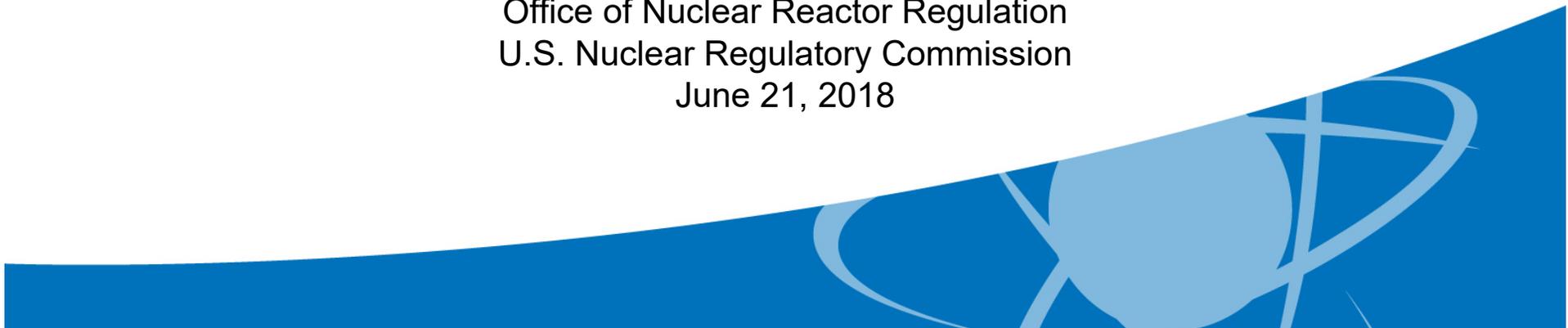


A Week at the U.S. Nuclear Regulatory Commission
Summer 2018

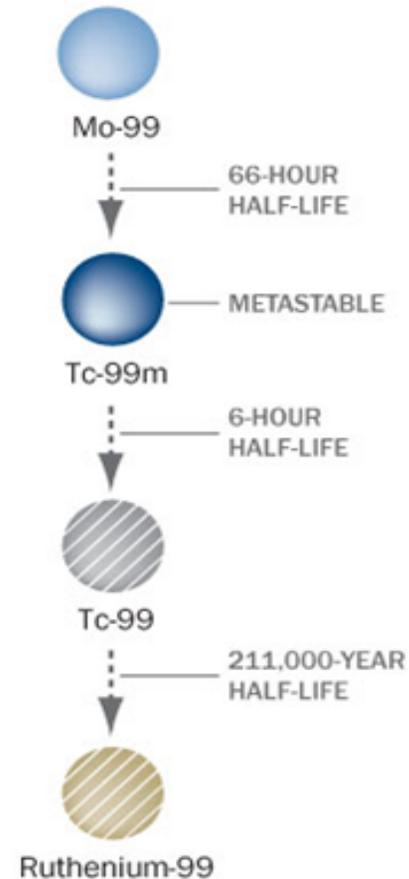
U.S. Nuclear Regulatory Commission Activities Related to Domestic Molybdenum-99 Production

Steven T. Lynch
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
June 21, 2018



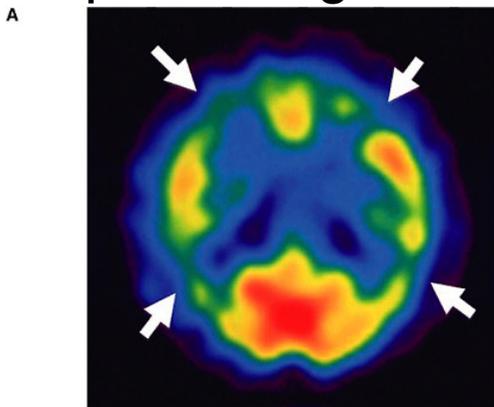
Purpose of ^{99}Mo is to Produce Technetium-99m

- Molybdenum-99 (^{99}Mo) decays radioactively to Technetium-99m ($^{99\text{m}}\text{Tc}$)
- The life of $^{99\text{m}}\text{Tc}$ is long enough for effective diagnosis, but short enough to minimize radiation exposure

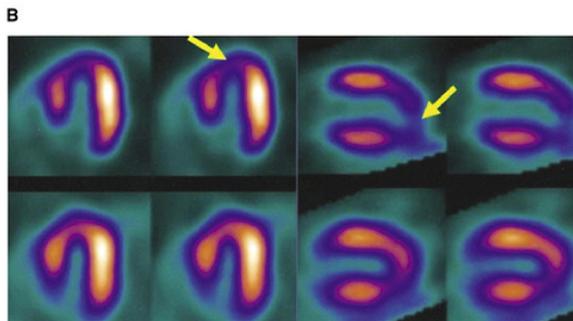


^{99m}Tc Diagnostic Imaging

- In the United States, approximately 50,000 scans performed daily
- Compounds readily tagged with ^{99m}Tc and carried to specific organs under evaluation



