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MOLYBDENUM-99 TECHNOLOGICAL DEVELOPMENT**

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**U.S. Nuclear Regulatory Commission Environmental Reviews Related  
to Molybdenum-99 Production**

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**ABSTRACT**

This paper describes the U.S. Nuclear Regulatory Commission's (NRC) environmental review of proposed activities relating to the establishment of a domestic molybdenum-99 supply in the United States. The NRC is currently conducting two environmental reviews for construction permits for proposed molybdenum-99 production facilities. In May 2015, the NRC staff published a draft Environmental Impact Statement for SHINE Medical Technologies, Inc.'s construction permit application. The NRC staff is addressing several unique considerations during these first-of-a-kind reviews, such as evaluating the applicability of the NRC's licensing and environmental regulatory frameworks, determining the appropriate level of detail for NRC's environmental documents, and implementing various methods to ensure efficient and effective reviews for first-time applicants. Future environmental reviews will incorporate lessons learned from the ongoing environmental reviews, including technical considerations, public participation, and coordination with other government agencies and Tribes, as well as other unique site- and project-specific considerations.

**1. Introduction**

In support of the national initiative to establish a domestic non-highly-enriched uranium-based supply of molybdenum-99 (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 of 2005, and the American Medical Isotopes Production Act of 2012, the NRC has been preparing for and actively reviewing potential applications proposing to construct and operate facilities to produce Mo-99 [1, 2]. The NRC staff is currently reviewing two construction permit applications and one operating license amendment request for radioisotope irradiation and separation facilities [3]. In addition, in March 2015, the NRC issued a material possession license for small-scale demonstration of superconducting linear accelerator technology [3].

The NRC's process to review Mo-99 applications consists of two separate, parallel reviews: safety and environmental. The safety review evaluates the applicant's ability to meet the NRC safety requirements. The NRC staff documents the findings of the safety review in a Safety Evaluation Report. This process is further described in Lynch et al. (2015) [3]. The environmental review is performed in accordance with the National Environmental Policy Act of 1969, as amended, 42 U.S.C. § 4321 et seq., (NEPA) [4]. NEPA established a national policy for considering environmental impacts. This Act requires federal agencies to follow a systematic approach in evaluating potential impacts of the proposed action and alternatives. An important component of this process involves public participation and public disclosure. The NRC's environmental protection regulations in 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," implement these NEPA requirements. These regulations describe the type of actions for which NRC must conduct environmental reviews in order to disclose and consider the environmental impacts of a proposed action under NRC regulatory purview.

This paper describes NRC staff's efforts to prepare for Mo-99 environmental reviews, especially when considering the first-of-a-kind technology for many of the proposed projects. Additionally, this paper describes how the NRC staff applied these initial efforts to the environmental review for the first construction permit application received from SHINE Medical Technologies, Inc. (SHINE). Lastly, the paper discusses the NRC staff's preliminary finding for the SHINE environmental review.

## **2. Unique Considerations Preparing for Mo-99 Applications**

Over the past few decades, the NRC staff has conducted NEPA reviews for new and existing nuclear power reactors by following an established environmental review process as described in 10 CFR Part 51 and relevant environmental standard review plans [5]. However, many of the potential and current Mo-99 applicants are proposing first-of-a-kind facilities that require the NRC staff to assess the unique considerations for facilities that may include the construction and operation of novel technologies, or the novel application of technologies.

The NRC staff has conducted a variety of activities to prepare for these first-of-a-kind reviews. Below describes three specific efforts that the NRC staff completed in order to prepare for the environmental reviews for proposed facilities to produce Mo-99. These efforts included evaluating the applicability and relevance of the current licensing and regulatory framework, establishing a framework for evaluating the appropriate environmental review methodology for each application, and developing several methods to promote efficient and effective communication with applicants working with the NRC for the first time. For each of these efforts, the NRC staff assessed the existing licensing, regulatory, and other frameworks to determine whether any additional guidance or support was required to help ensure timely and effective environmental reviews for Mo-99 applications.

