



Regulatory Information Conference 2018
 Progress Toward a Reliable Domestic Supply of Molybdenum-99

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

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 March 2018

Medical Isotope Licensing Reviews

- Construction permit and operating license applications
 - Northwest Medical Isotopes (NWMI)
 - SHINE Medical Technologies (SHINE)
- License amendment requests from University of Missouri Research Reactor Center (MURR) in support of General Atomics
- Additional license amendment requests anticipated from Oregon State University (OSU) and MURR in support of NWMI project
- Materials license amendment issued to Niowave

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Northwest Medical Isotopes

- NWMI proposes to manufacture and process low enriched uranium (LEU) targets for ⁹⁹Mo production in Columbia, Missouri
 - Target manufacturing to be licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70
 - LEU targets irradiated at existing research reactors
 - Irradiated targets returned to NWMI for processing in a 10 CFR Part 50 *production facility*
- NRC staff applied best practices to support 23-month review
 - Emphasis on most safety-significant technical aspects
 - Focused requests for additional information
 - Weekly status calls

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Status of NWMI Review

- Final environmental impact statement published in May 2017
- Advisory Committee Meeting on Reactor Safeguards full committee meeting held in November 2017
- Safety evaluation report completed in November 2017
- Commission held mandatory hearing in January 2018
 - Staff and applicant presented on unique licensing considerations
 - Commission decision on permit expected in before mid-2018

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SHINE Medical Technologies, Inc.

- SHINE proposes to fission LEU target solution in 8 irradiation units licensed as 10 CFR Part 50 *utilization facilities*
- SHINE proposes to recover ⁹⁹Mo by processing irradiated target solution in hot cells licensed as a 10 CFR Part 50 *production facility*
- Construction permit issued in February 2016
- Construction expected to begin in 2018
- Operating license application expected in 2018
- Proposed site: Janesville, Wisconsin

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Periodic Reports on Permit Conditions

- SHINE construction permit requires the submission of periodic reports to verify certain design elements related to nuclear criticality safety and radiation protection
 - Criticality accident alarm system
 - Nuclear criticality safety evaluations
 - Design information demonstrating shielding and occupancy times consistent with as low as reasonably achievable practices and dose requirements
- SHINE has submitted three periodic reports since the issuance of its construction permit
- NRC staff may request clarifying or more detailed information, if necessary, prior to the completion of construction

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Annual Financial Reports

- NRC requires certain licensees to submit annual financial reports
- While annual financial reports are submitted for informational purposes, NRC staff keeps reports available for future reviews of financial qualifications
- SHINE has submitted two annual financial reports since the issuance of its construction permit
- NRC staff may request additional or more detailed information regarding ability of SHINE to continue the conduct of activities authorized by its construction permit

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Reactor License Amendments

- First of two anticipated amendment requests supporting General Atomics ⁹⁹Mo production project submitted by MURR in May 2017
 - If granted, amendment would allow modification of reactor reflector and installation of supporting systems for LEU target irradiation
 - Second license amendment request would support installation of gaseous extraction hot cells to process irradiated targets
- Additional license amendment requests expected from MURR and OSU to support commercial target irradiation for NWM

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Materials and Medical Use Licenses

- Materials license issued to Niowave in 2015
 - Production of small amounts of ⁹⁹Mo through uranium fission using superconducting linacs for proof of concept
- NorthStar Medical Radioisotopes
 - Proposes to produce ⁹⁹Mo from molybdenum targets enriched in ⁹⁸Mo
 - Initial target irradiation to be performed by MURR
 - Developed RadioGenix ^{99m}Tc generator system
 - NRC staff developed 10 CFR Part 35 licensing guidance for medical use applicants and licensees that possess RadioGenix system

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Oversight, Infrastructure, and Support Activities

- Developing construction and operation inspection programs
 - Construction inspection program established in December 2015
 - Inspections commensurate with risk of facility, focusing on most safety-significant structures, systems, and components
- Updating regulatory framework
 - Published proposed rule to streamline license renewal in 2017
 - Supporting development of proposed rule for emergency planning
- Coordinating technical and licensing expertise through inter-office working group
- Providing updates on public website:
 - <http://www.nrc.gov/reactors/medical-radioisotopes.html>
