

**Mo-99 2013 TOPICAL MEETING ON  
MOLYBDENUM-99 TECHNOLOGICAL DEVELOPMENT**

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**Regulatory Preparations for Licensing Medical Radioisotope  
Production Facilities**

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**ABSTRACT**

The U.S. Nuclear Regulatory Commission (NRC) has received five letters of intent from potential applicants seeking to domestically produce molybdenum-99 utilizing low-enriched uranium technologies. In preparation for anticipated construction permit and operating license applications, NRC staff organized a working group to address the licensing process for medical radioisotope production facilities. The working group developed Interim Staff Guidance augmenting the standard review plan, NUREG-1537, used for licensing research and test reactors. The NRC staff held public meetings with potential applicants to discuss the guidance and encourage submission of high-quality applications. The NRC staff coordinated efforts with other federal and state government representatives to promote the efficient review of applications. Through early planning, diligent coordination, and frequent communication with potential applicants, NRC staff is confident it will provide an efficient, thorough, and timely review of submitted applications for medical radioisotope production facilities.

**1. Introduction**

In support of the national initiative to establish a domestic supply of molybdenum-99 (Mo-99) utilizing low-enriched uranium (LEU) technologies, the U.S. Nuclear Regulatory Commission (NRC) is prepared to receive construction permit and operating license applications for medical isotope production facilities. To date, the NRC has received five letters of intent to produce Mo-99 from potential producers. Babcock and Wilcox Technical Services Group, Coqui Radiopharmaceuticals, General Electric Hitachi Nuclear Energy, SHINE Medical Technologies, Inc. (SHINE), and the University of Missouri-Columbia have all indicated interest in producing Mo-99 to the NRC. These entities have proposed Mo-99 production utilizing technologies ranging from a non-power reactor for either the neutron activation of Mo-98 targets or the fission of LEU targets in a uranium solution to a sub-critical solution tank for the fission of uranium in a target solution.

The licensing process for the proposed medical radioisotope production facilities will vary between technologies. However, it is anticipated that applications for these facilities will be licensed under Part 50, “Domestic Licensing of Production and Utilization Facilities,” of Title 10 of the *Code of Federal Regulations* (10 CFR). The environmental aspects of licensing will be addressed by the requirements of 10 CFR Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.” Additionally, the NRC staff developed Interim Staff Guidance (ISG) augmenting the standard review plan for non-power reactor licensing to address the unique licensing considerations given to medical radioisotope production facilities.

## **2. Outreach and Communication**

Given the significant interest in Mo-99 production, early and frequent communication with potential applicants has been an important part of the development of an effective licensing framework. Fostering this communication began with the issuance of Regulatory Issue Summary (RIS) 2011-06, “Pre-application Communication and Voluntary Submittal of Schedule for Future Molybdenum-99 Facility Licensing Actions for NRC Review,” dated July 1, 2011. The intent of this RIS was to promote early and frequent communication between the NRC and potential applicants regarding pre-application activities, including, but not limited to, the scheduling and coordination of application submittals and reviews, associated with the licensing of proposed medical radioisotope production facilities intending to produce Mo-99. Early and frequent communication between the NRC and potential applicants promotes the development and submission of high-quality, complete applications. Specifically, the RIS posed several questions to potential applicants regarding the scheduling of pre-application licensing activities and scheduling. These questions requested information regarding the number and type of applications a potential applicant anticipated submitting for NRC review, the timing of application submittals, consideration of applicable regulations in 10 CFR, site selection, and facility design. The information received in response to this RIS helped the NRC staff develop application review schedules and allocate the necessary resources to support pre-application and application review activities based, in part, on the number and complexity of applications proposed to be submitted for review in upcoming fiscal years. At this time, the NRC has budgeted for the review of one construction permit and operating license application.

