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

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ABSTRACT

The U.S. Nuclear Regulatory Commission (NRC) engages in licensing and oversight activities related to establishing a domestic molybdenum-99 (Mo-99) supply in the United States. Since issuing a construction permit to SHINE Medical Technologies, Inc. (SHINE) in February 2016, the NRC continues to review the Northwest Medical Isotopes construction permit application, develop construction and operation inspection programs, ensure the applicability of regulations, and apply lessons-learned from the SHINE review. Within the next year, the NRC expects to receive its first operating license application for a Mo-99 facility. In anticipation of this, the NRC will continue to hold public meetings on proposed applications; discuss and develop guidance; and inform the development of high-quality applications. These activities support the national initiative to establish a reliable, domestically-available supply of Mo-99 while ensuring the safe use of radioactive materials to protect public health and safety, promote the common defense and security, and protect the environment.

1. Introduction

In support of the national initiative to establish a domestic supply of molybdenum-99 (Mo-99), and in accordance with its statutory responsibilities, the U.S. Nuclear Regulatory Commission (NRC) is responsible for licensing new utilization facilities; production facilities; and special nuclear, byproduct, and source material. As such, the NRC staff considers both initial license applications and license amendment requests for nuclear reactors, subcritical operating assemblies, and processing facilities. These technologies are used for irradiating either natural molybdenum or low enriched uranium (LEU) targets and processing irradiated LEU targets to separate Mo-99 from other fission products. The NRC may also license some accelerator-based technologies under stand-alone materials licenses (assuming that these facilities do not fall under Agreement State jurisdiction) and medical uses of byproduct material.

Since the 2015 Topical Meeting on Molybdenum-99 Technological Development, the NRC staff issued a construction permit to SHINE Medical Technologies, Inc. (SHINE) and a license amendment to Oregon State University (OSU) [1, 2]. Additionally, the NRC staff docketed a construction permit application submitted by Northwest Medical Isotopes, LLC (NWMI) in December 2015 [3]. Also under NRC review are license amendment requests submitted by Niowave, Inc. in support of its demonstrations of Mo-99 production using superconducting linacs under a Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30 materials licenses.

The NRC staff continues to prepare for future licensing and oversight activities by evaluating its regulatory and oversight frameworks. In late 2016, the NRC staff expects to receive an amendment request from the University of Missouri Research Reactor (MURR). This request would support a General Atomics (GA) proprietary gaseous Mo-99 extraction technology to be used following the irradiation of LEU targets at MURR. In 2017, the NRC staff anticipates receiving at least one operating license application and beginning construction inspection activities at the SHINE site.

2. Completion of the SHINE Construction Permit Application Review

The NRC staff received a two-part construction permit application from SHINE, consisting primarily of an environmental report and preliminary safety analysis report (PSAR). The environmental report and PSAR were submitted on March 26 and May 31, 2013, respectively. The NRC staff docketed both parts of the construction permit application for review on June 25 and December 2, 2013, respectively [4, 5]. 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.

Areas of Review

The review of SHINE's construction permit application consisted of two concurrent reviews: (1) a safety review of SHINE's PSAR and (2) an environmental review of SHINE's environmental report. The NRC staff reviewed the SHINE PSAR against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design of the SHINE irradiation facility (IF) and radioisotope production facility (RPF). As part of this review, the NRC staff evaluated descriptions and discussions of SHINE's structures, systems, and components (SSCs), with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the SHINE IF and RPF was evaluated to ensure the sufficiency of principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions. In addition, the NRC staff reviewed SHINE's identification and justification for the selection of those variables, conditions, or other items that were determined to be probable subjects of technical specifications for the facility, with special attention given to those items that may significantly influence the final design. The SSCs were also evaluated to ensure that they would adequately provide for the prevention of accidents and the mitigation of consequences of accidents. The conclusions of the NRC staff's evaluation and findings are documented in NUREG-2189, "Safety Evaluation

Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility" [6].