^{99m}Tc cerebral blood flow brain scan of a person with Alzheimer's disease

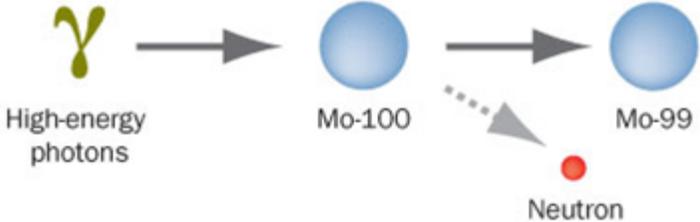


Cardiac perfusion SPECT study at stress and rest using a ^{99m}Tc radiotracer

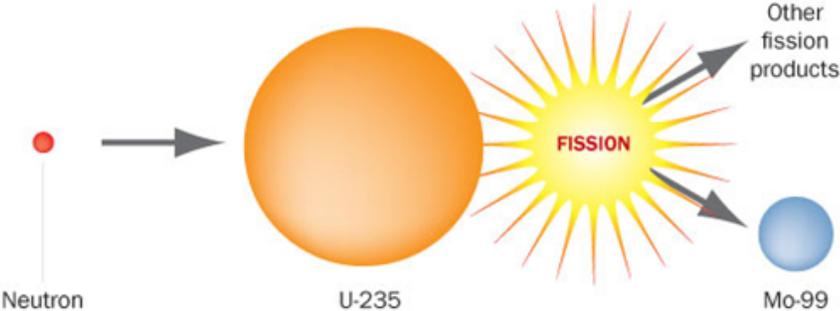
Methods of ⁹⁹Mo Production



Neutron Capture



Transmutation

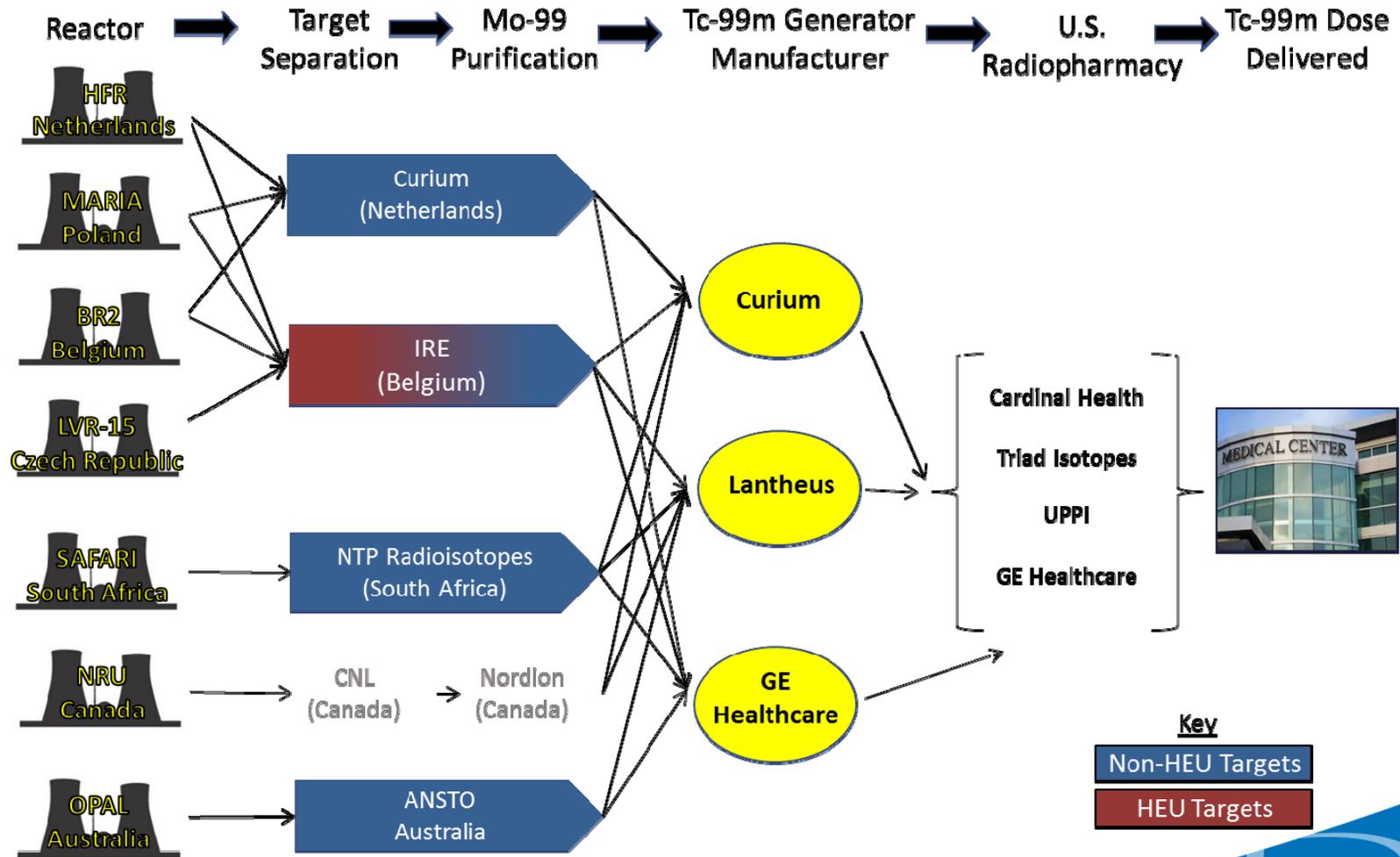


Fission

Status of Domestic ^{99}Mo Supply

- Currently, no domestically-produced supply
- Aging international reactors, dependence on foreign suppliers, and extended repairs jeopardize and disrupt international supply
- The United States ^{99}Mo policy objectives are to 1) ensure a reliable supply of ^{99}Mo , 2) eliminate highly-enriched uranium use in ^{99}Mo production, and 3) eliminate market subsidies
- Domestic production encouraged by cost-sharing cooperative agreements between National Nuclear Security Administration and commercial partners

Current United States ⁹⁹Mo Supply Matrix



Source: National Nuclear Security Administration presentation given at 2018 NRC Regulatory Information Conference

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 ($^{99\text{m}}\text{Tc}$) from ^{99}Mo

Similarities to Non-power Reactors

- Safety considerations comparable 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

Medical Radioisotope Licensing Reviews

- Construction permit and operating license applications
 - Northwest Medical Isotopes (NWMI)
 - SHINE Medical Technologies (SHINE)
- License amendment requests anticipated from Oregon State University (OSU) and University of Missouri Research Reactor Center (MURR) in support of NWMI project
- Materials license, and subsequent amendments, issued to Niowave
- Licensing guidance issued for NorthStar RadioGenix generator system

Northwest Medical Isotopes

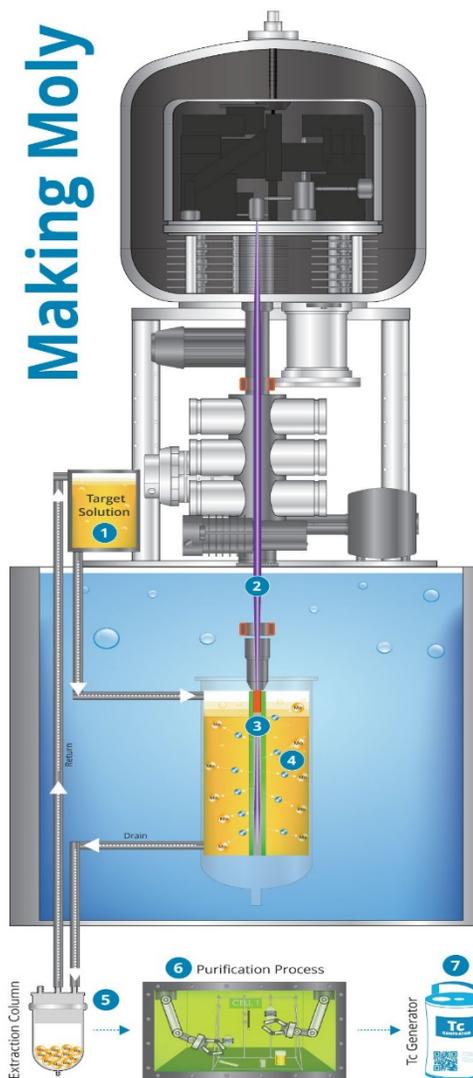
- NWMI proposes to manufacture and process low enriched uranium (LEU) targets for ^{99}Mo production
- Target manufacturing to be licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70
