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MOLYBDENUM-99 TECHNOLOGICAL DEVELOPMENT

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U.S. Nuclear Regulatory Commission Licensing Activities Related to Molybdenum-99 Production

S.T. Lynch, M.F. Balazik, L.N. Tran, and A. Adams
Research and Test Reactors Licensing Branch
U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, 20852 Rockville – United States

ABSTRACT

This paper provides an update on U.S. Nuclear Regulatory Commission (NRC) licensing activities relating to the establishment of a domestic molybdenum-99 (Mo-99) supply in the United States. Currently, two construction permit applications and one operating license amendment request supporting Mo-99 production are under NRC staff review. In March 2015, the NRC issued a material possession license for small-scale demonstration of superconducting linear accelerator technology. Thorough and timely reviews of current and anticipated license applications are facilitated by public engagement and guidance development. Ongoing infrastructure development efforts include the analysis of the NRC's regulatory framework and development of guidance. Public meetings supplement application reviews, serving as an effective forum for applicants to engage with NRC staff on facility-specific technical and licensing considerations. As applicable, the NRC is coordinating environmental review work with the U.S. Department of Energy and supporting utilization facility site Department of Homeland security vulnerability assessments conducted by the U.S.

1. Introduction

For the past two decades, the United States (U.S.) has relied on imported molybdenum-99 (Mo-99) to perform approximately 50,000 medical procedures daily. Since 2009, global shortages of medical radioisotopes have underscored the need for prompt action to ensure a reliable domestic Mo-99 supply. In response to this need, in 2011 the Office of Science and Technology Policy established Mo-99 policy objectives of ensuring a reliable, internationally available supply of Mo-99, abolishing highly-enriched uranium (HEU) from use in Mo-99 production, and eliminating Mo-99 market subsidies [1]. Subsequently, Congress passed the American Medical Isotopes Production Act of 2012 to phase out exportation of HEU and ensure a reliable domestic supply of non-HEU based Mo-99 [2]. This is consistent with the Energy Policy Act of 2005, which amended the Atomic Energy Act of 1954, as amended, in part, to provide for the National Academies of Sciences to study ways to ensure a reliable supply of medical isotopes and, furthermore, to do so without the use of HEU [3, 4]. In

conjunction with the passage of this legislation, the U.S. Department of Energy (DOE) National Nuclear Security Administration (NNSA) has entered into cooperative cost-sharing agreements with domestic firms to encourage the expeditious construction of facilities dedicated to the production of Mo-99, most of which will require U.S. Nuclear Regulatory Commission (NRC) licensing.

In support of the national initiative to establish a domestic non-HEU-based supply of Mo-99, and in accordance with statutory responsibilities under the Atomic Energy Act of 1954, as amended, 42 U.S.C. § 2011 et seq., the Energy Policy Act, and American Medical Isotopes Production Act, the NRC has issued a materials license and is reviewing two construction permit applications, as well as one license amendment application for radioisotope irradiation and separation facilities. These reviews are facilitated through meetings with applicants and members of the public; coordination with other Federal agencies, such as the DOE and Department of Homeland Security (DHS); and the development of regulatory guidance documents and procedures.

2. Outreach and Communication

Given the significant interest in Mo-99 production, early and frequent communication with current and potential applicants, the public, and other governmental bodies has been an important part of the NRC's regulatory activities related to medical radioisotope production.

Letters of Intent

Since the 2014 Mo-99 Topical Meeting, the NRC has received two additional letters of intent to domestically produce Mo-99 from potential applicants from Niowave, Inc. and Zevacor Molecular. In total, the NRC has received eleven letters of intent from potential applicants. In addition to the two recent letters of intent, Babcock and Wilcox Technical Services Group, Coqui Radiopharmaceuticals (Coqui), General Electric Hitachi Nuclear Energy, SHINE Medical Technologies, Inc. (SHINE), the University of Missouri-Columbia Research Reactor Center (MURR), Northwest Medical Isotopes, LLC. (NWMI), Eden Radioisotopes, LLC., Flibe Energy, and Precision Engineering Consultants, Inc. have all indicated intent to produce Mo-99 utilizing technology that falls under NRC jurisdiction.

