

**Mo-99 2014 TOPICAL MEETING ON
MOLYBDENUM-99 TECHNOLOGICAL DEVELOPMENT**

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**Regulatory Activities Related to Licensing Medical Radioisotope
Production Facilities**

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ABSTRACT

This paper provides an update on U.S. Nuclear Regulatory Commission (NRC) activities related to the licensing of medical radioisotope production facilities. The NRC has received nine letters of intent from potential applicants seeking to domestically produce molybdenum-99. The NRC staff is reviewing a construction permit application for a medical radioisotope production facility and is coordinating its environmental review with the U.S. Department of Energy consistent with the American Medical Isotopes Production Act of 2012. To promote efficient review of applications, the NRC staff has clarified regulatory requirements and issued exemptions to facilitate processing of applications. The NRC staff continues to hold public meetings with potential applicants to receive information on proposed designs and schedule, discuss relevant guidance, and encourage submission of high-quality applications. These efforts and the NRC's regulatory framework will allow the NRC staff to perform an efficient, thorough, and timely review of any submitted application for a medical radioisotope production facility.

1. Introduction

For the past two decades, the U.S. has relied on imported medical radioisotopes to perform approximately 50,000 medical procedures daily. The Energy Policy Act of 2005, amended the Atomic Energy Act of 1954, providing 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 highly enriched uranium (HEU) [1][2]. This is consistent with the mission of the U.S. Department of Energy (DOE) National Nuclear Security Administration's (NNSA's) Global Threat Reduction Initiative to reduce the civilian use of HEU and ensure a reliable domestic supply of non-HEU based molybdenum-99 (Mo-99). Multiple global shortages of medical isotopes have underscored the need for prompt action to ensure a reliable domestic supply. The NNSA has subsequently entered into cooperative agreements with domestic firms to encourage the expeditious construction of medical radioisotope production facilities, most of which will require U.S. Nuclear Regulatory Commission (NRC) licensing.

In support of the national initiative to establish a domestic supply of Mo-99 without the use of HEU and in accordance with statutory responsibilities under the Atomic Energy Act of 1954, as amended, 42 U.S.C. § 2011 et seq., the NRC is prepared to receive and review construction permit and operating license applications for 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 NRC's regulatory activities related to medical radioisotope production.

Regulatory Issue Summaries

Regulatory Issue Summary (RIS) 2011-06, "Pre-application Communication and Voluntary Submittal of Schedule for Future [Mo-99] Facility Licensing Actions for NRC Review," contained a voluntary request for potential applicants to engage in communication with the NRC. This request for communication with potential applicants continued with the issuance of RIS 2013-03, "Pre-application Communication and Scheduling for Medical Radioisotope Facilities Intending to Produce [Mo-99]." Both RISs promoted 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. Specifically, both RISs posed several questions to potential applicants regarding the scheduling of pre-application licensing activities. These questions requested information regarding the number and type of applications a potential applicant anticipated submitting for NRC review, the timing of application submittals, site selection, facility design, and consideration of applicable regulations in Title 10 of the *Code of Federal Regulations* (10 CFR), "Energy." Early and frequent communication between the NRC and potential applicants promotes the development and submission of high-quality, complete applications [3][4].

Information received in response to these RISs help the NRC staff allocate the necessary resources to support application review activities during fiscal years. For fiscal year (FY) 2014, the NRC submitted a budget justification to Congress and received appropriations that provide resources for medical radioisotope application reviews [5]. For FY 2015, the NRC has submitted a budget justification to Congress that includes resources for medical radioisotope application reviews [6].

Letters of Intent

Since the NNSA's 2013 Mo-99 Topical Meeting, the NRC has received an additional four letters of intent to domestically produce Mo-99 from potential applicants. In total, the NRC has received nine letters of intent from potential applicants. Babcock and Wilcox Technical Services Group, Coqui Radiopharmaceuticals, General Electric Hitachi Nuclear Energy, SHINE Medical Technologies, Inc. (SHINE), the University of Missouri-Columbia,

Northwest Medical Isotopes, LLC., Eden Radioisotopes, LLC., Flibe Energy, and Precision Engineering Consultants, Inc., have all indicated intent in producing Mo-99 to the NRC.