### *Licensing and Regulatory Framework*

The primary regulatory guidance document used to prepare and organize non-power reactor applications is *NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications*

*for the Licensing of Non-Power Reactors: Format and Content*” [6]. Prior to receiving any Mo-99 applications, the NRC staff reviewed NUREG-1537 and determined that the content needed to be updated and expanded upon for licensing aqueous homogeneous reactors and radioisotope production facilities. In October 2012, the NRC staff issued an interim staff guidance (ISG), augmenting NUREG-1537 that provided specific guidance for applicants to prepare environmental reports for Mo-99 facilities and for the NRC staff to conduct its environmental review of Mo-99 applications [7]. For the environmental review, the ISG states that applicants should prepare a detailed environmental report that describes the environment on and surrounding a proposed site as well the potential impacts from proposed construction, operations, and decommissioning activities.

In developing the ISG, the NRC staff considered that potential applicants were proposing a broad range of technologies, designs, and construction methods to build and operate facilities to produce Mo-99. To address this variability, the ISG was written using an approach that covers a range of potential technologies and construction methods. As such, the ISG also contains a range of potential data needs. Each applicant should consider whether or not such data are applicable for its proposed project. For example, an applicant that is discharging water to a river would need to provide additional details regarding discharge rates and required Federal and State permits; an applicant obtaining water from a public water system would not need to provide this information.

In the discussion of the data needs for the affected environment, the description of environment on and near the proposed site, the ISG states that applicants should present a thorough description of each affected resource area, with more detail and focus on resources that may be significantly effected by the proposed project. This approach is consistent with the provisions set forth in NRC’s regulations implementing NEPA, 10 CFR 51.45(b)(1), which states that the level of detail describing the affected environment should be discussed in proportion to each resource area’s importance and potential significance. Similarly, one of the goals of NEPA is that environmental documents concentrate on issues significant to the proposed action and its potential environmental impacts. For example, construction and operation of a new nuclear facility at a previously undisturbed, forested site would require more detail regarding ecological resources than modification and operation of a facility within an existing building at an industrial site.

### *Environmental Review Methodology*

Another unique consideration is determining the appropriate environmental review methodology and level of detail for the NRC staff’s findings. Environmental reviews for licensing actions, such as construction permits, operating licenses, or license amendments, fall into one of three categories: those identified as categorical exclusions, those requiring the preparation of an Environmental Assessment (EA), and those requiring the preparation of an Environmental Impact Statement (EIS) [7]. 10 CFR 51.20, “Criteria for and identification of licensing and regulatory actions requiring environmental impact statements,” describes several types of actions that would require an EIS. Construction permits and operating licenses for medical radioisotope facilities are not specifically included in 10 CFR 51.20.

Such activities may require an EA or an EIS, depending on the action's potential for significant impacts that may affect the quality of the human environment.

An EA is used to determine if the impacts from the proposed action may be significant and whether a finding of no significant impact (FONSI) can be made. If an EA concludes that the proposed action could result in significant impacts to the human environment, then an EIS will be prepared. In some cases, the NRC may decide to prepare an EIS, rather than an EA, if there is the potential for significant impacts to the human environment or the proposed action involves a matter that the Commission, by discretion, has determined should be covered by an EIS.

Therefore, a case-by-case decision will be made for each application to determine the most appropriate environmental review process. As described above, depending on the site-specific conditions and the project-specific technology, the NRC staff will consider which environmental documentation is most appropriate depending on the requirements in 10 CFR 51.20, the potential for significant environmental impacts, and other project-specific considerations.

#### *Efficient and Effective Communications with First-time Applicants*

For most applicants and potential applicants, applying to the NRC for a permit or license to produce Mo-99 will be the first time the applicant has applied to the NRC for a permit or license. Therefore, the NRC staff developed several communication tools to help ensure that potential applicants are aware of NRC's licensing framework and environmental review process. Lynch et al. (2015) summarizes general communication tools for potential applicants [3].