To ensure the accuracy of current resource estimates, the NRC staff is developing a follow-up RIS to RIS 2011-06. This RIS is expected to be issued by early May 2013 and will request similar information as the previous RIS. Going forward, the NRC staff plans to issue similar requests for information on an annual basis. Responses to these information requests will greatly influence resource allocations for application reviews. Therefore, the NRC staff strongly encourages potential applicants to promptly provide scheduling information to the NRC to promote an efficient and thorough review of requested licensing actions. In addition to providing information in response to a RIS, the NRC staff encourages potential applicants to communicate with the NRC through public meetings to discuss application submittal schedules, proposed technology designs, and regulatory compliance.

Since the issuance of RIS 2011-06, the NRC has hosted five Category 1 public meetings and one Commission meeting with potential applicants. For potential applicants, public meetings can assist an effective application review. NRC staff use public meetings as an opportunity to ask questions about proposed application submissions to allow better planning and allocation of resources to ensure a thorough and efficient application review. These meetings are also an opportunity for potential applicants to provide updates on their latest design plans and overall application status. While the NRC staff hopes that this exchange will invite a mutually beneficial dialogue between NRC staff and potential applicants, these meetings are not intended to be a forum for NRC staff to provide a design review nor to make regulatory decisions. Public meetings are also an opportunity for members of the public to observe NRC proceedings and to communicate with the NRC staff to gain a better understanding of the regulatory process.

### **3. Pre-application Preparation and Regulatory Applicability**

In addition to early and frequent communication with potential applicants, preparation for the review of applications for medical radioisotope production facilities has also required effective communication and planning across the NRC. The Research and Test Reactor Licensing Branch in the Office of Nuclear Reactor Regulation has primary responsibility for coordinating the review of all medical radioisotope production facility applications. Recognizing the unique technical review needed for these applications, an inter-office working group was formed to address the licensing process for these facilities. The working group provides a collaborative environment to address all aspects of licensing medical radioisotope production facilities, drawing the necessary expertise from across the NRC to ensure an efficient and thorough review of all applications. The working group consists of representatives from the following Offices:

- Nuclear Reactor Regulation
- Nuclear Material Safety and Safeguards
- Federal and State Materials and Environmental Management Programs
- General Counsel
- Nuclear Regulatory Research
- Nuclear Security and Incident Response
- International Programs
- Congressional Affairs
- Public Affairs
- Chief Financial Officer

Understanding the need to provide applicants guidance on the preparation and organization of applications, the working group developed and published Parts 1 and 2 of the ISG Augmenting NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors,” for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors in October 2012. The ISG updates and expands on the content of NUREG-1537 Parts 1 and 2, respectively, to provide guidance for preparing and evaluating a license application for a heterogeneous or aqueous homogeneous non-power reactor as a utilization or production facility for the separation of byproduct material from

special nuclear material (SNM). The ISG anticipated that applications for these types of facilities would be requested pursuant to the regulations contained in 10 CFR Part 50. As part of the development and update to NUREG-1537, the NRC staff found it necessary to incorporate portions of NUREG-1520, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,” Revision 1, into the ISG, addressing the unique aspects of facility description and accident analysis associated with production facilities separating radioisotopes from irradiated SNM.

While NUREG-1537, as supplemented by the ISG, provides guidance on formatting, content, and acceptance criteria to assist in the preparation of quality license applications, it is not a set of regulatory requirements. Statutory authority to regulate production and utilization facilities has been granted to the NRC primarily by the Atomic Energy Act of 1954, as Amended, the Energy Reorganization Act of 1974, as Amended, and the Energy Policy Act of 2005. From this authority, the NRC has promulgated the regulations contained in 10 CFR. While NRC staff anticipate most applications for medical radioisotope production facilities to request licensing actions pursuant to 10 CFR Part 50, it is possible that other licensing actions may be more appropriate depending on the specifics of a particular facility’s design. For example, facilities separating radioisotopes from irradiated SNM will be licensed as production facilities under 10 CFR Part 50, unless an exemption is applied for and granted, or the facility meets one of the Subpart (3) exceptions to the definition for a *production facility* found in 10 CFR 50.2. A facility meeting any of these exceptions is, by definition, not a production facility, and is therefore not subject to the requirements of 10 CFR part 50; rather, the facility would be considered a SNM fuel cycle facility subject to the requirements of 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material.” In addition to 10 CFR Parts 50 and 70, other parts of 10 CFR relevant to medical radioisotope production include:

- Part 2, “Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders,”
- Part 20, “Standards for Protection Against Radiation,”
- Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,”
- Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,”
- Part 55, “Operators’ Licenses,”
- Part 73, “Physical Protection of Plants and Materials,”
- Part 74, “Material Control and Accounting of Special Nuclear Material,”
- Part 150, “Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters under Section 274,”
- Part 170, “Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services under the Atomic Energy Act of 1954, as Amended,” and
- Part 171, “Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Material Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC.”

The NRC staff also maintains communication channels with other federal and state authorities involved in activities supporting the domestic production of Mo-99. Additionally, in preparation for reviewing applications, members of the working group visited representatives from the Canadian Nuclear Safety Commission and toured the Chalk River site and Nordion in August 2012. The tours of the Chalk River site and Nordion afforded NRC staff the opportunity to observe the production, processing, and purification of Mo-99. As a result of this trip, NRC staff gained insight on the regulatory practices, design, operation, and safety issues associated with medical radioisotope production facilities already in operation.

Through the communication, outreach, and licensing framework preparation activities discussed above, the NRC staff is prepared to conduct the review of a construction permit application for a medical isotope production facility.

#### **4. Construction Permit Application Review Process**

A construction permit application for a production or utilization facility submitted to the NRC pursuant to the requirements of 10 CFR Part 50 consists of two primary components: an environmental report and a preliminary safety analysis report (PSAR). The review of both the environmental report and PSAR will occur simultaneously. Each review will take approximately 18-24 months to complete. Generally, within 30 days of receiving the construction permit application, NRC staff will make a determination on the completeness and acceptability of the submittal. Should the staff determine that it has enough information to begin a thorough review of the submittal, the application will be docketed for review. Should the NRC staff determine that the application is incomplete or otherwise unacceptable for processing, the applicant will be notified of the respects in which the application is deficient. The applicant will then have the opportunity to correct the deficiencies of the application. Following an application's acceptance for docketing, there are several significant review milestones. For the safety review of the PSAR, these milestones include:

- Initial NRC staff review of the application
- Request(s) for additional information
- Development of a Safety Evaluation Report (SER)
- Advisory Committee on Reactor Safeguards (ACRS) SER review

For review of the environmental report, the following review milestones are significant:

- Determination to prepare an environmental assessment (EA) or environmental impact statement (EIS), resulting in either:
  - Preparation and issuance of an EA, with Finding of No Significant Impact, or
  - Preparation of an EIS
    - Environmental scoping period
    - Environmental site audit
    - Request(s) for additional information
    - Issuance of draft EIS with public comment period
    - Issuance of the final EIS, including response to comments

Following the completion of the ACRS review of the SER and the issuance of an EIS, the Commission will hold a mandatory hearing, as required by 10 CFR 50.58. At the conclusion of the mandatory hearing, the NRC will prepare and issue to the applicant either a construction permit application or a letter denying the application for a construction permit.

The NRC staff expects to begin the review of the construction permit application for SHINE in April 2013. It is anticipated that SHINE's construction permit application will be submitted in two parts in accordance with 10 CFR 2.101(a)(5). The current provisions of 10 CFR 2.101(a)(5) state that one part of the submittal must include the environmental report required by 10 CFR 50.30(f), while the other part must include the PSAR required by 10 CFR 50.34(a). The first part of the application submittal must also contain:

- The filing fee required by 10 CFR 50.30(e) and 10 CFR 170.21,
- The general information required by 10 CFR 50.33,
- The description and safety assessment of the site required by 10 CFR 50.34(a)(1), and
- The agreement limiting access to Classified Information required by 10 CFR 50.37.

