2017 Mo-99 Topical Meeting on Molybdenum-99 Production Technology Development

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

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Supporting Domestic $^{99}$Mo Production

- NRC is conducting efficient reviews of applications submitted in accordance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR)

- Reviews support U.S. national security interests and nuclear nonproliferation policy objectives by contributing to the establishment of a domestically-available and reliable supply of molybdenum-99 ($^{99}$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
Regulated Production Processes

- Target manufacturing
  - Preparation of low enriched uranium targets for irradiation

- Target irradiation
  - Nuclear reactors
  - Subcritical operating assemblies
  - Accelerators

- Target processing
  - Hot cell separation of $^{99}$Mo from low enriched uranium targets

- Medical uses of byproduct material
  - Generators for extracting technetium-99m ($^{99m}$Tc) from $^{99}$Mo
Current and Anticipated Licensing Reviews

• Construction permit and operating license applications
  – Northwest Medical Isotopes (NWMI)
    • Construction permit application under review
  – SHINE Medical Technologies (SHINE)
    • Construction permit issued February 2016
    • Operating license application expected 2018

• 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 request from Niowave
Northwest Medical Isotopes

• NRC received two-part construction permit application
  – Environmental Report (February 2015)

• NWMI proposes to manufacture low enriched uranium targets for irradiation at existing research reactors (MURR and OSU)

• $^{99}$Mo recovered through processing of irradiated targets

• Proposed site: Columbia, MO
NWMI Licensing Approach

• Hot cells reviewed as *production facility* under 10 CFR Part 50
• Special nuclear material, including target manufacturing, will be licensed under 10 CFR Part 70
• NRC staff applying best practices from SHINE review:
  − Emphasis on most safety-significant technical aspects
  − Focused requests for additional information
  − Weekly status calls
  − Twenty-two month safety review schedule
Construction Permit Review Process

• Acceptance and docketing of application
• Parallel development of safety evaluation report and environmental impact statement (or environmental assessment)
• Request(s) for additional information, as needed
• Advisory Committee on Reactor Safeguards review
• Potential contested hearing; mandatory hearing (adequacy of staff safety and environmental review)
• Decision to grant or deny construction permit
Construction Permit Regulatory Requirements

- Regulatory considerations for NWMI construction permit:
  - 10 CFR 50.22, Commercial and industrial facility licenses
  - 10 CFR 50.30, Environmental Report
  - 10 CFR 50.34(a), Preliminary safety analysis report
  - 10 CFR 20.1201, Occupational dose requirements
  - 10 CFR 20.1301, Public and accident dose requirements
  - 10 CFR 50.35, Issuance of construction permits

- Note: 10 CFR Part 50 Appendices A, “General Design Criteria…” and B, “Quality Assurance Criteria…” are only applicable to nuclear power reactors.

- 10 CFR Part 100, “Reactor Site Criteria,” siting and accident dose criteria are only applicable to nuclear power and test reactors.
Regulatory Guidance and Acceptance Criteria

- NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors”

- Interim Staff Guidance Augmenting NUREG-1537
  - Radioisotope production facilities

- Other guidance (e.g., regulatory guides and ANSI/ANS standards) and engineering judgement used, as appropriate, to determine what is necessary for construction permit
NRC Review Methodology

• Since construction permit only allows construction, level of detail needed in application and staff’s SER different than for combined operating license or operating license

• For the purposes of issuing a construction permit, the facility may be adequately described at a functional or conceptual level in the PSAR

• Applicants may defer providing many design and analysis details until the submission of its final safety analysis report (FSAR) with its operating license application

• Staff’s review tailored to unique and novel technology described in construction permit application using appropriate regulatory guidance
Basis for Issuing Construction Permit

