

Mo-99 Stakeholders Meeting

Insights on Adapting Licensing Frameworks to New Radioisotope Production Technologies

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Non-Power Facility Licensing and Oversight

- U.S. Nuclear Regulatory Commission (NRC) responsible for 31 non-power reactors
 - Routine licensing actions
 - License renewal reviews
 - Digital instrumentation and control upgrades
 - Highly enriched uranium to low-enriched uranium fuel conversions
 - Inspection and operator licensing
- Licensing infrastructure and policy
 - Guidance development
 - American Nuclear Society standard committee participation
 - Advanced reactor licensing support
 - Rulemaking development and support
- International activities, including International Atomic Energy Agency support
- Initial licensing reviews for medical radioisotope facilities

Supporting ⁹⁹Mo 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 ⁹⁹Mo 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

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}Mo from irradiated LEU targets
- Medical uses of byproduct material
 - Generators for extracting technetium-99m from ^{99}Mo

Similarities to Existing Facilities

- Safety considerations comparable to 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

Non-Power Licensing Process

- Applications contain both general and technical information
- Construction permit application
 - Environmental report
 - Preliminary safety analysis report (PSAR)
- Operating license application
 - Update to environmental report, as necessary
 - Final safety analysis report (FSAR)
- Applications may be submitted separately or together
- Testing facilities and commercial facilities may request limited work authorization to allow certain construction activities prior to the issuance of a construction permit

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

NUREG-1537 Review Areas

1. The Facility/Introduction
2. Site Characteristics
3. Design of Structures, Systems, and Components
4. Facility Description
5. Coolant Systems
6. Engineered Safety Features
7. Instrumentation and Control
8. Electrical Power Systems
9. Auxiliary Systems
10. Experimental Facilities*
11. Radiation Protection and Waste Management
12. Conduct of Operations
13. Accident Analysis
14. Technical Specifications
15. Financial Qualifications
16. Other License Considerations*
17. Decommissioning*
18. Uranium Conversions*
19. Environmental Review

* May not be applicable to construction permit application for ⁹⁹Mo facility

NRC Review Methodology

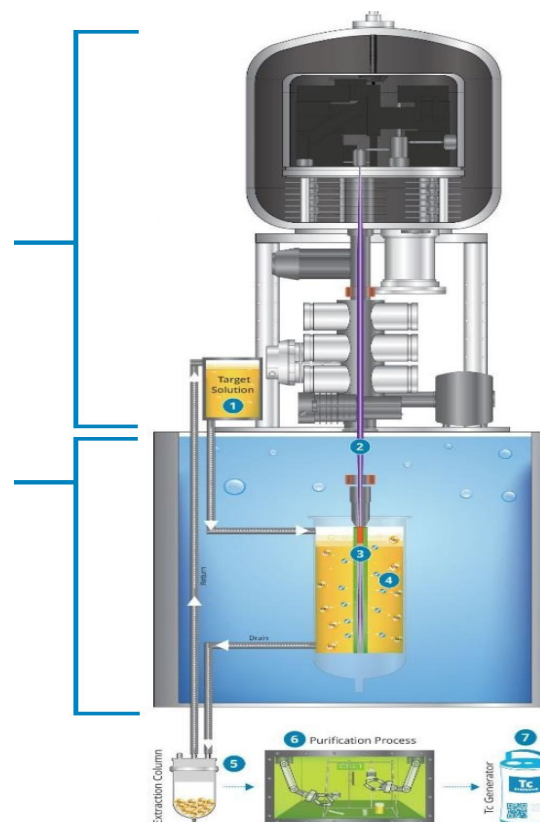
- For a construction permit application review, level of detail needed in application different than for an operating license application
- For the purposes of issuing a construction permit, the facility may be adequately described at a functional or conceptual level in the PSAR
- Applicants may defer 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

Resolving Technical Issues of Preliminary Designs

- For technical areas requiring additional information, the staff has several options:
 - The staff may determine that such technical issues must be resolved prior to the issuance of a construction permit
 - The staff may determine that such information may be left until the submission of the FSAR
 - The staff may require that such technical issues be resolved prior to the completion of construction, but after the issuance of the construction permit
- In all cases, staff may issue requests for additional information
- In the second and third options, staff may track regulatory commitments or identify necessary license conditions

SHINE Operating License Application Review

- ^{99}Mo produced by fissioning of low enriched uranium (LEU) solution using eight accelerator-driven subcritical operating assemblies
- ^{99}Mo recovered by processing irradiated solution in three hot cells
- Facility to be located in Janesville, Wisconsin
- Operating license application submitted in July 2019 and accepted for review in October 2019



Northwest Medical Isotopes

- NWMI proposes to manufacture and process LEU targets for ^{99}Mo production
 - Target manufacturing
 - LEU targets irradiated at existing research reactors, including Oregon State University
 - Irradiated targets returned to NWMI for processing



Oregon State University TRIGA Reactor
Source: OSTR Webpage

Prospective Applicants

- Niowave
 - Accelerator-driven subcritical operating assembly, target processing facility, and target fabrication facility
 - Currently conducting proof-of-concept technology demonstrations under an NRC materials license
- Eden Radioisotopes
 - 2-megawatt thermal reactor with hot cell and target fabrication facilities to produce medical radioisotopes
 - Construction permit in development
- Atomic Alchemy
 - Four non-power, pool type reactors and processing facility
 - Topical reports under review, construction permit in development

Licensing Accomplishments

- Issued two construction permits
 - SHINE Medical Technologies (February 2016)
 - Northwest Medical Isotopes (May 2018)
 - Reviews completed in under two years from time of application docketing
- Published guidance in 2018 for medical use applicants and licensees possessing the NorthStar Medical Radioisotopes RadioGenix system
 - Supported first commercial domestic production of ^{99}Mo since Cintichem ceased operations in 1989
- Issued license amendment to OSU in 2016 for demonstration of ^{99}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

Construction Inspection

- NRC staff developed IMC 2550 in 2015 for construction inspection of new non-power facilities, consisting of three inspection procedures:
 - 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. SHINE building weather-tight building in March 2021



***SHINE Construction Site in February
2020***

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

- Continuing review of SHINE operating license application
- Updating licensing framework
- Anticipating technical and licensing challenges
- 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

Impact of Medical Radioisotope Facility Reviews

- Experience gained from reviews supporting a more responsive and efficient technology-inclusive regulatory framework at the NRC
- Considering initial licensing of 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>