

National Nuclear Security Administration  
Mo-99 Stakeholders Meeting

# Update on Licensing Reviews Supporting Domestic Molybdenum-99 Production

Office of Nuclear Reactor Regulation  
U.S. Nuclear Regulatory Commission  
May 16, 2018



# Medical Isotope Licensing Reviews

- Construction permit and operating license applications
  - Northwest Medical Isotopes (NWMI)
  - SHINE Medical Technologies (SHINE)
- License amendment requests anticipated from Oregon State University (OSU) and University of Missouri Research Reactor Center (MURR) in support of NWMI project
- Materials license, and subsequent amendments, issued to Niowave
- Licensing guidance issued for NorthStar RadioGenix generator system

# Northwest Medical Isotopes

- NWMI proposes to manufacture and process low enriched uranium (LEU) targets for  $^{99}\text{Mo}$  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

# Status of NWMI Review

- Construction permit application submitted in 2015
- 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
- Construction permit issued in May 2018

# 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  $^{99}\text{Mo}$  by processing irradiated target solution in hot cells licensed as a 10 CFR Part 50 *production facility*
- Construction permit issued in February 2016
  - Periodic reports on permit conditions
  - Annual financial reports
- Pre-construction and pre-application meetings scheduled in April and May 2018
  - Construction expected to begin in 2018
  - Operating license application expected in 2018
- Proposed site: Janesville, Wisconsin

# Reactor License Amendments at MURR

- First of two anticipated amendment requests related to General Atomics (GA) selective gas extraction (SGE) technology submitted in May 2017
  - If granted, would have allowed modification of reactor reflector and installation of supporting systems for LEU target irradiation
  - Second amendment would have supported installation of SGE hot cells to process irradiated targets
- In an April 2018 press release, Nordion, Inc. announced withdrawal of support for medical isotope production project partnership with GA and MURR
  - Consequently, GA terminated its contract with MURR, who subsequently withdrew its license amendment request to produce Mo-99 using the GA SGE process

# Materials and Medical Use Licenses

- Materials license issued to Niowave in 2015
  - Production of small amounts of  $^{99}\text{Mo}$  through uranium fission using superconducting linacs for proof of concept
  - NRC staff has issued amendments increasing LEU possession limit and supporting irradiation of natural uranium targets
- NorthStar Medical Radioisotopes
  - Proposes to produce Mo-99 from molybdenum targets enriched in Mo-98
  - Developed RadioGenix Tc-99m generator system
  - NRC staff published licensing guidance for medical use applicants and licensees that possess RadioGenix system in February 2018
  - NRC staff currently considering updated information on generator system and potential changes to licensing guidance

# 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>