While there is no regulatory requirement for submitting letters of intent, these letters establish formal communication between applicants and the NRC and support the NRC's promotion of early and frequent communication on anticipated licensing actions related to medical radioisotope production, as described in Regulatory Issue Summary (RIS) 2013-03, "Pre-application Communication and Scheduling for Medical Radioisotope Production Facilities Intending to Produce [Mo-99]" [5]. Ideally, letters of intent should describe, at a minimum, the number and type of applications a potential applicant anticipates submitting for NRC review, the timing of application submittals, probable site selection, conceptual facility design, and consideration of applicable regulations in Title 10 of the *Code of Federal Regulations* (10 CFR), "Energy." This engagement between the NRC and potential applicants promotes the development and submission of high-quality, complete applications.

Anticipated scheduling information provided in letters of intent also allows the NRC staff to adequately allocate resources to support application reviews.

Public Meetings

Public meetings are planned formal interactions between the NRC and external stakeholders with the expressed purpose of discussing issues directly associated with the NRC's regulatory and safety responsibilities. While public meetings are designed to allow members of the public the opportunity to enhance their understanding of the NRC's regulatory process, they are not intended to be a forum for NRC staff to provide a design review or to make regulatory decisions [6, 7]. Portions of public meetings may be closed to the public in order to discuss information that has been withheld from public disclosure in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding" (e.g., contains trade secrets, privileged, or confidential commercial or financial information).

In the context of the NRC's reviews of facilities proposing to produce Mo-99, public meetings are an effective means for applicants and NRC staff to communicate information related to forthcoming application submittals, discuss relevant guidance, and promote the submission of high-quality applications. These meetings are also an opportunity for potential applicants to provide updates on their overall application status to allow better planning and allocation of resources to ensure a thorough and efficient application review. The NRC staff may also conduct public meetings with applicants to discuss technical information related to an ongoing review.

Since August 2014, the NRC staff has conducted nine public meetings related to medical radioisotope production [8, 9, 10, 11, 12, 13, 14, 15, 16]. These meetings have included several pre-application meetings with Coqui and NWMI to discuss licensing and technical issues surrounding the development of each company's respective construction permit application. Niowave and General Atomics (GA) also engaged with the NRC for the first time regarding plans to produce Mo-99 through the fission of low enriched uranium (LEU). Details on each of these projects are provided below in Section 3, "Regulatory Activities." In addition to these public meetings with potential applicants, the NRC staff conducted two public meetings in Janesville, Wisconsin on June 10, 2015, to discuss the publication of the draft environmental impact statement (EIS) supporting the SHINE construction permit application and receive comments on this document from the Janesville community and other Federal, State, and local agencies. These meetings are a part of the NRC's environmental review process and followed-up on previous meetings related to the development of the SHINE EIS held in Janesville in July 2013[1].

Commission Meetings

In addition to hosting public meetings, the NRC staff may be asked to participate in meetings with the Commission to discuss agency business. These so-called Commission Meetings are

[1] For additional information on the SHINE environmental review, including the EIS and supporting public meetings, please refer to, "U.S. Nuclear Regulatory Commission Environmental Reviews Related to Molybdenum 99 Production," as written and presented by Michelle Moser at the Mo-99 2015 Topical Meeting [17].

conducted in accordance with the Government in the Sunshine Act and open to public observation unless they involve information that is classified, information that is confidential, trade secrets, personnel matters, personal privacy, investigations, or adjudicatory matters [18]. Members of the public are not allowed to participate in public Commission meetings unless specifically requested to do so by the Commission. Should the subject of the Commission meeting be a staff-written issues paper, also known as a SECY Paper, the Office of the Secretary (SECY), will record the Commission's decision in a Staff Requirements Memo, which provides a concise statement of the Commission's decision as well as any additional requirements or tasks to be performed by the staff. A Commission Voting Record is also issued, which includes an indication of affirmative votes, negative votes, abstentions, non-participation, and individual view of all Commissioners.

In December 2014, the NRC staff provided the Commission with an update on the status of the staff's efforts to develop and implement an effective licensing approach for new applicants proposing to produce Mo-99 [19]. The staff first briefed the Commission on its initial efforts to develop a licensing framework for these facilities in May 2012 [20]. At that time the staff had been actively engaged with potential applicants, but had not yet received an application. However, since meeting with the Commission in 2012, the staff has made significant progress in the review of two construction permit applications, including the issuance of interim staff guidance and a direct final rule. During the 2014 Commission Meeting, the staff discussed background on Mo-99 production, including support of national Mo-99 policy objectives; communication with anticipated and current applicants; the status of current application reviews; the construction permit and operating license application process; and staff infrastructure development. SHINE also participated in this Commission Meeting, providing an update on the status of its application and interactions with the NRC staff.