Public Meetings

Public meetings are planned, formal interactions with the expressed purpose of discussing issues directly associated with the NRC's regulatory and safety responsibilities. However, these meetings are not intended to be a forum for NRC staff to provide a design review or to make regulatory decisions. Each public meeting provides members of the public the opportunity to enhance their understanding of the NRC's regulatory process [7][8].

Since April 2013, the NRC staff has conducted seven public meetings related to medical radioisotope production [9][10][11][12][13][14][15]. Public meetings are an effective means of communicating information related to a forthcoming application submittal, discussing relevant guidance, and encouraging 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 to receive technical information related to an ongoing review. Early and frequent communication with the NRC promotes the development and submission of high-quality, complete licensing applications.

In addition to holding meetings that are open to the public, the NRC staff may also close a portion of the meeting to the public if information discussed with the NRC can be 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).

Regulatory Information Conference

The 26th Annual Regulatory Information Conference (RIC) was held March 11-13, 2014 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 [16].

A technical session at this year's RIC focused on medical radioisotope production. Panelists from NRC, DOE, SHINE, and the U.S. Food and Drug Administration discussed their roles in implementing the national policy objective to establish a reliable domestic supply of Mo-99. The NRC staff panelists discussed the construction permit and operating license review process for radioisotope production facilities, including the status of preparations for current and anticipated reviews [17].

3. Regulatory Activities

The NRC staff is reviewing a construction permit application for a medical radioisotope production facility and is coordinating its environmental review with the DOE consistent with the American Medical Isotopes Production Act of 2012. To promote efficient review of applications, the NRC staff has clarified regulatory requirements and issued exemptions to facilitate processing of applications. These efforts and the NRC's regulatory framework will allow the NRC staff to perform an efficient, a thorough, and a timely review of any submitted application for a medical radioisotope production facility

Exemptions from NRC requirements

Requirements in NRC regulations must be met unless an exemption is granted. The Commission may, upon the application of any interested person, or upon its own initiative, grant exemptions from the requirements in NRC regulations, provided the requisite findings are made. The NRC staff received and approved an exemption request from certain requirements of 10 CFR 2.101, "Filing of Application," to allow SHINE to submit its construction permit application in two parts (i.e., to submit its environmental report required by 10 CFR 50.30(f) and its preliminary safety analysis report (PSAR) required by 10 CFR 50.34(a) up to six months apart). Since the NRC staff determined that the proposed licensing of the SHINE radioisotope production facility was not an action that requires an environmental impact statement or supplemental environmental impact statement under 10 CFR 51.20(b), 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. In granting the exemption, the staff noted that allowing SHINE to submit its construction permit in two parts would facilitate the licensing process and efforts to respond to the nation's demand for a domestic supply of Mo-99 [18].

In the past year, the NRC staff received and approved a similar exemption request from certain requirements of 10 CFR 2.101(a)(5) to allow Northwest Medical Isotopes, LLC, to also submit its construction permit application in two parts [19].

Interpretations of NRC Regulations

Sometimes potential applicants might want the NRC to provide an interpretation that clarifies provisions in NRC regulations. The NRC'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, any and all legal, technical or other information that support the requestor's approach or position. It should also be noted that interpretations of regulations (i.e. 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material") may be obtained in writing from the General Counsel. See 10 CFR 50.3, "Interpretations;" 10 CFR 70.6, "Interpretations."

The NRC has previously responded to requests for pre-licensing guidance on potential policy questions associated with licensing medical radioisotope production facilities. The questions received have asked for clarifications related to licensing process, the classification of wastes, and procedural requirements [20][21].