In accordance with Section 102(2)(A) (42 [United States Code] U.S.C. § 4332(2)(A)) of the National Environmental Policy Act, the NRC staff prepared a Final Environmental Impact Statement (EIS) based on its independent assessment of the information provided by SHINE and information developed independently by the NRC staff. The NRC staff conducted an independent evaluation of the application and conducted a systematic, interdisciplinary review of the potential impacts of the proposed action on the human environment and reasonable alternatives to SHINE's proposal. Before development of the Draft EIS, the NRC staff issued a notice of intent and invited the public to provide information relevant to the environmental review. The NRC staff also provided opportunities for governmental and general public participation during the public meeting on the Draft EIS and used publicly available guidance in the development of its Final EIS. The Final EIS, published as NUREG-2183, "Final - Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility Final Report," meets the requirements of 10 CFR Part 51 [7].

Preliminary Safety Analysis Report Review Procedures

The NRC staff's review was tailored to the nature of SHINE's application and informed by NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," Interim Staff Guidance Augmenting NUREG-1537 [8, 9, 10, 11]. The NRC staff also referred to other relevant guidance cited within the NUREG, cited in the application, or used based on the NRC staff's technical judgment. Since SHINE's application only sought authorization for construction, the SHINE facility could be adequately described at a functional or conceptual level in the PSAR. As such, SHINE deferred providing many design and analysis details until the submission of its final safety analysis report (FSAR) with its operating license application.

The objective of the NRC staff's evaluation was to assess the sufficiency of information contained in the PSAR for the issuance of a construction permit, in accordance with 10 CFR 50.35(a) and 10 CFR 50.40. Further evaluation of the SHINE design will be performed following the NRC staff's receipt of SHINE's FSAR.

Resolving Technical Issues

For those technical areas in the construction permit application that required additional information supported by research and development (i.e., a maturation of facility design), the NRC staff had several options for resolution:

1) The NRC staff could have determined that such technical issues required resolution prior to the issuance of a construction permit.

2) The NRC staff could have determined that such information could be left until the submission of the FSAR.

3) The NRC staff could require that such technical issues be resolved prior to the completion of construction, but after the issuance of the construction permit.

Technical issues that fell within the scope of the first option require the issuance of requests for additional information (RAIs). Responses to these requests provide information necessary to establish principal design criteria and/or design bases for the facility.

In the second and third options, the NRC staff may also issue RAIs to resolve identified technical issues. These types of technical issues are those that require a design maturity beyond what is required by 10 CFR 50.34(a) to issue a construction permit. Although determining what constitutes a preliminary versus a final design may be somewhat subjective, according to 10 CFR 50.34, a preliminary design must only include principal design criteria, the design bases, general facility arrangement, and approximate dimensions. The information submitted in the application should be sufficient to provide reasonable assurance that the final design of the facility will conform to the design bases with adequate margin for safety. The NRC staff may issue RAIs if it determines that it is necessary for the applicant to acknowledge certain technical deficiencies that could impact final design. Appropriate responses to these RAIs include commitments to resolving these deficiencies either in the FSAR or before the completion of construction.

During its review of the SHINE construction permit application, the NRC staff determined that additional information was required to complete its review of the PSAR and prepare its SER. Therefore, the NRC staff prepared and issued RAIs dated September 19, 2014, January 6, 2015, March 25, 2015, April 15, 2015, and September 24, 2015 [12, 13, 14, 15, 16].

As of September 2015, SHINE acceptably responded to all NRC staff RAIs. However, the NRC staff determined that additional information was needed to address certain matters related to nuclear criticality safety and radiation protection in the RPF. Appendix A, "Permit Conditions and Regulatory Commitments," to the NRC staff's SER identifies permit conditions that the NRC staff included in the SHINE construction permit. The conditions are confirmatory in nature and must be satisfied prior to the completion of construction. Additional details on the basis and timing of satisfaction for each condition appear in the technical evaluations of the SHINE construction permit SER, Chapter 6, "Engineered Safety Features," and Chapter 11, "Radiation Protection Program and Waste Management."

Additionally, Appendix A of the SER contains a listing of those elements of design, analysis, and administration identified as requiring additional research and development or correction. The NRC staff determined that resolution of these items was not necessary for the issuance of a construction permit, but SHINE should ensure that these items are fully addressed in the FSAR supporting the issuance of an operating license. The NRC staff is tracking these items as regulatory commitments and will verify their implementation during the review of SHINE's operating license application.

