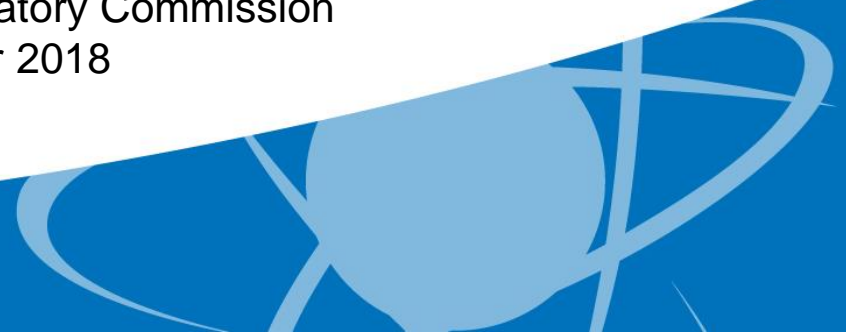


2018 Test, Research, and Training Reactors  
Annual Conference

Medical Radioisotope Facility  
Application Reviews and Construction Inspection

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# Supporting Domestic $^{99}\text{Mo}$ Production

- NRC staff committed to efficient reviews of applications and inspections in accordance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR)
- Licensing and oversight activities support U.S. national security interests and nuclear nonproliferation policy objectives of establishing a domestically-available and reliable supply of molybdenum-99 ( $^{99}\text{Mo}$ ) 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 and molybdenum targets
- Oversight activities focused on preparation for construction inspection of utilization and production facilities

# Regulated Production Processes

- Target manufacturing
  - Preparation of low enriched uranium (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  $^{99}\text{Mo}$

# Similarities to Non-power Reactors

- Safety considerations comparable non-power reactors:
  - Fission heat removal
  - Decay heat generation
  - Fission gas release
  - Fission product buildup
  - Accident scenarios
- ...and fuel cycle facilities:
  - Target manufacturing
  - Radiation protection
  - Material processing
  - Criticality control
  - Chemical hazards

# Medical Radioisotope Licensing and Oversight

- Construction permit and operating license applications
  - Northwest Medical Isotopes (NWMI)
  - SHINE Medical Technologies (SHINE)
- License amendment requests supporting NWMI production project
  - Oregon State University (OSU)
  - University of Missouri Research Reactor Center (MURR)
- Materials license and medical use applications
  - Niowave, Inc.
  - NorthStar Medical Radioisotopes RadioGenix generator system
- Inspection preparation for anticipated construction of SHINE and NWMI facilities

# Northwest Medical Isotopes

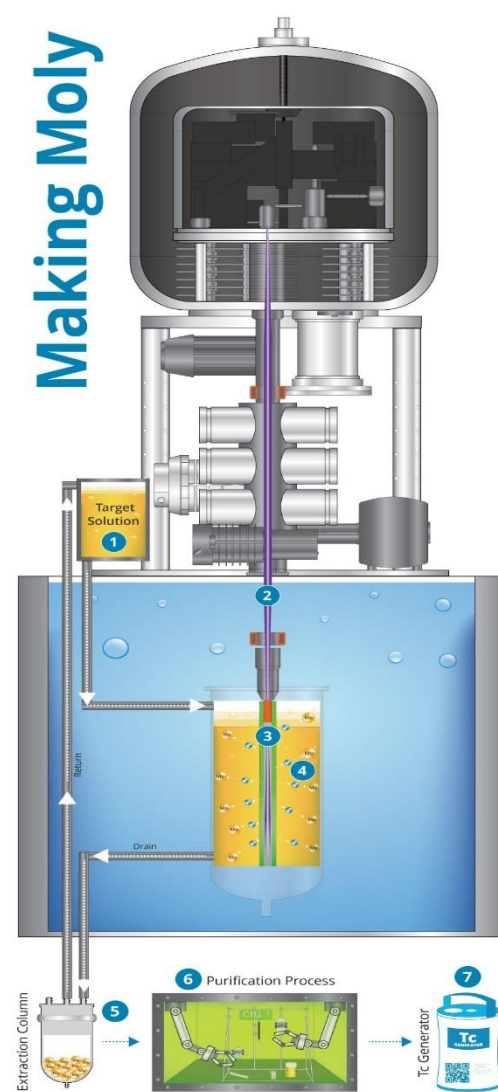
- NWMI proposes to manufacture and process LEU targets for  $^{99}\text{Mo}$  production
  - Target manufacturing to be licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70
  - LEU targets irradiated at existing research reactors, including OSU and MURR
  - Irradiated targets returned to NWMI for processing in a 10 CFR Part 50 *production facility*
- Proposed site: Columbia, Missouri