SHINE Construction Permit Application

The NRC staff received a two-part construction permit application from SHINE, consisting primarily of an environmental report and preliminary safety analysis report. The environmental report and preliminary safety analysis report 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 [22][23]. 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 from the applicant, completion of a safety evaluation report and environmental assessment or environmental impact statement, interaction with Commission's Advisory Committee on Reactor Safeguards, 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 [24][25]. The NRC staff is continuing to review SHINE's construction permit application. The NRC staff is developing requests for additional information and is preparing a draft environmental impact statement, which will be made available for public comment in accordance with the Commission's National Environmental Policy Act regulations in 10 CFR Part 51.

Oregon State University Research Reactor License Amendment Application

There is also another application pending before the NRC that relates to the domestic production of medical radioisotopes. Oregon State University (OSU) has submitted a license amendment application requesting approval to place targets in the OSU TRIGA® reactor (OSTR) for the explicit purpose of demonstrating the production of Mo-99 in a small nuclear reactor [26]. 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 requests for additional information to OSU. OSU provided timely responses to both requests for additional information. The NRC staff will determine whether to grant or deny the application after completion of its review.

4. Conclusion

Frequent and early communication and coordination with potential applicants are essential components of the ongoing regulatory activities conducted in support of licensing medical radioisotope production facilities. In support of the national initiative to establish a domestic supply of Mo-99 without the use of HEU, the ongoing NRC regulatory activities related to medical radioisotope production facilities include outreach and communication, determinations based on submitted requests, and review of requested licensing actions. The NRC's regulatory framework and guidance will allow the NRC staff to perform an efficient, a thorough, and a timely review of all applications for medical radioisotope production facilities in accordance with statutory responsibilities under the Atomic Energy Act of 1954, as amended, and with its mission to protect public health and safety, promote the common defense and security, and protect the environment.

5. References

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- [2] *Energy Policy Act of 2005*, Section 630, Pub. L. No. 109-58 (2005).
- [3] U.S. Nuclear Regulatory Commission, "Pre-application Communication and Voluntary Submittal of Schedule for Future Molybdenum-99 Facility Licensing Actions for NRC Review," RIS 2011-06, July 2011 (ADAMS Accession No. ML110770331).
- [4] U.S. Nuclear Regulatory Commission, "Pre-application Communication and Scheduling for Medical Radioisotope Facilities Intending to Produce Molybdenum-99," RIS 2013-03, April 2013 (ADAMS Accession No. ML13078A385).
- [5] U.S. Nuclear Regulatory Commission, "FY 2014 Congressional Budget Justification," NUREG-1100, Volume 29, April 2013 (ADAMS Accession No. ML13100A059).
- [6] U.S. Nuclear Regulatory Commission, "FY 2015 Congressional Budget Justification," NUREG-1100, Volume 30, March 2014 (ADAMS Accession No. ML14064A167).
- [7] U.S. Nuclear Regulatory Commission, "Attendance at NRC Staff-Sponsored Meetings," Management Directive 3.5, December 2011 (ADAMS Accession No. ML112971635).
- [8] U.S. Nuclear Regulatory Commission, "Enhancing Public Participation in NRC Meetings; Policy Statement," 67 FR 36920 (May 28, 2002).
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- [14] U.S. Nuclear Regulatory Commission, "Summary Of April 22, 2014, Meeting With Coqui Radiopharmaceuticals Corp. To Discuss The Potential Application For Medical Isotope Production Facility," May 2014 (ADAMS Accession No. ML14135A463).
- [15] U.S. Nuclear Regulatory Commission, "04/29/2014 Summary Of Meeting With Northwest Medical Isotopes, LLC, Regarding Medical Isotope Production," May 2014, (ADAMS Accession No. ML14136A508).
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- [18] U.S. Nuclear Regulatory Commission, "SHINE Medical Technologies, Inc.; Exemption," 78 FR 19537 (Apr. 1, 2013).
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- [21] U.S. Nuclear Regulatory Commission, "Coqui Radiopharmaceuticals Corporation - United States Nuclear Regulatory Commission Response to Part I of the Proposed Licensing Strategy Regarding Medical Isotope Production Facility's License Class," October 2010 (ADAMS Accession No. ML102020515).

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