Ongoing Research and Development

The provisions of 10 CFR 50.34(a)(8) allow for ongoing research and development to confirm the adequacy of the design of structures, systems, and components to resolve safety questions

prior to the completion of construction. SHINE identified two ongoing research and development activities [17, 18]:

1) Irradiation and corrosion testing at Oak Ridge National Laboratory to study mechanical performance of materials, as described in the PSAR.

2) Precipitation studies at Argonne National Laboratory to ensure precipitation of uranyl peroxide in the target solution will not occur, as described in response to RAI G-1.

In support of these activities, SHINE provided descriptions of affected SSCs, the remaining work to be performed, and anticipated schedules for completion. By letter dated September 29, 2015, SHINE has stated that the latest date for completion of construction is expected to be December 31, 2022 [19]. Based on the schedules provided in response to RAI G-1, SHINE's two research and development activities would be resolved in advance of the estimated completion of construction. As described in Appendix A to the SER, the NRC staff is tracking these activities and will verify their resolution prior to the completion of construction.

Advisory Committee on Reactor Safeguards Review

To support the Advisory Committee on Reactor Safeguards (ACRS) in providing an independent review and report to the Commission regarding the SHINE construction permit application, the NRC staff presented the results of its safety evaluation to the Radiation Protection and Nuclear Materials Subcommittee at four meetings on: June 23 - 24, 2015, August 19, 2015, and September 22, 2015 [20, 21, 22]. The NRC staff presented the results of its SHINE construction permit application review to the ACRS Full Committee on October 8, 2015 [23]. The ACRS issued a letter on October 15, 2015, fulfilling the requirement of 10 CFR 50.58 that the ACRS review and report on construction permits for a facility of the type described in 10 CFR 50.22 [24].

The ACRS letter to the Commission recommended that the SHINE construction permit should be approved. The ACRS identified two safety concerns that could impact the operation of the SHINE facility, if not sufficiently addressed during construction. To address these concerns, the ACRS requested and SHINE and the NRC staff provided additional information on (1) the facility's layup capability, and (2) the facility's ability to withstand potential aircraft impact. The ACRS noted that, "nuclear chemical processing facilities need to have built-in capability to support layup following unexpected process interruptions. It must be possible to stop the process, safely remove materials within the system, clean the system, and place it in a safe condition for an extended period in a way that does not challenge the facility piping systems and chemical reactors." During the ACRS subcommittee and full committee meetings, SHINE and the NRC staff: (1) provided information addressing the provisions made to address facility layup, and (2) clarified the analysis of the SHINE facility's ability to withstand aircraft impacts. Based on discussions during the subcommittee and full committee meetings, the ACRS determined that SHINE and the NRC staff provided sufficient information to address facility layup and potential aircraft impact, such that it could recommend the issuance of a construction permit. Additionally, SHINE clarified the relationship between safety-related

SSCs and safety-related activities by defining safety-related activities. SHINE has committed to providing procedures for facility layup and an updated quality assurance program description that includes its definition of safety-related activities in its FSAR [25, 26]. The NRC staff is tracking these commitments in Appendix A of the SER.

Mandatory Hearing and Issuance of Construction Permit

On December 15, 2015, the Commission conducted a mandatory hearing to receive testimony and exhibits related to SHINE's construction permit application, fulfilling the requirement of 10 CFR 50.58 that the Commission hold a hearing for each application for a construction permit for a facility of the type described in 10 CFR 50.22 [27]. Testimony provided in support of the hearing, including pre-filed written testimony, was used by the Commission to determine whether the NRC staff's review adequately supported the findings in 10 CFR. 50.35(a) and 51.105(a).

The testimony provided by the NRC staff and SHINE representatives focused on unique features of the facility, novel issues that arose as part of the review process, and other significant technical and policy issues. Specific presentation discussions included an overview of SHINE construction permit application and contents, summary of key safety and environmental information associated with the SHINE construction permit application, and a summary of regulatory findings. The NRC staff also provided details on the unique licensing considerations for SHINE's subcritical utilization facilities and production facility; the novel application of 10 CFR Parts 50 and 70 accident analysis methodologies for radiological and chemical exposure accidents; and the environmental impacts of the proposed action.