 - LEU targets irradiated at existing research reactors, including OSU and MURR
 - Irradiated targets returned to NWMI for processing in a 10 CFR Part 50 *production facility*
- Construction permit issued in May 2018
- Proposed site: Columbia, Missouri



Oregon State University TRIGA Reactor
Source: OSTR Webpage

SHINE Medical Technologies

- SHINE proposes to fission LEU target solution in 8 irradiation units licensed as 10 CFR Part 50 *utilization facilities*
- SHINE proposes to recover ^{99}Mo by processing irradiated target solution in hot cells licensed as a 10 CFR Part 50 *production facility*
- Construction permit issued in February 2016
- Pre-construction and pre-application meetings scheduled in April and May 2018
 - Construction expected to begin in 2018
 - Operating license application expected in 2018
- Proposed site: Janesville, Wisconsin



SHINE ^{99}Mo Production Process
Source: SHINE Webpage

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 has issued amendments increasing LEU possession limit and supporting irradiation of natural uranium targets
- NorthStar Medical Radioisotopes
 - Proposes to produce ^{99}Mo from enriched molybdenum target irradiation
 - Developed RadioGenix $^{99\text{m}}\text{Tc}$ generator system compatible with lower specific activity ^{99}Mo
 - NRC staff published licensing guidance for medical use applicants and licensees that possess RadioGenix system in February 2018
 - NRC staff currently considering updated information on generator system and potential changes to licensing guidance

Developing Technology-Inclusive Framework

- Considering technologies beyond light water and non-power reactors
- 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
- Coordinating technical and licensing expertise through inter-office working group
- Supporting advanced reactor pre-application meetings
- Providing updates on public website:
 - <http://www.nrc.gov/reactors/medical-radioisotopes.html>