Regulatory Information Conference

The 27th Annual Regulatory Information Conference (RIC) was held during March 10-12, 2015, in Rockville, Maryland. Co-sponsored by the NRC Office of Nuclear Reactor Regulation and the NRC Office of Nuclear Regulatory Research, the RIC is the largest annual meeting hosted by the NRC and brings together more than 3,000 participants from over 30 countries. The RIC provides opportunities for open dialogue and meaningful exchanges of information about significant NRC actions, planned or in progress, related to the regulation of nuclear power plants and nuclear safety research. The conference also provides opportunities to share different perspectives on emerging safety and security issues facing both the domestic and the international nuclear community [21].

A technical session at this year's RIC focused on unique aspects of regulating research and test reactors, which included an update on the status of the NRC's reviews of applications supporting medical radioisotope production. Panelists from NRC and DOE discussed their roles in implementing the national policy objective to establish a reliable domestic supply of Mo-99. The NRC staff panelist focused on the status of preparations for current and anticipated application reviews [22]. This session served, in part, as an update to the information provided at the 26th Annual RIC, which included an entire session devoted to

the status of the NRC's review of applications supporting medical radioisotope production and featured panelists representing the NRC, DOE, SHINE, and the U.S. Food and Drug Administration [23].

Outreach with Federal, State, and Local Government

Outside of public meetings hosted by the staff and Commission, NRC outreach efforts include presenting at various conferences and meetings, including the annual Mo-99 Topical Meetings hosted by Argonne National Laboratory, quarterly meetings with the Office of Science and Technology Policy, and meetings with Congressional staff and organizations such as the National Academy of Sciences. NRC presentations at these meetings typically highlight the status of the NRC's active Mo-99 licensing reviews and initial licensing process for non-power utilization and production facilities.

The NRC staff has also organized government-to-government meetings with state and local government representatives in those states and cities where applicants have proposed to construct facilities for medical radioisotope production. These meetings, which may also include other Federal agencies such as DOE and DHS, are often scheduled to coincide with NRC-hosted public meetings held near the proposed construction site, such as environmental meetings. These meetings serve as a forum to establish roles and responsibilities for reviews among Federal, state, and local government agencies, explain the NRC licensing process, provide updates on the status of relevant NRC application reviews, and allow state and local officials to ask any questions they have about the NRC's role in licensing facilities intending to produce medical radioisotopes, such as Mo-99. Most recently, in June 2015, a government-to-government meeting was held in support of the review of the SHINE construction permit application with affected state, county, and city government representatives, as well as emergency responders, from Wisconsin, Rock County, and Janesville, respectively.

3. Regulatory Activities

The majority of proposals for facilities intending to produce medical radioisotopes, such as Mo-99, involve the fission of LEU in either reactor or non-reactor technologies. Designs have featured both solid clad and aqueous solution targets for use at both new and existing facilities. While there are significant variations in the methods proposed to fission uranium, all of these facilities feature hot cells for the chemical separation of Mo-99 from other fission products. The NRC may also license some accelerator-based technologies involving natural molybdenum, assuming that these facilities do not fall under Agreement State jurisdiction.

The NRC staff anticipates licensing most facilities as either utilization or production facilities under 10 CFR Part 50. The proposed utilization facilities share many characteristics of existing non-power reactors. For example, consistent with most existing non-power reactors, thermal power ranges at these facilities are not expected to exceed 10 megawatts. Consequently, these facilities share many similar technical and safety considerations with respect to fission heat removal and accident scenarios.

A limited number of facilities may be licensed under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," or 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." While the Office of Nuclear Reactor Regulation coordinates activities across the agency, in these cases, the Office on Nuclear Material Safety and Safeguards and regional offices will take the technical lead for the reviews.

The NRC staff is currently reviewing construction permit applications for SHINE and NWMI and a license amendment request submitted by Oregon State University (OSU). In February 2015, the NRC issued a materials license to Niowave in support of its medical radioisotope production project, and more recently, in April 2015 met with GA and MURR to discuss potential license amendment application supporting Mo-99 production at MURR. As applicable, the NRC is coordinating its environmental review work with DOE, consistent with the American Medical Isotopes Production Act of 2012, for those applications with Federal actions under each agency, as described in Moser (2015) [17].

Within the last year, the NRC has promoted the efficient review of current and anticipated applications by conducting a direct final rulemaking and developing a construction inspection program. These endeavors, along with the NRC's ongoing efforts to clarify regulatory requirements and develop regulatory guidance, have allowed the NRC staff to perform thorough and timely reviews of applications supporting domestic medical radioisotope production.