Finding that the NRC staff's review was adequate to support the findings necessary to issue a construction permit, on February 25, 2016, the Commission issued Memorandum and Order CLI-16-04, authorizing the Director of the Office of Nuclear Reactor Regulation to issue the SHINE construction permit, including the Environmental Protection Plan [28]. The Commission also directed the NRC staff to publish the Summary Record of Decision (ROD), which states, in part, that the standards for issuance of a construction permit, as described in 10 CFR Part 50, had been met and the requirements of Section 102 of the National Environmental Policy Act were satisfied. Both the construction permit and Summary ROD were published on February 29, 2016 [29, 30]. This represents the first construction permit issued for either a non-power utilization or production facility by the NRC since 1985.

As stated during the mandatory hearing proceedings, SHINE intends to begin construction of its facility and submit its operating license application in 2017. In preparation for these activities, the NRC staff held a public meeting on construction inspection on May 26, 2016 [31]. Discussion topics included the NRC's construction in inspection program for non-power production and utilization facilities, as well as SHINE's construction schedule, change control process, commitments to codes and standards, corrective action program, and enforcement policy. The NRC staff also discussed lessons learned from previous construction inspection efforts [32, 33].

In parallel with its construction inspection efforts, the NRC staff is also developing operational inspection procedures and analyzing the applicability of regulations needed to issue an operating license under 10 CFR Part 50 to SHINE's subcritical irradiation units and production facility.

3. Review of Northwest Medical Isotopes, LLC 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 NRC staff accepted and docketed the two-part NWMI construction permit for review on May 29, 2015 and December 24, 2015, respectively [34, 3]. Publicly available portions 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.

As with the SHINE review, the NRC staff's evaluation of NWMI's construction permit application includes safety and environmental reviews supported by RAIs, preparation of an SER and EIS, interactions with Commission's 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.

Public Meetings

Public meetings continue to serve as valuable forums for the NRC staff to engage with the public and applicant. Since docketing the NWMI construction permit application, the NRC staff's environmental and safety reviews have been supported by five public meetings, including an environmental scoping meeting [35, 36, 37, 38, 39]. These public meetings have provided an opportunity for the NRC staff to clarify expectations, licensing processes, applicable regulations and guidance, and review timelines. Representatives from NWMI have used these meetings to discuss the technical content of the construction permit application, discuss the status of the operating license application, and clarify the licensing approach for its facility.

Environmental Review

Pursuant to 10 CFR 51.25 and 51.20(a)(2), the NRC staff determined that an EIS should be prepared for the construction of the proposed NWMI facility [40]. The NRC staff based its decision on the similarities between NWMI's proposed target fabrication process to fuel fabrication and scrap recovery activities, both of which require the preparation of an EIS under 10 CFR 51.20(b)(7).

In support of its preparation of an EIS, the NRC staff conducted a site audit on September 16 -17, 2015 [41, 42]. The results from the site audit supported the NRC staff's initial RAIs related to the NWMI environmental review, issued on November 2, 2015 [43]. Supplemental RAIs were issued on January 19, March 28, and June 16, 2016 [44, 45, 46]. The NRC staff

continues to review NWMI's RAI responses and is on track to publish the Draft EIS in December 2016. Publication of the Final EIS is anticipated in May 2017.

Safety Review

To ensure an efficient review of the NWMI construction permit application, the NRC staff has applied its experience and best practices from the SHINE construction permit application review to its evaluation of the NWMI PSAR. Specifically, the NRC staff is focusing on the most safety-significant technical issues, requesting only the additional information necessary to issue a construction permit, engaging in weekly status calls with the applicant, and following a 22-month review schedule. Additionally, the NRC staff has reduced the expenditure of administrative resources by arranging monthly standing public meetings, which can be used to clarify RAIs, engage in technical discussions, and discuss future licensing actions [37].

Following the acceptance of NWMI's construction permit application, the NRC staff issued an initial set of RAIs in March 2016 based on the results of its acceptance review [45]. These RAIs focused primarily on NWMI's analysis of structures, systems, and components; criticality safety; and accident sequences. A comprehensive set of RAIs is currently under development. The NRC staff is currently on schedule to complete its safety evaluation report on the NWMI PSAR in September 2017. Based on the NRC staff's review schedule, the availability of the ACRS, and the availability of the Commission to conduct a mandatory hearing, a construction permit could be issued to NWMI by early 2018.