For environmental reviews, pre-application meetings are an effective tool for applicants to meet with the NRC licensing and environmental staff and discuss the information needed to support an efficient and effective environmental review. Such meetings are beneficial for the applicant to better understand the scope and detail of information that should be provided in its environmental report. In addition, pre-application meetings provide the NRC staff with information to allow for internal resource planning, such as a better understanding of the complexity of various technical issues and the need to coordinate or consult with other Federal or State agencies. Pre-application meetings may occur at the NRC offices, or the NRC staff may benefit from viewing the proposed site to better understand the environment where proposed activities would occur. All pre-application meetings are public and provide an opportunity for members of the public to better understand the status and scope of potential projects, as well as ask the NRC staff questions regarding the review process [8, 9].

While public meetings are designed to allow members of the public and potential applicants 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, consult with the applicant, or make regulatory decisions [8, 9]. If potential applicants want the NRC to provide an interpretation that clarifies provisions in NRC regulations, the applicant should submit the request in writing to the NRC staff. The NRC staff's ability to respond to requests for

interpretations can be enhanced if such requests include: a clear identification of the regulatory provision(s) in question, a summary of the requestor's proposed approach or position with respect to the regulation in question, and any and all legal, technical or other information that support the requestor's approach or position.

The NRC has previously responded to requests for pre-licensing guidance on potential policy questions associated with licensing Mo-99 facilities. The questions received have asked for clarifications related to the licensing process, the classification of wastes, and procedural requirements. Most recently, the NRC staff responded to a request regarding the necessary information that should be included in an updated environmental report as part of an application for an operating license, as described in 10 CFR 51.95(b), "Initial operating license stage" [10]. In response to this request, the NRC staff stated that in accordance with 10 CFR 51.53(b), "Postconstruction environmental reports," an applicant may submit a supplemental environmental report as part of its application for an operating license that only discusses different and/or new information that has become available since the publication of the final EIS [11]. Therefore, the supplemental environmental report does not need to be a complete resubmittal of the environmental report.

### **3. Considerations for the SHINE Environmental Review**

By letter dated March 26, 2013, SHINE Medical Technologies, Inc. (SHINE), submitted Part 1 of a two-part application to the NRC for a construction permit for a facility (SHINE facility) in Janesville, Wisconsin [12]. The proposed site encompasses approximately 91 acres (ac) (37 hectares (ha)) of undeveloped land that is currently an agricultural field [13]. SHINE would 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.

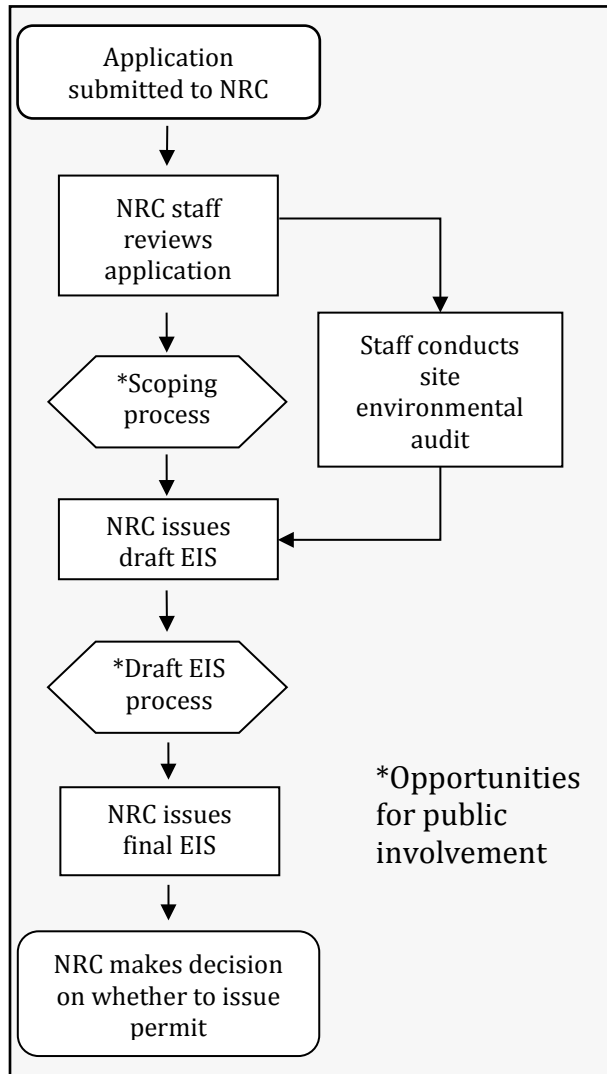
For the SHINE environmental review, the NRC staff applied the generic, pre-licensing efforts along with project- and site-specific considerations. The following sections describe the NRC staff's environmental review process for SHINE's construction permit application, including public involvement, coordination with Department of Energy, and the NRC staff's preliminary findings.

#### *Environmental Review Process*

As described above, to issue a construction permit, the NRC is required to consider the environmental impacts of the proposed action under NEPA. 10 CFR 51.20 does not specifically identify construction permits for production and utilization facilities such as the SHINE facility as an action that would require an EIS. For the SHINE environmental review, the NRC staff determined that an EIS was appropriate to assess the environmental impacts of the proposed action. This determination was made because of the potential for significant environmental impacts and the unique considerations of a first-of-a-kind application for a medical radioisotope production facility with a unique application of technologies. The EIS process also allows for maximum public involvement in the environmental review process, as described in detail below.

The NRC staff followed its typical environmental review process for preparing an EIS (see Figure 1). This process started with a 60-day scoping period. Scoping is the process by which the NRC staff identifies the specific impacts and significant issues to be considered in preparation of an EIS. During this time, the NRC held two public scoping meetings in Janesville, Wisconsin to gather input from the public and other Federal, State, and local agencies and Tribes regarding issues of importance to consider in the EIS. The NRC staff responded to all comments received during the scoping period in a scoping summary report [14] and relevant information was included in the draft EIS [15].

**Figure 1. Environmental Review Process**



In order for the NRC staff to familiarize itself with the proposed site and to verify information in SHINE’s environmental report, the NRC staff conducted a site audit at the proposed SHINE site in July and August 2013 [16]. During the site audit, the NRC staff met with SHINE personnel; reviewed specific documentation; toured the proposed and alternative sites; and met with interested Federal, State, and local agencies. Following the site audit, the NRC staff issued requests for additional information (RAIs). The purpose of the RAIs is to

clarify information in SHINE's environmental report and to ask for additional information to assess the environmental impacts of the proposed action.

In addition to the National Environmental Policy Act, the NRC staff addressed other regulatory requirements within its EIS. For example, other Federal regulations may require the NRC to consult with applicable Federal and State agencies and groups before taking actions that may affect endangered species, fisheries, or historic and archaeological resources [17, 18].

After reviewing the information in the environmental report and RAIs, comments received during the scoping period, information that the NRC staff independently obtained, and input from other Federal, State, and local governments and Tribes, the NRC staff compiled its findings in a draft EIS [15]. The draft EIS was made publically available on May 12, 2015. A 45-day comment period on the draft EIS began on May 22, 2015 and ended on July 6, 2015 during which the NRC staff gathered input from the public and other Federal, State, and local agencies and Tribes in regards to the findings in the EIS. The NRC staff also hosted two public meetings in Janesville, Wisconsin on June 10, 2015. The NRC staff is currently updating the draft EIS based on the comments received and other applicable information. The final EIS will respond to all comments received on the draft EIS and update the data, analyses, and findings as appropriate.

### *Public Involvement*

Public involvement is an important component of the NRC's staff environmental review and is required as part of the NRC's environmental review process for developing an EIS, as described in 10 CFR Part 51. The NRC staff gathered input from the public during the initial development of the EIS to define the scope of the EIS and issues of importance. A second comment period occurred when the draft EIS was published to gather input on the data, analyses, and findings in the draft EIS. During both of these comment periods, the NRC staff held public meetings in Janesville, Wisconsin and received several letters from the public as well as Federal, State, and local agencies and Tribes. The NRC staff responds to all comments received during both comment periods [14, 15]. As appropriate, the NRC staff is updating the EIS based on information received within comment letters. The NRC staff found both comment periods to be valuable tools to coordinate with other Federal, State, and local agencies and Tribes, as well as learn from the public regarding the environmental issues that were most important to the local community.

Each public meeting was preceded by an open house, which was an informal opportunity for the public to meet with the NRC staff and ask questions regarding the environmental review process, NRC's regulatory role, and the scope or findings in the EIS. The NRC staff found the open house to be an important tool to help explain the environmental review process to the public, as well as to answer several questions from members of the Janesville community. In addition to the NRC staff's public meetings, SHINE has been hosting public meetings in Janesville, Wisconsin since 2013. These meetings occur approximately every six months and the purpose of the meetings is to share information with and respond to questions from the Janesville community [19]. The NRC staff notes that many members of the Janesville

community are well aware of the SHINE project, especially those that have attended SHINE's meetings as a forum to learn more about the project and to directly express concerns to SHINE. The NRC staff notes that separate meetings hosted by the applicant are not required, but could be a valuable tool for the applicant to help explain the proposed project to the local community and address public concerns.

#### *Department of Energy as a Cooperating Agency*

NEPA lays the groundwork for coordination between two (or more) agencies that may both have special expertise on an environmental issue or that have jurisdiction by law. One agency is considered the lead agency and has the primary role in preparing an EIS, while the other Federal agency, referred to as a "cooperating agency," is responsible for assisting the lead agency in the development of the EIS. The cooperating agency provides technical input to the environmental analysis and provides staff support, as needed, to the lead agency.

The American Medical Isotopes Production Act of 2012 directs the Department of Energy (DOE) and the NRC to ensure, to the maximum extent practicable, that environmental reviews for facilities to produce medical radioisotopes are complementary and not duplicative [20]. For the SHINE review, both the NRC and DOE must analyze the environmental impacts in public disclosure documents as required by NEPA. The NRC is required to conduct an environmental review under NEPA to decide whether to grant SHINE a construction permit. DOE is required to conduct an environmental review under NEPA for providing financial support to SHINE.

Based on NEPA groundwork for coordinating environmental review efforts and the need to coordinate environmental reviews as described in the American Medical Isotope Production Act, the NRC and DOE decided to enter into a cooperative agreement to make the most effective and efficient use of Federal resources in reviewing SHINE's proposal. On December 1, 2014, and February 3, 2015, the NRC and DOE signed a Memorandum of Agreement on the review of the SHINE application [21]. The goal of this agreement is to develop one EIS that serves the NRC licensing process and the DOE funding process. The Memorandum of Agreement designates the NRC as the lead Federal agency and DOE as a cooperating agency in developing an EIS for the proposed SHINE facility. As a cooperating agency, DOE plans to adopt the final EIS in accordance with the DOE/NEPA implementing procedures in 10 CFR 1021.103.

#### *Environmental Impact Determinations*

The NRC staff evaluated the potential environmental impacts related to the proposed construction, operations, and decommissioning of the SHINE facility in the EIS. The NRC standard of significance for impacts uses the Council on Environmental Quality (CEQ) terminology for "significantly" [22]. Because the significance and severity of an impact can vary with the setting of the proposed action, both "context" and "intensity," as defined in CEQ regulation 40 CFR 1508.27, "Terminology- Significantly," were considered. Context is the geographic, biophysical, and social context in which the effects would occur. Intensity is the severity of the impact. Based on this, the NRC established three levels of significance for potential impacts: SMALL, MODERATE, and LARGE. The definitions of these three



significance levels, which are presented in the Interim Staff Guidance to NUREG-1537 [7], follow:

- **SMALL**—environmental effects are not detectable or are so minor that they would neither destabilize nor noticeably alter any important attribute of the resource. In assessing radiological impacts, the NRC has concluded that those impacts that do not exceed permissible levels in the NRC’s regulations are considered **SMALL**.
- **MODERATE**—environmental effects are sufficient to alter noticeably, but not to destabilize, important attributes of the resource.
- **LARGE**—environmental effects are clearly noticeable and are sufficient to destabilize important attributes of the resource.