Direct Final Rule Modifying the Definition of Utilization Facility

In 2013, SHINE Medical Technologies submitted a two-part construction permit application, proposing to produce Mo-99 through uranium fission in 8 accelerator-driven subcritical irradiation units, comprising an irradiation facility, and 3 hot cell structures, which make up the radioisotope production facility. After an initial review of SHINE's application, staff determined that while SHINE's irradiation units shared many of the characteristics of non-power reactors, they did not meet the definition of a nuclear reactor and could not be licensed as utilization facilities. At that time, according to 10 CFR 50.2, a utilization facility was defined as a nuclear reactor, which the SHINE irradiation units are not. As subcritical operating assemblies, the SHINE irradiation units are not designed or intended to be used to sustain nuclear fission in a self-supporting chain reaction, which is the defining characteristic of a nuclear reactor in 10 CFR. Therefore, the 10 CFR Part 50 regulations governing the licensing of production and utilization facilities could not be applied to SHINE's irradiation facility or irradiation units.

Based on the information provided in SHINE's preliminary safety analysis report (PSAR), NRC staff determined that, while subcritical, the thermal power level and safety considerations of the SHINE irradiation units were comparable to existing non-power reactors, which are licensed under 10 CFR Part 50 as utilization facilities. As a result, the staff recommended and the Commission issued a direct final rule on October 17, 2014, which went into effect on December 31, 2014, adding SHINE's irradiation units to the definition of utilization facility in 10 CFR Part 50 [24]. Since SHINE had anticipated licensing its

irradiation units under 10 CFR Part 50, albeit as part of a production facility, the existing technical content of the PSAR was sufficient to continue the NRC staff's evaluation.

Construction Inspection Program

The Office of New Reactors is currently developing a construction inspection program to support the licensing of facilities intending to produce medical radioisotopes. The program applies to all construction activities, including, design, procurement, fabrication, construction, pre-operational testing activities, and development of programs required for operation. The full construction inspection program will consist of an overall inspection manual chapter and three inspection procedures, which will examine structures, systems, and components; quality assurance; and operational readiness.

Niowave Materials License

On February 11, 2015, Niowave submitted a materials license application, requesting less than a critical mass of LEU. The application proposed to produce small amounts of Mo-99 (up to 10 millicuries [mCi]) through the fission of LEU using superconducting linacs to "demonstrate safe, reliable operations, and to benchmark simulations of Mo-99 production rates."

A materials license was issued to Niowave on March 26, 2015 [25]. This license authorized Niowave to possess and use small quantities of individual isotopes (1 mCi per isotope) for research and development. These isotopes include 0.015 g of U-234, 2.3 g of U-235, and 21 g of U-238. Niowave's authorization is limited to demonstrating the ability to make small quantities of Mo-99. As such, chemical separation of the Mo-99 from LEU targets is not performed or authorized.

SHINE Construction Permit Application

The NRC staff received a two-part construction permit application from SHINE, consisting primarily of an environmental report and PSAR. The environmental report and PSAR were submitted on March 26 and May 31, 2013, respectively. The staff found both parts of the construction permit application to be acceptable for docketing on June 25 and December 2, 2013,
respectively [26, 27]. Publicly available portions (i.e., non-sensitive and non-proprietary) of SHINE's application may be accessed under Docket Number 50-608 in the NRC's Agencywide Documents Access and Management System (ADAMS) public document collection at http://www.nrc.gov/reading-rm/adams.html.

NRC review of a construction permit application includes the commencement of the NRC staff's safety and environmental reviews, staff requests for additional information (RAIs) from the applicant, completion of a safety evaluation report (SER) and environmental assessment or EIS, interaction with Commission's Advisory Committee on Reactor Safeguards (ACRS), a mandatory hearing conducted by the Commission or an assigned

Atomic Safety and Licensing Board, and a decision to grant or deny a construction permit. The environmental review typically requires the NRC staff to coordinate or consult with various Federal, State, and local agencies, as appropriate or required by, for example, the Endangered Species Act, 16 U.S.C. §1531 et seq. As required by the American Medical Isotopes Production Act, the NRC staff will also coordinate the environmental review with the Department of Energy.

