. producers and the reality of other producers outside of the U.S. who still receive substantial public support from their respective governments. The CA project that seems most likely, at present,

to produce ⁹⁹Mo at the earliest date uses a process that takes advantage of existing infrastructure at MURR.

NNSA expressed concern that providing extra funds (which are only needed by some partners) would be unfair, and potentially against U.S. commitments to full cost recovery principles. However, it appears unlikely that a ⁹⁹Mo producer requiring major new infrastructure will succeed unless the financial ground rules are modified. There is also substantial concern in the medical industry that full cost recovery pricing will significantly increase the cost of these procedures. Some solutions to these problems require legislation or Secretarial level action.

Are the risks identified in implementation being appropriately managed?

In some cases the risk mitigation actions have become increasingly responsive. For example, NNSA has taken an active role in the development of the ULTB program and there is now a schedule in place for the issuance of draft model contracts. In other cases the risk management could be enhanced. For example:

- The risk due to lack of progress in the move to full cost recovery in the international community is largely outside the control of NNSA. This impacts the ability of CA partners to gain funding in cases where significant infrastructure investment is required. It is possible that DOE could mitigate this risk if NNSA were able to increase their level of investment.
- The risk mitigation actions still leave uncertainty with the ULTB program that appears to be discouraging private investment. This program is not the direct responsibility of the NNSA. The publication of a draft of the ULTB model contracts is an urgent need and NNSA has taken very credible actions to move the program definition forward. Agency level engagement will be important in reducing this risk by ensuring model contracts are finalized as soon as possible.

Has the NNSA-MMM Program addressed concerns and/or recommendations articulated in the 2014 NSAC assessment of the ⁹⁹Mo Program appropriately and adequately?

It is clear that the NNSA-M³ program has paid attention to the 2014 assessment. This has occurred in spite of numerous organizational and personnel changes in the program.

The 2014 Subcommittee report recommended that NNSA should look carefully across the domestic production part of the ⁹⁹Mo program in view of known facts (such as progress on CA projects, economic environment for capital and projected operating costs) in order to focus resources on the most promising CA agreements. Two CA projects were already inactive at the last review. Since the review NNSA has stopped national lab work related to these inactive CA

projects. At this point the NNSA appears to have sufficient resources to continue or increase investment in the active CA projects.

The 2014 report recommended that based on the slowness of progress toward implementation of full cost recovery internationally, NNSA should consider relaxing their present \$25M cap on investment in any project. NNSA stated in this review that they have carefully considered the issue of increasing the \$25M limit or otherwise increasing funds available to CAs and that options are still under consideration. To date the \$25M limit has not been reached on any project. NNSA stated that stakeholder input on the topic has been mixed; the Subcommittee observed this as well. NNSA has also investigated the current DOE loan program and found that it could not be used to support ⁹⁹Mo program efforts without legislative action. Risks identified by the Subcommittee have been added to the NNSA ⁹⁹Mo program risk register.

Since the last review, the dates at which domestic ⁹⁹Mo is expected to first appear in the domestic market have been delayed by 1-2 years. The progress of the international community toward full cost recovery has been slower than expected, and this impacts the financial viability of the domestic projects. For these reasons, the Subcommittee concludes the NNSA actions in response to the 2014 report are less than the subcommittee would have expected given the lack of progress.

Ultimately the success of the program will need to be judged based on the interpretation of the intended goal of the AMIPA. If one of the cooperative agreement partners achieves domestic production, then the NNSA will have provided assistance that accelerated domestic production. If another party who is not a cooperative agreement partner successfully enters the market and provides sufficient U.S. supply to avoid shortages, the NNSA efforts in converting irradiations internationally to LEU targets and in encouraging full cost recovery prices may be a material component of this success. If shortages in domestic supply do materialize in the 2016-2018 time frame (as seems quite possible) and no domestic production capacity exists, then the NNSA program will not have met the spirit of AMIPA.

Recommendations

The NNSA-M³ is working toward their high level goal to accelerate domestic production of ⁹⁹Mo. The CA partners have very specific and measurable goals and delivery dates; these have seen significant additional delay over the last year. The NNSA has worked with funding limitations that are consistent with the principles of full cost recovery. However, the international community of ⁹⁹Mo producers has not made adequate progress toward full cost recovery according to the OECD-NEA. The \$25M limit, coupled with the 50/50 cost share being applied to all phases of the projects, is proving to be a serious impediment to projects that do not take advantage of significant existing infrastructure, even

preventing them from spending up to the present \$25M limit. One partner stated explicitly that the delays in the last year were due to difficulty in obtaining funds. The CA project that anticipates producing ^{99}Mo in the near term relies heavily on existing infrastructure at the Missouri University Research Reactor (MURR) that has been operating since 1966. If the terms and amount of funding available through the M³ program is not changed, it is likely the only new production in the U.S. will rely on the MURR reactor.

Based on these findings, the Subcommittee has four recommendations:

Recommendation #1: DOE should increase funds available to individual Cooperative Agreement projects sufficient to significantly accelerate their ability to rapidly establish domestic production. This could be accomplished, for example, by increasing the \$25M cap or increasing the NNSA cost share fraction during the R&D phase of projects.

Recommendation #2: DOE must support NNSA in their continued efforts to advocate for the timely establishment of the Uranium Lease and Take Back (ULTB) Program. The publication of a draft of the ULTB model contracts is an urgent need and NNSA has taken very credible actions to move the program definition by the DOE intra-agency working group forward. However, high-level agency engagement will be essential in reducing this risk by ensuring model contracts are finalized as soon as possible.

Recommendation #3: NNSA should document a contingency plan to ensure a supply of ^{99}Mo from Canada within a few months if a significant shortage of ^{99}Mo appears imminent during the period 2016-2018. This plan should include details on working within the U.S. government and with the Canadian producers/government to address the definition of a trigger mechanism for ^{99}Mo production at NRU and ensure that valid import and export licenses for HEU are in place prior to the need for them. This contingency plan document should be available by the next NSAC review.

Recommendation #4: NNSA should develop a contingency plan to adapt the program should OECD-NEA continue to determine that the global community is not making adequate progress toward full cost recovery in order for domestic production to be economically feasible. This should be available by the next NSAC review.

On the present path, there is substantial risk of shortages in ^{99}Mo available in the United States in the next few years, with potential for negative impact on the health of the population. The recommendations above are meant to improve the outlook relative to this substantial risk. Implementation of these mitigation measures reduces but does not remove this risk. Further, a domestic producer that does succeed in entering the market might ultimately fail because they are not able to compete in the (*still*) subsidized international market. The relative

priority of competing national goals of domestic availability, enabling domestic producers, nuclear non-proliferation, and full cost recovery in the international market may need to be re-visited. This may be beyond the scope of the NNSA ⁹⁹Mo program and is beyond the scope of this NSAC review.

References

[1] Press release by the Canadian government, February 6, 2015
<http://www.newswire.ca/en/story/1483497/government-of-canada-announces-extension-of-national-research-universal-nru-reactor>

[2] OECD/NEA (2014), *The Supply of Medical Radioisotopes: Medical Isotope Supply in the Future: Production Capacity and Demand Forecast for the ⁹⁹Mo/^{99m}Tc Market, 2015-2020*, OECD, Paris, France.

[3] OECD/NEA (2014), *The Supply of Medical Radioisotopes: Results from the Second Self Assessment of the Global ⁹⁹Mo/^{99m}Tc Supply Chain*, OECD, Paris, France.

Appendix 1 – Charge Letter



U.S. Department of Energy
and the
National Science Foundation



March 10, 2015

Dr. Donald Geesaman
Chair, DOE/NSF Nuclear Science Advisory Committee
Argonne National Laboratory
9800 South Cass Avenue
Argonne, Illinois 60439

Dear Dr. Geesaman:

This letter is to request that, in accordance with direction given to the DOE in the National Defense Authorization Act (NDAA) for FY2013, the Nuclear Science Advisory Committee (NSAC) standing Subcommittee on Mo-99 conduct its annual assessment of the effectiveness of the National Nuclear Security Administration, Office of Material Management and Minimization's (NNSA-MMM) Domestic Molybdenum-99 (Mo-99) Program (formerly known as the Global Threat Reduction Initiative).

The American Medical Isotopes Production Act of 2012 (Act), formerly known as S.99 and H.R. 3276, was incorporated into the National Defense Authorization Act (NDAA) for FY2013. On January 2, 2013, President Obama signed the NDAA into law, enacting this legislation. A stipulation of the NNDA under section 3173 - *IMPROVING THE RELIABILITY OF DOMESTIC MEDICAL ISOTOPE SUPPLY* is that:

"... the Secretary [of Energy] shall... use the Nuclear Science Advisory Committee to conduct annual reviews of the progress made in achieving the [NNSA MMM] program goals and make recommendations to improve program effectiveness."

The Department of Energy (DOE) and National Science Foundation (NSF) very much appreciate NSAC's initial assessment of the NNSA-MMM Mo-99 Program, and the subsequent report transmitted to the agencies on May 8, 2014.

Subsequently, we request that NSAC reconvene the Subcommittee to provide an annual assessment of the following charge elements:

- What is the current status of implementing the goals of the NNSA-MMM Mo-99 Program? What progress has been made since the initial NSAC assessment?
- Is the strategy for continuing to implement the NNSA goals complete and feasible, within an international context?
- Are risks identified in implementing those goals being appropriately managed?




Printed with soy ink on recycled paper

- Has the NNSA-MMM Program addressed concerns and/or recommendations articulated in the 2014 NSAC assessment of the Mo-99 Program appropriately and adequately?
- What steps should be taken to further improve NNSA program effectiveness in establishing a domestic supply of Mo-99?

It is requested that this annual assessment be submitted by July 2015. Subsequent assessments are to be provided annually.

We are aware that this charge represents an additional burden on your time. However, the involvement of NSAC is essential to inform the Agency regarding the effectiveness of efforts to steward Mo-99, an isotope essential for the health and well-being of the Nation.

