



Mo-99 Stakeholders Meeting 2023

Licensing and Oversight of ^{99}Mo Programs at the U.S. Nuclear Regulatory Commission

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Non-Power Production and Utilization Licensing Branch

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Supporting ⁹⁹Mo Production

- NRC staff is committed to efficient reviews of applications and inspections in accordance with the provisions of Title 10 of the *Code of Federal Regulations*
- Licensing and oversight activities support U.S. national security interests and nuclear nonproliferation policy objectives of establishing a domestically-available and reliable supply of ⁹⁹Mo without the use of highly-enriched uranium
- Applications include initial license and license amendment requests for facilities proposing to manufacture, irradiate, and process low enriched uranium (LEU) and molybdenum targets
- Oversight activities include construction inspection, operational readiness review, safety and security inspection, licensing of operators, and operator licensing examination

Regulated Production Processes

- Target manufacturing
 - Preparation of LEU targets for irradiation
- Target irradiation
 - Nuclear reactors
 - Subcritical operating assemblies
 - Accelerators
- Target processing
 - Hot cell separation of ^{99}Mo from irradiated LEU targets
- Medical uses of byproduct material
 - Generators for extracting technetium-99m from ^{99}Mo

Licensing Accomplishments

- Issued two construction permits
 - SHINE Technologies (February 2016)
 - Northwest Medical Isotopes (May 2018)
- Issued amendments to SHINE construction permit
 - To receive and possess byproduct and source material (2021)
 - Extend the latest date of construction to December 31, 2025 (2022)
 - To receive and possess special nuclear material in the form of neutron detectors (2023)
- Issued safety evaluation and final supplemental environmental impact statement for SHINE's operating license application (2023)
- Published guidance for medical use applicants and licensees possessing the NorthStar Medical Radioisotopes RadioGenix system (2018)
- Issued safety evaluation on Atomic Alchemy's, Topical Report - Quality Assurance Program Description (2022)

Practices Supporting Review Efficiency

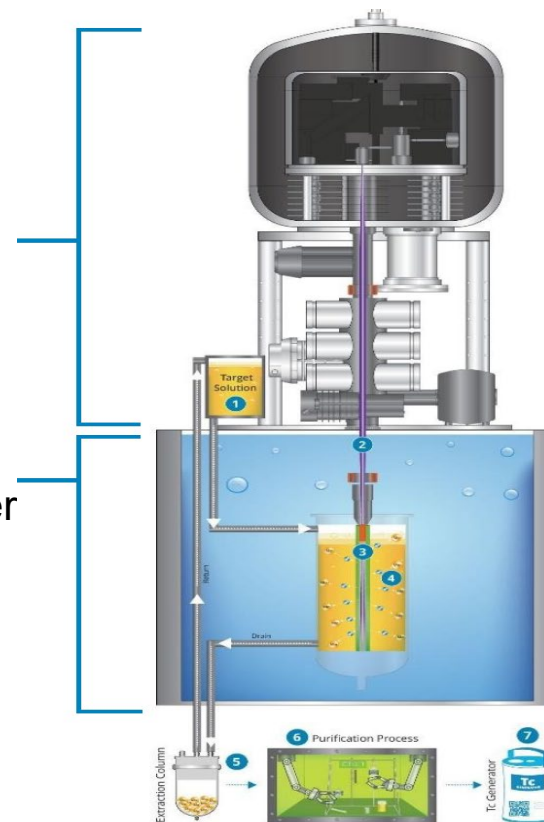
- For novel technologies, early interactions between NRC staff and applicants support efficient application processing and review
- Public pre-application meetings
 - Promote engagement between NRC and potential applicant
 - Inform the development of high-quality applications
 - Inform budgeting and resource allocation
 - Inform public of NRC process
- Best practices from application reviews:
 - Emphasis on most safety-significant technical aspects
 - Early engagement and frequent communication to develop focused requests for additional information
 - Routine engagement at all levels to identify and address issues efficiently and effectively

Tools for Success

- Pre-application Phase
 - **Topical Reports** - Used to submit technical information for NRC review and approval
 - **White Papers** - Used to request general written feedback on a specific topic
 - **Pre-Application Readiness Assessment** - Used to identify major issue or information gaps
 - **Public Meetings** - Used to provide initial feedback on a draft application or topic
- Post-Application Phase
 - **Requests for Additional Information** - Used to obtain information needed for a regulatory decision
 - **Public Meetings** - Used to support ongoing reviews of submitted information
 - **Audits** - Used to gain understanding, verify information, and identify information need to support a decision

SHINE Operating License Application Review

- ^{99}Mo is produced by the fissioning of LEU target solution using eight accelerator-driven subcritical operating assemblies
- ^{99}Mo is recovered by processing the irradiated solution in three hot cells
- Facility is located in Janesville, WI
- Operating license application submitted in July 2019 and accepted for review in October 2019
- Advisory Committee on Reactor Safeguards issued report in December 2022 (ML22342A144)
- Issued safety evaluation report in February 2023 (ML23047A025)
- Issued final supplemental environmental impact statement in January 2023 (ML23026A312)



SHINE[®]
Health. Illuminated.

SHINE Construction Inspection

- NRC staff developed Inspection Manual Chapter (IMC) 2550 in 2015 for construction inspection of new non-power facilities, consisting of three inspection procedures (IPs):
 - IP 69020 for safety-related structures, systems, and components (SSCs)
 - IP 69021 for quality assurance program
 - IP 69022 for programmatic inspections
- Inspections commensurate with risk of facility, focusing on most safety-significant SSCs
- Formal construction activities began in October 2019 with the initial pouring of subgrade concrete.
- Most recent construction inspection completed May 2022 (ML22154A405)



SHINE Construction Site in May 2022

Prospective Applicants

- Niowave
 - Accelerator-driven subcritical operating assembly, target processing facility, and target fabrication facility
 - Conducting proof-of-concept technology demonstrations under an NRC materials license, engaging in preapplication activities
- Eden Radioisotopes
 - 2-megawatt thermal reactor with hot cell and target fabrication facilities to produce medical radioisotopes
 - Engaging in preapplication activities
- Atomic Alchemy
 - Four non-power, pool type reactors and two processing facilities
 - Engaging in preapplication activities, issued two pre-application audit reports (ML22286A167 and ML22325A246)

Looking Forward

- Continuing oversight of SHINE construction activities
- Continuing licensing activities to support regulatory findings for issuance of an operating license
- Updating licensing and oversight framework
- Engaging with potential construction permit applicants
- Supporting ongoing activities related to materials and medical use licensees
- Continuing interactions with construction permit holders on facility-specific conditions and annual reports
- Leveraging lessons learned and technical experience gained to inform future pre-application engagements and application reviews

Thank you!

Additional Information can be found at

<https://www.nrc.gov/reactors/medical-radioisotopes.html>

<https://www.nrc.gov/about-nrc/generic-schedules.html>

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