Oregon State University TRIGA Reactor  
Source: OSTR Webpage

# SHINE Medical Technologies

- SHINE proposes to fission LEU target solution in 8 irradiation units licensed as 10 CFR Part 50 *utilization facilities*
- SHINE proposes to recover  $^{99}\text{Mo}$  by processing irradiated target solution in hot cells licensed as a 10 CFR Part 50 *production facility*
- Proposed site: Janesville, Wisconsin
- Pre-construction and pre-application meetings held in April, May, June, and August 2018



SHINE  $^{99}\text{Mo}$  Production Process  
Source: SHINE Webpage

# Licensing Accomplishments

- Issued two construction permits for non-power production or utilization facilities
  - SHINE Medical Technologies (February 2016)
  - Northwest Medical Isotopes (May 2018)
  - Reviews completed in under two years from time of application docketing
- Published guidance in February 2018 for medical use applicants and licensees possessing the NorthStar Medical Radioisotopes RadioGenix system
  - Supports first anticipated commercial domestic production of  $^{99}\text{Mo}$  since Cintichem ceased operations in 1989
- Issued license amendment to OSU in 2016 for demonstration of  $^{99}\text{Mo}$  production in small nuclear reactor with experimental uranium targets
- Issued materials license to Niowave in 2015
  - License amendments issued increased LEU possession limit and supported irradiation of natural uranium targets using superconducting linacs for proof of concept



# Reflecting Back...

- 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 construction permit application reviews:
  - Emphasis on most safety-significant technical aspects
  - Focused requests for additional information
  - Weekly status calls

# ...And Looking Forward

- Anticipating operating license application reviews and construction inspection activities expected to begin in fiscal year 2019
- Updating licensing framework
- Anticipating technical and licensing challenges
- Engaging with potential construction permit applicants
- Supporting ongoing activities related to materials and medical use licensees
- Preparing for license amendment requests from existing research reactor licensees supporting the NWMI production project
- Continuing interactions with construction permit holders on facility-specific conditions and annual reports

# Construction Inspection Preparation

- Developing construction and operation inspection programs
  - Construction inspection program established in December 2015
  - Inspections to be commensurate with risk of facility, focusing on most safety-significant structures, systems, and components (SSCs)
- Updating construction inspection manual chapter
- Planning for initial construction inspections related to quality assurance and civil engineering
- Working with licensees to identify most safety-significant SSCs to prioritize and focus construction inspections ahead of final safety analysis report submission
  - Information shared through public meetings, site visits, and electronic reading rooms
- Reviewing previous construction inspection reports

# Estimated Level of Effort for Operating License Application Reviews

	Low-Complexity Review	Base-Complexity Review	High-Complexity Review
<b>Review Hours</b>	13,000	22,000	34,000
<b>Increase in Review Hours from Construction Permit Application</b>	1,400	5,400	17,000

- Assumptions
  - NRC staff familiarity with proposed technology
  - Efficiencies gained from initial use of review guidance
  - Decrease in level of effort for environmental review
  - Increase in level of effort for safety review
- Factors impacting level of effort estimates
  - Complexity of review
  - Quality and completeness of application
  - Number of requests for additional information and need for follow-up
  - Use of NRC staff vs. contract resources to complete review
  - Number of Advisory Committee on Reactor Safeguards meetings
  - Potential for contested hearing
- Challenges and uncertainty in estimates
  - First-of-a-kind technology and licensing reviews
  - Lack of similar reviews for comparison
  - Limited information on new and/or different information in operating license applications
- Cost considerations
  - 2018 professional hourly rate is \$275
  - Estimates do not include fee-billable construction inspection costs
  - Estimates do not include non-fee-billable overhead associated with:
    - Policy paper development
    - Rulemaking
    - Guidance development
    - Staff training

# Impact of Medical Radioisotope Facility Reviews

- Experience gained from reviews supporting a more responsive and efficient technology-inclusive regulatory framework at the NRC
- Leading initial licensing activities at NRC by considering technologies beyond light water and non-power reactors
- Review of construction permit applications setting example for future advanced reactor reviews
- Success made possible through technical and licensing expertise provided by inter-office working group
- Updates on medical radioisotope facility activities available through NRC public website:
  - <http://www.nrc.gov/reactors/medical-radioisotopes.html>