Sincerely,



Patricia M. Dehmer
Acting Director
Office of Science



F. Fleming Crim
Assistant Director
Directorate for Mathematical
and Physical Sciences

Appendix 2 – Molybdenum-99 Sub-committee membership

Susan Seestrom, Chair, Los Alamos National Laboratory
 Carolyn Anderson, University of Pittsburgh
 Jeff Binder, University of Illinois
 Ronald Crone, Idaho National Laboratory
 Jack Faught, LINDE
 Mitch Ferren, Oak Ridge National Laboratory
 Donald Geesaman, Argonne National Laboratory
 Suzanne Lapi, Washington University Saint Louis
 Meiring Nortier, Los Alamos National Laboratory
 Steve Mattmuller, Kettering Medical Center
 Berndt Mueller, Brookhaven National Laboratory
 Ken Nash, Washington State University
 Joseph Natowitz, Texas A&M University
 Thomas Ruth, TRIUMF

Committee Expertise		
Reactor Design and Operation	Radioisotope Production	Radiopharmaceutical Chemistry
Ron Crone Jeff Binder	Mitch Ferren Jeff Binder Suzanne Lapi Meiring Nortier Thomas J. Ruth	Carolyn Anderson Suzanne Lapi Thomas J. Ruth
Nuclear and Radio Chemistry	Commercial Isotope Sales	Project Management
Carolyn Anderson Suzanne Lapi Ken Nash Joe Natowitz Meiring Nortier Thomas J. Ruth	Jack Faught Mitch Ferren	Berndt Mueller Don Geesaman Susan Seestrom Ron Crone
Nuclear Physics	Nuclear Engineering	Radiopharmacist
Don Geesaman Berndt Mueller Joe Natowitz Susan Seestrom	Ron Crone Jeff Binder Meiring Nortier	Steve Mattmuller

Appendix 3 – Meeting Agenda
Agenda NSAC Mo-99 Program Review
May 7-8, 2015

Gaithersburg Marriott Washingtonian Center, Salon C
9751 Washingtonian Boulevard, Gaithersburg, Maryland

Thursday, May 7

08-12 Open Session

08:00 Discussion of Charge (DOE NP/NSF) (30 minutes)

08:30 Overview of Mo-99 Program (NNSA)

- Focus on strategy, goals, risks

09:00 Review of 2014 Recommendations (Seestrom) (30 minutes)

09:30 Changes made by NNSA in response to recommendations (NNSA) (30 minutes)

09:30 Developments in the Mo-99 Program since the last review (NNSA) (60 minutes)

- Summary changes in national/international landscape; potential producers
- Changes in NNSA approach

10:30 Break

11-5 Closed Session (Committee and DOE NP/NSF)

11:00 Review of Progress by Active Cooperative Agreement Partners (NNSA) (60 minutes)

12:00 -01:00 Working Lunch/OECD Developments (Parrish Staples, Committee and DOE NP/NSF and NNSA)

01:00- 04:00 Updates from Cooperative Agreement Partners (Committee, DOE NP/NSF)

Questions for Partners to address:

- Are the NNSA MMM Mo-99 Program goals sufficiently well defined for you to execute your part in the program?
- What is your assessment of the risk involved?
- Do you receive clear communication on NNSA expectations?
- What improvements have you seen in the management of this program?
- What improvements would you suggest in the management of this program?

04:00 Discussion (Committee and DOE NP/NSF and NNSA)(1 hour minutes)

05:00 Committee Discussion Committee and DOE NP/NSF)

Friday, May 8 (Open Session)

08:30-09:00 Overview of the NAS Study (30 minutes)

09:00-12:00 Stakeholder Input and Public Comment Session

12:00 Working lunch (Committee and DOE NP/NSF and NNSA) (60 minutes)

01:00 Committee Working Session (Committee and DOE NP/NSF only)

05:00 Adjourn

Appendix 4 – Acronym List

AMIPA - American Medical Isotopes Production Act of 2012
CA- Cooperative Agreement
CNL - Canadian Nuclear Laboratories
DOE – U. S. Department of Energy
FDA - U.S. Food and Drug Administration
GA – General Atomic
GTRI - Global Threat Reduction Initiative
HEU - Highly Enriched Uranium
HLG-MR - High Level Group on the Security of Supply of Medical Radioisotopes
LEU – Low-Enriched Uranium
MURR - Missouri University Research Reactor
M³ – NNSA Material Management and Minimization Program
NDA – New Drug Application
NNSA - National Nuclear Security Administration
NNSA-M3 - NNSA Material Management and Minimization
NSAC - Nuclear Science Advisory Committee
NNSA-M3 - the NNSA Material Management and Minimization
NRC - U.S. Nuclear Regulatory Commission
NRU - National Research Universal reactor
OECD-NEA - Organization for Economic Cooperation and Development's
Nuclear Energy Agency
PMDA - Plutonium Management Disposition Agreement
SGE – selective gas extraction
TRIGA – Training, Research and Isotopes, General Atomic reactor
ULTB – Uranium Lease and Take Back Program