Office of Nuclear Reactor Regulation

Medical Radioisotope Production

Status of Supply

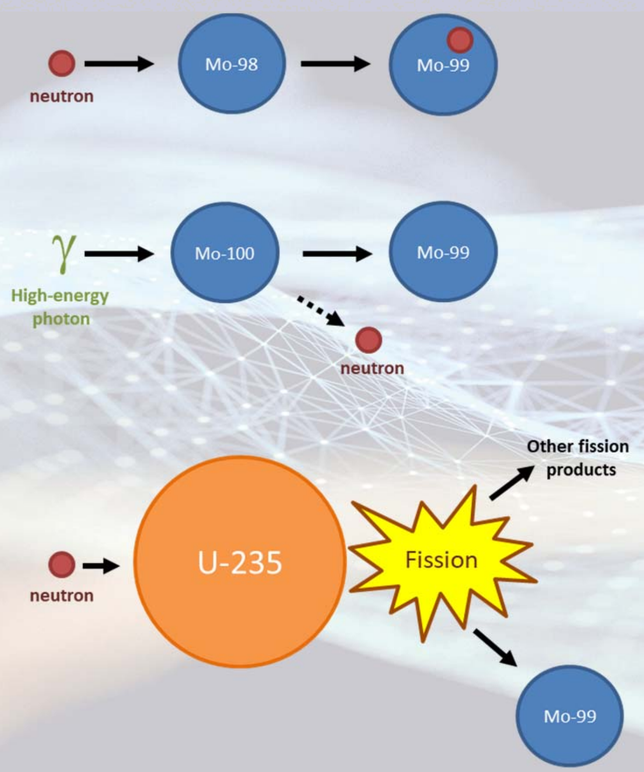
Molybdenum (Mo)-99 and its daughter product, technetium (Tc)-99m, are the most widely used medical radioisotopes in the world. In the United States, 50,000 medical procedures are performed daily. However, there is currently no widely available domestic supply of Mo-99 for use in Tc-99m diagnostic treatments such as cardiac perfusion testing. Additionally, the reliability of global supplies is jeopardized by extended maintenance shutdowns at aging international reactors.

The Ideal Medical Radioisotope

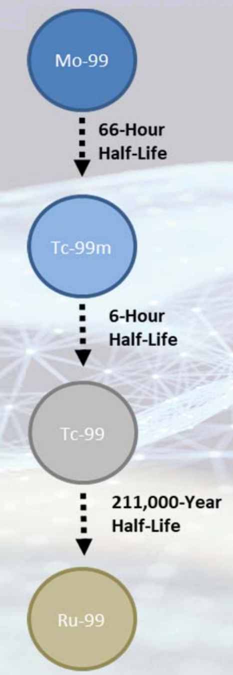
Mo-99 is most commonly produced through the fission of uranium targets in a reactor; however, it may also be produced through neutron capture or photonuclear reactions of enriched Mo-98 or Mo-100 targets, respectively. The properties of Tc-99m are ideal for medical diagnostic treatments:

- The 6-hour half-life is long enough for effective diagnosis but short enough to minimize radiation exposure.
- Gamma emission supports camera detection and imaging.
- Compounds are readily tagged and carried to the organ of interest.

Methods of Mo-99 Production



Mo-99 Decay Scheme



Establishing a Domestic Supply of Mo-99

The Role of the NRC

The NRC's licensing and oversight activities support U.S. national security interests and nuclear nonproliferation policy objectives of establishing a domestically available and reliable supply of Mo-99 without the use of highly enriched uranium.

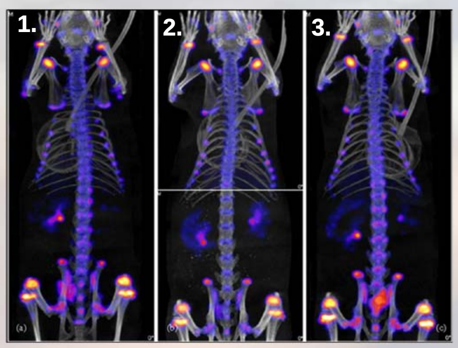
Applications include initial license and license amendment requests for facilities proposing to manufacture, irradiate, and process low-enriched uranium and molybdenum targets.

Many proposed technologies share operating and safety characteristics with non-power reactors and fuel cycle facilities.

A.

B.

C.



Exploring Technology

A. Non-power reactors, like the Oregon State University TRIGA Reactor, may be used to irradiate uranium and molybdenum targets for companies like Northwest Medical Isotopes (NWMI). *Source: OSTR Web page*

B. SHINE Medical Technologies, LLC (SHINE) plans to produce Mo-99 using an accelerator-driven subcritical operating assembly and hot cell facility. *Source: SHINE Web page*

C. NorthStar Medical Radioisotope's (NorthStar) RadioGenix generator is compatible with non-fission-produced Mo-99. For comparison, here are single photon emission tomography images of a rat using the following:

1. fission-produced Tc-99m
2. linac[1]-produced Tc-99m (with buffer)
3. linac-produced Tc-99m (no buffer)

Source: Galea, R., et al. "A Comparison of Rat SPECT Images Obtained Using Tc-99m Derived from Mo-99 Produced by an Electron Accelerator with that from a Reactor."

[1]linac — linear accelerator

Making Progress

Issuing Licenses

The NRC has issued construction permits to SHINE and NWMI, authorizing the construction of facilities for medical radioisotope production.

Beginning Production

In 2018, NorthStar became the first commercial domestic supplier of limited quantities of Mo-99 since 1989.

Breaking Ground

Following the submission of its operating license application, SHINE began construction of its Medical Isotope Production Facility in the fall of 2019.

Ongoing Engagement

Eden Radioisotopes and Atomic Alchemy have also indicated interest in submitting applications for reactor-based production of Mo-99.

Effecting Change

The experience gained from medical radioisotope facility reviews supports a more responsive, and efficient, and technology-inclusive approach to regulating nuclear technologies.

SHINE Construction Site (February 2020)

Mo-99 Generator Cutaway with Kit, Vial, and Shield

SHINE Construction Permit Signing Ceremony
February 29, 2016

The issuance of construction permits to SHINE and NWMI demonstrated the NRC's capability to evaluate technologies beyond light-water and non-power reactors, setting an example for forthcoming advanced reactor reviews.

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