U.S.NRC
United States Nuclear Regulatory Commission
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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)
  - Preliminary Safety Analysis Report (July 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
  - Incorporates relevant non-reactor guidance from NUREG-1520, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility, Rev. 1”
- 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:
  - http://www.nrc.gov/reactors/medical-radioisotopes.html