

*2021 Annual Meeting of the
National Organization of Test, Research, and Training Reactors*

Update on Licensing New Radioisotope Production Technologies

Steven Lynch, Senior Project Manager
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
October 2021



Supporting ^{99}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 ^{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
- Oversight activities focused on preparation for construction inspection

Regulated Production Processes

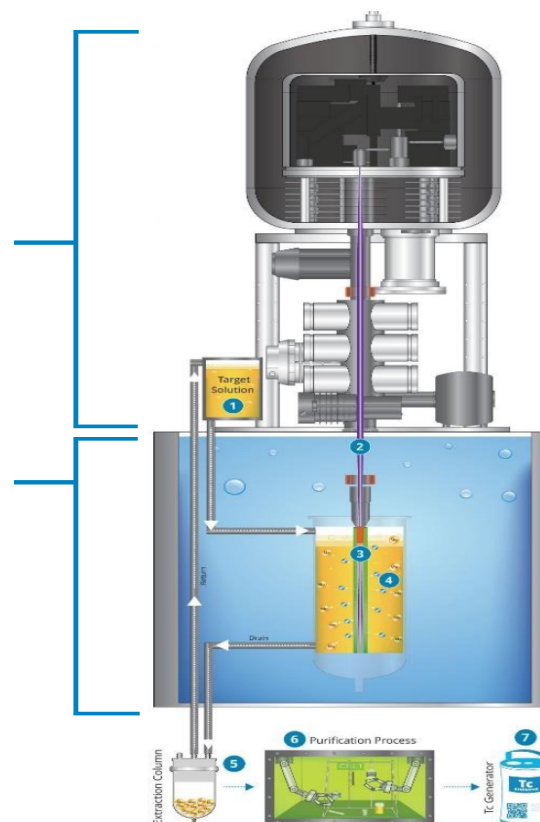
- Target manufacturing
 - Preparation of low enriched uranium (LEU) targets for irradiation
- Target irradiation
 - Nuclear reactors
 - Subcritical operating assemblies
 - Accelerators
- Target processing
 - Hot cell separation of ^{99}Mo from irradiated LEU targets
- Medical uses of byproduct material
 - 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

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



SHINE[®]
Health. Illuminated.

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 is moving toward completion of its weather-tight building in March 2021



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

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>