4. Other Licensing Actions

In addition to the SHINE and NWMI construction permit application reviews, the NRC has also considered license amendment requests, materials license applications, and medical uses of byproduct material.

Oregon State University Research Reactor License Amendment Application

On April 13, 2012, OSU submitted a license amendment application requesting approval to place LEU targets in the OSU TRIGA® reactor (OSTR) to demonstrate Mo-99 in a research reactor [47]. Publicly available portions 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. On January 13, 2016, the NRC staff issued Amendment No. 23 to the OSU operating license, allowing for the irradiation of up to three LEU targets in the OSTR [2]. OSU intends to submit a license amendment application in 2017 to support the commercial irradiation of LEU targets for NWMI [48].

Niowave Materials License

On February 11, 2015, Niowave submitted a materials license application, requesting possession and use of less than a critical mass of LEU [49]. 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 [50]. 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 uranium-234 (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. In an effort to move towards commercial production, Niowave has requested to increase its LEU possession limit [51]. The NRC staff is currently reviewing this request.

NorthStar Medical Radioisotopes

NorthStar Medical Radioisotopes (NorthStar) has proposed to produce Mo-99 through two separate efforts involving neutron activation. In one production technique, NorthStar is supplying Mo-98 targets for irradiation in the University of Missouri Research Reactor (MURR). However, this neutron-activation-produced Mo-99 has a lower specific activity than its fission-produced counterpart. However, in order to address this, NorthStar has developed a new microwave-sized technetium-99m (Tc-99m) generator system, RadioGenix, that is compatible with low specific activity Mo-99 [52, 53]. This generator would operate similar to exiting generators (i.e., at room temperature and atmospheric pressure); however, due to its small size, it can be stored and used at the end user site (i.e., the hospital or radiopharmacy) for direct Tc-99m production.

NorthStar is in the process of obtaining approval from the U.S. Food and Drug Administration (FDA) to begin commercial use of its generator [52]. To address the unique design features of NorthStar's generator, the Organization of Agreement States and the NRC formed a working group to determine whether the RadioGenix system should be regulated under 10 CFR Part 35, Subpart K [54]. As a result, NRC staff is developing 10 CFR Part 35 licensing guidance for medical use applicants and licensees that possess the RadioGenix system. This guidance will be the subject of an upcoming public meeting with the Advisory Committee on the Medical Uses of Isotopes on October 6, 2016 [55].

General Atomics and MURR

Like NorthStar, General Atomics also intends to produce Mo-99 using MURR for target irradiation. However, unlike NorthStar, GA intends to irradiate LEU targets [56]. The GA proposal uniquely involves a gaseous extraction technology capable of selectively removing Mo-99 from the LEU in onsite hot cells. Molybdenum-99 produced using GA's technology would be compatible with existing Tc-99m generators [52]. While GA and MURR have met with the NRC in April 2015 and June 2016 for preliminary technology and licensing discussions, as of August 2016, a formal licensing request to the NRC has not been made [57, 58, 59].

5. Conclusion

In support of the national initiative to establish a domestic supply of Mo-99 without the use of highly-enriched uranium, the NRC's licensing and oversight activities include outreach and communication through public meetings, infrastructure development, and the review of requested licensing actions. While the NRC staff has considered unique technological licensing requests, it has conducted efficient and thorough reviews, as highlighted by the issuance of the SHINE construction permit. To ensure continued success, the NRC staff are focused on developing inspection programs and licensing guidance as part of its preparation for anticipated activities and applications. Applying the experience and expertise gained through the SHINE construction permit application review, the NRC staff will continue to review current and anticipated future applications from SHINE, NWMI, Niowave, OSU, NorthStar, and MURR with the same priority and attention to detail. In accordance with the NRC's statutory responsibilities, the NRC's activities related to establishing a domestic Mo-99 supply align with the Agency's mission statement to protect public health and safety, promote the common defense and security, and protect the environment.

6. References

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