In the course of reviewing SHINE's application, the staff determined that additional information was required to complete the review of SHINE's preliminary safety analysis and environmental reports in order to prepare an SER and EIS, respectively. Therefore, the staff issued RAIs in September 2013, September 2014, January 2015, March 2015, and April 2015 [28, 29, 30, 31, 32]. As of August 2015, SHINE has responded to all outstanding RAIs. The NRC published the DEIS in May 2015 [33]. Both the final EIS and SER are scheduled to be published in October 2015.

To date, NRC staff and SHINE have made presentations to the Radiation Protection & Nuclear Materials Subcommittee of the ACRS on chapters 1, "Introduction to the Facility," 2, "Site Characteristics," 3, "Design of Structures, Systems, and Components," 4, "Facility Description," 5, "Cooling Systems," 6a, "Irradiation Facility Engineered Safety Features," 7, "Instrumentation and Control Systems," 8, "Electrical Power Systems," 9, "Auxiliary Systems," 12, "Conduct of Operations" and "Preliminary Emergency Plan," 13a, "Irradiation Facility Accident Analysis," and 14, "Technical Specifications," of the SER and PSAR, respectively. The remaining SER and PSAR chapters will be presented at another ACRS subcommittee meeting in September 2015, followed by an ACRS full committee meeting in October 2015. Based on this schedule, it is expected that a mandatory hearing will be held on the SHINE construction permit application in the first or second quarter of fiscal year 2016.

Northwest Medical Isotopes Construction Permit Application

The NRC staff received a two-part construction permit application from NWMI, consisting primarily of an environmental report and PSAR. The environmental report and PSAR were submitted on February 5 and July 20, 2015, respectively. The staff found the environmental report to be acceptable for docketing on May 29, 2015 and is currently reviewing the PSAR to determine acceptability [34]. Publicly available portions (i.e., non-sensitive and non-proprietary) of NWMI's application may be accessed under Docket Number 50-609 in the NRC's ADAMS public document collection at http://www.nrc.gov/reading-rm/adams.html.

Oregon State University Research Reactor License Amendment Application

Oregon State University has submitted a license amendment application requesting approval to place LEU targets in the OSU TRIGA® reactor (OSTR) for the explicit purpose of demonstrating the production of Mo-99 [35]. Publicly available portions (i.e., non-sensitive and non-proprietary) of OSU's application may be accessed under Docket Number 50-243 in the NRC's ADAMS public document collection at http://www.nrc.gov/reading-rm/adams.html. The NRC staff is reviewing this application and has issued two RAIs to

OSU. OSU provided timely responses to both RAIs. The NRC staff will determine whether to grant or deny the application after completion of its review. OSU intends to submit a license amendment application in calendar year 2017 to supplement the amendment currently under NRC review to irradiate LEU targets for NWMI [36].

Anticipated Applications

Coqui is planning on constructing and operating a facility for the production of medical radioisotopes in Alachua, Florida. The facility will consist of two pool-type material testing reactors, designed by INVAP, each operating at power levels below 10 megawatts and using LEU fuel and targets to produce Mo-99. The planned production capacity for the facility is 7,000 six-day curies per week. Aside from the two reactors, the Coqui facility will also have a radioisotope processing plant, a waste management plant, and support offices. Coqui is currently preparing a construction permit application. The NRC staff expects to receive this application in fiscal year 2016 [12].

On April 27, 2015, MURR, in coordination with GA, met with NRC staff in a public meeting to provide an overview of a proposed Mo-99 production project, which could require an amendment to MURR's existing facility license. This project involves a proprietary gaseous extraction technology to be used following the irradiation of LEU targets within the MURR. In attendance at this meeting were representatives from MURR, General Atomics, and Nordion Medical. To date, no timeline has been provided for the submission of an application requesting a licensing action in support of this activity at MURR.

4. Conclusion

Frequent and early communication and coordination with current applicants, anticipated applicants, the public, and other stakeholders are essential components of the ongoing regulatory activities conducted in support of licensing facilities intending to produce medical radioisotopes, such as Mo-99. In support of the national initiative to establish a domestic supply of Mo-99 without the use of HEU, the ongoing NRC activities related to medical radioisotope production include outreach and communication, infrastructure development, and the review of requested licensing actions. Thorough and timely reviews of all applications are facilitated by public and applicant engagement throughout the licensing process. Ongoing infrastructure development efforts include the analysis of the NRC's regulatory framework and development of guidance. The conductance of these reviews, in accordance with the NRC's statutory responsibilities, align with the Agency's mission statement to protect public health and safety, promote the common defense and security, and protect the environment.

5. References

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