For this draft EIS, the NRC staff characterized impact levels using the above definitions for the following resource areas: land use and visual resources, air quality and noise, the geologic environment, water resources, ecological resources, historic and cultural resources, socioeconomics, human health, transportation at and near the proposed site, and waste management [15].

The NRC staff preliminarily concluded that construction, operations, and decommissioning of the proposed SHINE facility would have **SMALL** impacts for all resource areas with the exception of transportation [15]. The NRC staff based the **SMALL** findings on a variety of site-specific conditions, such as the condition of the previously disturbed site that is currently an agricultural field, the current zoning designation as light industrial use, the relatively limited ground disturbance that would occur, the use of a public water system rather than a surface water or groundwater features to obtain and discharge water, and adequate controls to ensure that radiological exposures to workers and the public would be within the regulatory limits specified in 10 CFR Part 20, “Standards for Protection Against Radiation” [13, 15].

The impacts to transportation would be **SMALL** to **MODERATE** because of the noticeable increase in average daily traffic flow. The addition of up to 465 vehicles per day (or approximately 1,000 trips per day) from construction activities and 261 vehicles per day (or approximately 580 trips a day) from decommissioning activities at the proposed SHINE facility would result in an increased traffic volume on U.S. Highway 51. This increase in traffic would not likely destabilize traffic conditions near the SHINE site because traffic analyses indicate that the level of construction- and decommissioning-related traffic would not affect the level of service anywhere in the transportation infrastructure; therefore, the transportation infrastructure would not require any modifications [13, 15]. During operations, a “slight degradation of service” (i.e., traffic delays) would occur at the intersection of westbound State Trunk Highway 11 onto southbound U.S. Highway 51 during the morning during peak hours of commuting. The NRC staff expects the overall daily traffic flow in the immediate vicinity of the proposed SHINE facility to increase slightly during the operation phase, but it would not be appreciable when compared with the average

daily and annual traffic flow of roads in the immediate vicinity of the proposed SHINE facility [15].

#### *NRC Staff's Recommendation*

In the draft EIS, the NRC staff weighed the environmental, economic, technical, and other benefits against environmental and other costs and considered reasonable alternatives, including the no-action alternative, two alternative sites, and an alternative technology. Based on this review, the NRC staff preliminarily recommended, unless safety issues mandate otherwise, the issuance of the construction permit to SHINE [15]. The NRC staff based its recommendation on the following factors:

- SHINE's environmental report;
- the NRC staff's consultation with Federal, State, and local agencies;
- the NRC staff's independent environmental review; and
- the NRC staff's consideration of public comments received.

The NRC staff is currently responding to public comments on the draft EIS and updating the EIS based on comments within the scope of the environmental review and newly available information. The NRC staff expects to publish the final EIS in October 2015. The NRC staff's recommendation in the final EIS, along with the NRC staff recommendations in the safety evaluation report, will be taken into consideration as part of the Commission's decision as to whether on or not to issue the construction permit.

#### **4. Conclusion**

In support of the national initiative to establish a domestic supply of Mo-99 without the use of highly-enriched-uranium, the NRC staff prepared for the submittal of several applications for facilities to produce Mo-99, some of which represented first-of-a-kind technologies. In preparation of these first-of-a-kind reviews, the NRC staff evaluated the applicability and relevance of the current licensing and regulatory framework, established a framework for evaluating the appropriate environmental review methodology for each application, and developed several methods to promote efficient and effective communication with applicants working with the NRC for the first time. In addition, the NRC staff is actively reviewing SHINE's construction permit application and recently published a draft EIS to present its findings on the potential environmental impacts from construction, operations, and decommissioning of the proposed SHINE facility.

Future environmental reviews will incorporate lessons learned from the development and publication of ongoing environmental reviews. In addition, the NRC staff will continue to assess the site-specific and project-specific details to determine the most appropriate and efficient methods to resolve any licensing, regulatory, or technical complexities. Based on the methodologies used to prepare for Mo-99 applications and lessons learned from the SHINE review to date, the NRC staff anticipates that sufficient tools and regulatory frameworks exist to continue to review additional Mo-99 applicants in a timely and efficient manner.

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