If the preliminary safety analysis report required by 10 CFR 50.34(a) is submitted second, the information required by 10 CFR 50.34(a)(2) - (a)(8) does not need to accompany the first part of the submittal. Either part of the construction permit application may be submitted first as long as the second part is submitted within six months. However, 10 CFR 2.101(a)(5) also stipulates that only production or utilization facility applicants subject to 10 CFR 51.20(b)<sup>1</sup> may take advantage of the two-part submittal provisions of the rule. The NRC staff determined that SHINE's proposed action for licensing a medical radioisotope production facility is not an action identified in 51.20(b); therefore, SHINE could not submit its application for a construction permit in two parts as described in 10 CFR 2.101(a)(5) without an exemption from that provision of the rule. Subsequently, SHINE requested and has been granted an exemption from certain requirements of 10 CFR 2.101(a)(5) to allow it to submit its construction permit application in two parts.

In its review of SHINE's exemption request, staff noted that while the current language of the 10 CFR 2.101(a)(5) limits its applicability to applications meeting the criteria of licensing and regulatory actions requiring environmental impact statements as described in the provisions of 10 CFR 51.20(b), over time the language of the rule has been expanded to include types of applications not originally considered at the time the initial rulemaking. For example, in 2007 the language of the rule was modified to include applicants seeking combined licenses under 10 CFR Part 52. As noted in the *Federal Register* (FR) notice on accompanying the August 28, 2007 final rule, the Commission determined that "[t]here are no considerations unique to combined licenses which would weigh against allowing a combined license applicant to submit a two part application under paragraph (a)(5) of §2.101" (72 FR 49412). Similarly, given the procedural nature of this rule, there are no unique considerations for medical isotope production facilities, which would weigh against allowing a license applicant such as SHINE to submit a two-part application under 10 CFR 2.101(a)(5).

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<sup>1</sup> 10 CFR 51.20(b) enumerates the types of licensing and regulatory actions requiring an environmental impact statement or a supplement to an environmental impact statement.

## 5. Conclusion

The NRC staff is prepared to receive and review anticipated applications for medical radioisotope production facilities through communicating proactively with potential applicants; establishing an inter-office working group, drawing expertise from across the agency; coordinating activities with other federal and state authorities; developing guidance to aid in the preparation of quality applications; and allocating the necessary resources to support requested licensing actions from applicants. The NRC staff is confident it can provide an efficient, thorough, and timely review of all applications for medical radioisotope production facilities in support of the establishment of a domestic supply of Mo-99 and in accordance with its mission to protect public health and safety, promote the common defense and security, and protect the environment.

## 6. References

- [1] *Atomic Energy Act, as Amended*, 42 U.S.C. § 2011 (1954).
- [2] *Energy Policy Act*, (2005), Public Law 109-58 (2005).
- [3] *Energy Reorganization Act, as Amended*, 42 U.S.C. §5851 (1974).
- [4] *U.S. Code of Federal Regulations*, Chapter I, Title 10, “Energy.”
- [5] U.S. Nuclear Regulatory Commission, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,” NUREG-1537, Part 1, February 1996, Agencywide Document Access and Management System (ADAMS) Accession No. ML042430055.
- [6] U.S. Nuclear Regulatory Commission, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,” NUREG-1537, Part 2, February 1996, ADAMS Accession No. ML042430048.
- [7] U.S. Nuclear Regulatory Commission, “Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” October 2012, ADAMS Accession No. ML12156A069.
- [8] U.S. Nuclear Regulatory Commission, “Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” October 2012, ADAMS Accession No. ML12156A075.

- [9] U.S. Nuclear Regulatory Commission, "SHINE Medical Technologies - Exemption from Certain Requirements of Paragraph 2.101(a)(5) of 10 CFR Part 2, Regarding the Submission of a Construction Permit Application in Two Parts," March 2013, ADAMS Accession No. ML1307B345.
- [10] U.S. Nuclear Regulatory Commission, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," NUREG-1520, Rev. 1, May 2010, ADAMS Accession No. ML101390110.