• The following findings must be made to issue a construction permit, based on 10 CFR 50.35:
  − Facility has been described, including the principal architectural and engineering criteria for the design
  − Further technical or design information may be reasonably left for later consideration in the FSAR
  − Safety features or components requiring research and development have been identified
  − Safety questions will be resolved prior to the completion of construction and the proposed facility can be constructed without undue risk to the health and safety of the public

• Staff’s conclusions also based on the considerations in 10 CFR 50.40 and 50.50
Status of NWMI Environmental Review

- Part one of application accepted for docketing (May 2015)
- Environmental site audit (September 2015)
- Issued environmental requests for additional information (November 2015, with follow-up requests January, March, and June 2016)
- Environmental scoping meeting (December 2015)
- Draft environmental impact statement (EIS) published (October 2016)
- Public meeting on draft EIS (December 2016)
- Final EIS published (May 2017)
Status of NWMI Safety Review

- Part two of application accepted for docketing (December 2015)
- Issued safety requests for additional information (March 2016, with follow-up requests in September 2016, as well as January and March 2017)
- Participated in Advisory Committee Meeting on Reactor Safeguards (ACRS) subcommittee meetings (June, July, August, and September 2017)
- Completion of staff review anticipated by October 2017
- Next Steps:
  - ACRS full committee meeting
  - Mandatory hearing (with Commission)
- Application supported by license amendments for existing research reactors
  - Prototypical target irradiation (OSU), issued
  - Commercial target irradiation (OSU, MURR), anticipated
SHINE Medical Technologies, Inc.

- Construction permit issued to SHINE in February 2016
- Construction expected to begin in 2018
- Operating license application expected in 2018
- SHINE proposes to produce $^{99}$Mo from fission of low enriched uranium target solution in Irradiation Facility consisting of 8 irradiation units
- $^{99}$Mo recovered through irradiated target solution processing in Radioisotope Production Facility consisting of 3 hot cells
- Proposed site: Janesville, WI
Periodic Reports on Permit Conditions

• Section 3.D.(1) of 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 (August 2016, February 2017, August 2017)

• NRC staff may request clarifying or more detailed information, if necessary, prior to the completion of construction
Annual Financial Reports

- In addition to financial qualifications during initial licensing, 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.
SHINE Demonstration Unit

• SHINE planning to conduct series of short-duration tests within an accelerator-driven subcritical operating assembly, with less than a critical mass of low enriched uranium (LEU)

• Unlike commercial irradiation units, demonstration unit would not require engineered safety features or physical protection system based on:
  • Thermal power level
  • Effective multiplication factor
  • Potential accident scenarios
  • Quantities of special nuclear material
  • Intended use

• NRC staff determined that proposed demonstration unit would not meet the definition of a “utilization facility” in 10 CFR Part 50 or Atomic Energy Act
Reactor License Amendments at MURR

• First of two anticipated amendment requests submitted in May 2017
  – If granted would allow modification of reactor reflector and installation of supporting systems for LEU target irradiation
  – Initial request for additional information issued in September 2017
  – Completion of technical review anticipated by June 2018
• Second license amendment request would support installation of hot cells to process irradiated targets using General Atomics gaseous extraction technology
  – Hot cells anticipated to be licensed as production facility
  – NRC staff considering licensing questions such as need for construction permit and commercial designation of production facility
  – Public meeting scheduled for October 2017
Materials and Medical Use Licenses

• Materials license issued to Niowave in 2015
  − Production of small amounts of $^{99}$Mo through uranium fission using superconducting linacs for proof of concept
  − NRC staff considering amendment request to increase LEU possession limit

• NorthStar Medical Radioisotopes
  − Proposes to produce $^{99}$Mo from enriched molybdenum target irradiation
  − Developed RadioGenix $^{99m}$Tc generator system compatible with lower specific activity $^{99}$Mo
  − NRC staff developing licensing guidance for medical use applicants and licensees that possess RadioGenix system
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
  - Developing proposed rule for emergency planning
- Coordinating technical and licensing expertise through inter-office working group
- Providing updates on public website: