

*Mo-99 International Symposium 2022*

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

Michael Balazik  
Office of Nuclear Reactor Regulation  
U.S. Nuclear Regulatory Commission  
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# Supporting $^{99}\text{Mo}$ 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  $^{99}\text{Mo}$  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  $^{99}\text{Mo}$  from irradiated LEU targets
- Medical uses of byproduct material
  - Generators for extracting technetium-99m from  $^{99}\text{Mo}$

# Licensing Accomplishments

- Issued two construction permits
  - SHINE Medical Technologies (February 2016)
  - Northwest Medical Isotopes (May 2018)
- Issued amendment to SHINE construction permit in 2021
- Continuing the safety and environmental review of the SHINE operating license application and supporting the review by the Advisory Committee on Reactor Safeguards
- Published guidance in 2018 for medical use applicants and licensees possessing the NorthStar Medical Radioisotopes RadioGenix system
  - Supported first commercial domestic production of  $^{99}\text{Mo}$  since Cintichem ceased operations in 1989
- Issued license amendment to Oregon State University in 2016 for demonstration of  $^{99}\text{Mo}$  production in small nuclear reactor with experimental uranium targets
- Issued materials license to Niowave in 2015

# Practices Supporting Review Efficiency

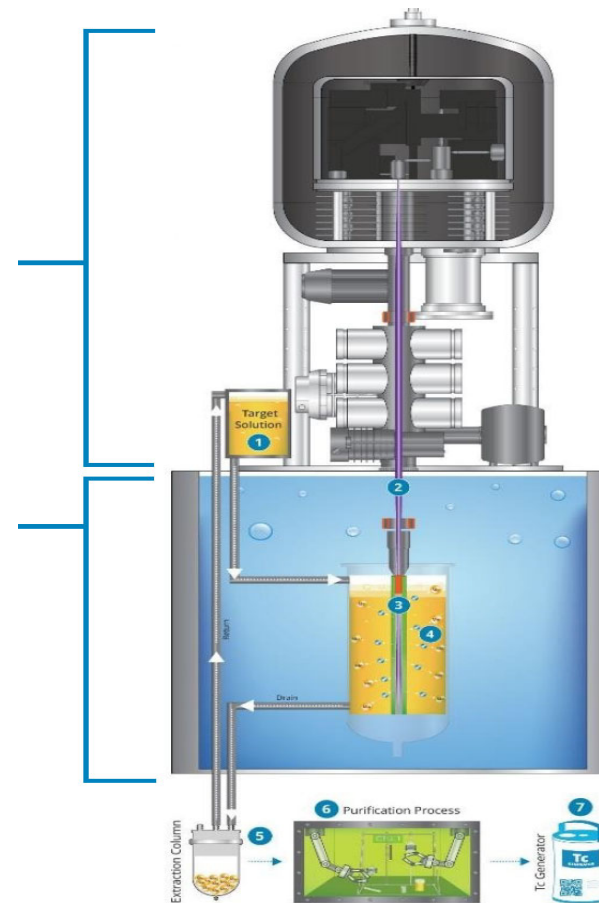
- For novel technologies, early interactions between NRC staff and applicants support efficient application processing and review
- Public pre-application meetings
  - Promote engagement between NRC and potential applicant
  - Inform the development of high-quality applications
  - Inform budgeting and 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

- $^{99}\text{Mo}$  is produced by the fissioning of LEU target solution using eight accelerator-driven subcritical operating assemblies
- $^{99}\text{Mo}$  is recovered by processing the irradiated solution in three hot cells
- Facility is located in Janesville, Wisconsin
- Operating license application submitted in July 2019 and accepted for review in October 2019



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# 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.



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
  - Topical reports under review, engaging in preapplication activities

# Looking Forward

- Continuing review of SHINE operating license application
- Updating licensing 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>

Contact Information:

Michael Balazik, Project Manager/Inspector, U.S. NRC

[Michael.Balazik@nrc.gov](mailto:Michael.Balazik@nrc.gov)