

2014 National Organization of Test, Research, and Training Reactors Conference

Licensing Medical Radioisotope Production Facilities

Steven Lynch
U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation
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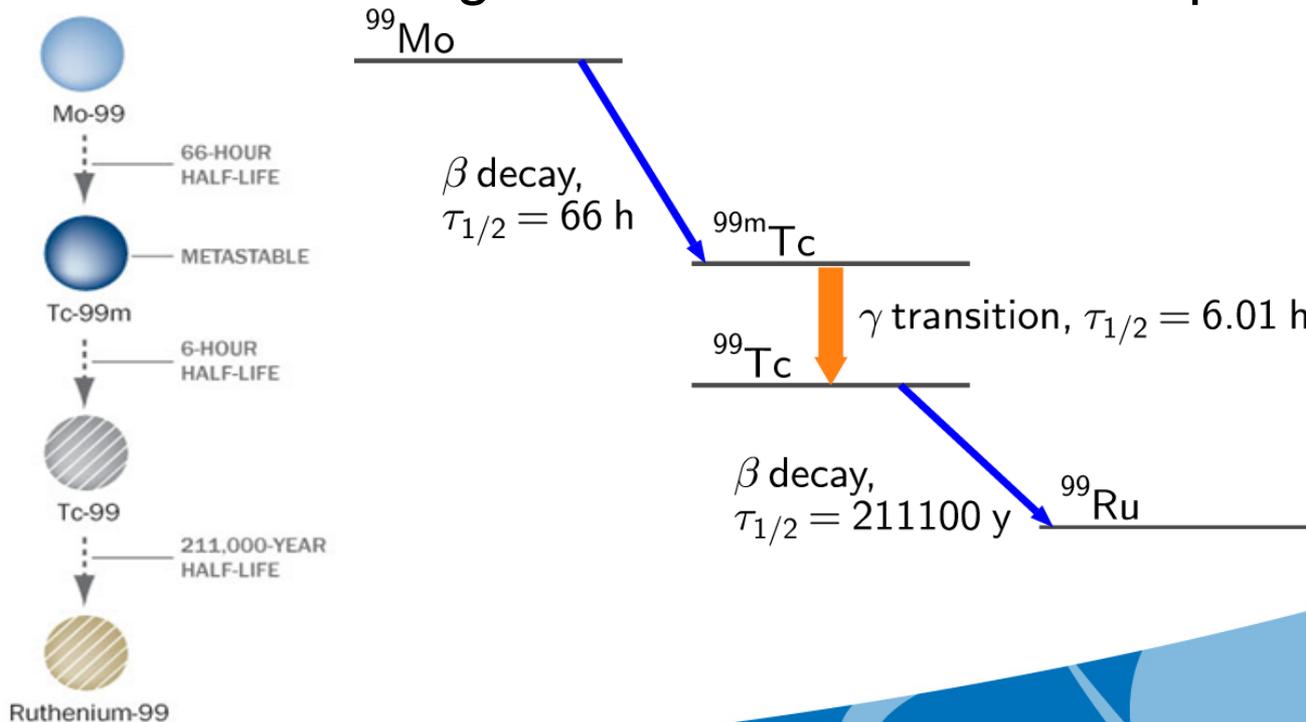


Today's Presentation will Cover...

- Background on molybdenum-99 (^{99}Mo) production
- Role of U.S. Nuclear Regulatory Commission (NRC)
- Proposed technologies for isotope production
- NRC initial licensing process
- Status of NRC review of applications

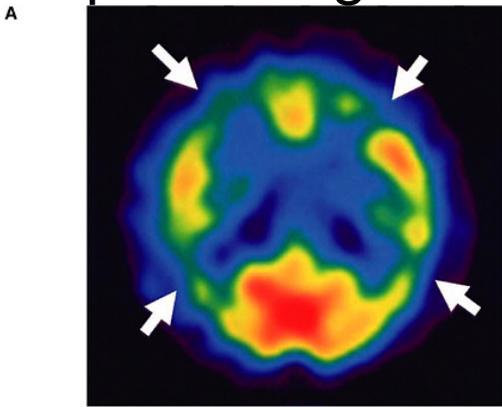
Purpose of ^{99}Mo is to Produce Technetium-99m

- Mo-99 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

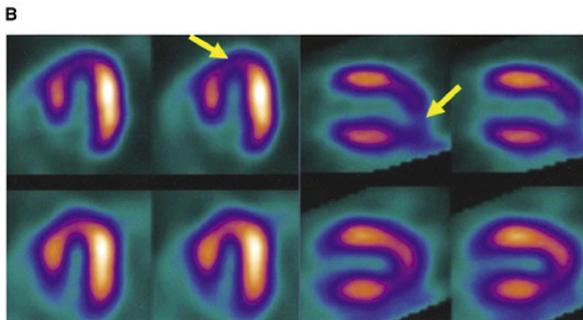


^{99m}Tc Diagnostic Imaging

- In the U.S., 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

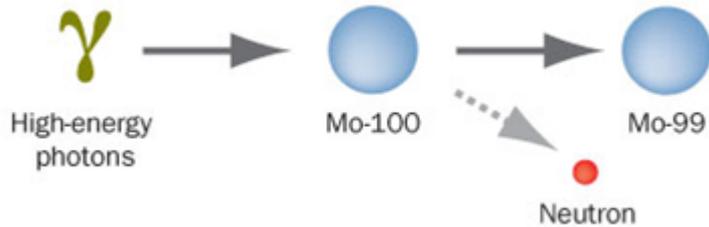


Cardiac perfusion SPECT study at stress and rest using a ^{99m}Tc radiotracer

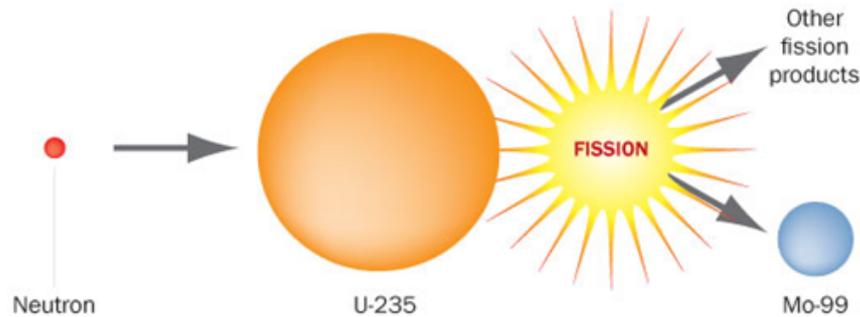
Methods of ^{99}Mo Production



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 jeopardizes and disrupts international supply
- Domestic production encouraged by cost-sharing cooperative agreements between NNSA and commercial partners

Supporting Domestic ^{99}Mo Production

- NRC is prepared to conduct reviews on all applications submitted in accordance with the provisions of Title 10 of the *Code of Federal Regulations*
- NRC is coordinating environmental review work with the Department of Energy (DOE), in accordance with American Medical Isotopes Production Act

Interest in ^{99}Mo Production

- Letters of Intent
 - Babcock and Wilcox
 - General Electric Hitachi
 - Technical Services Group
 - Northwest Medical Isotopes
 - Coquí Radiopharmaceuticals
 - Precision Engineering
 - Eden Radioisotopes
 - University of Missouri-Columbia
 - Flibe Energy
 - Zevacor Molecular
- Amendment Request
 - Oregon State University
- Construction Permit Application
 - SHINE Medical Technologies, Inc.

Production Techniques

- Majority of proposals involve low enriched uranium fission
 - Reactor and non-reactor technologies
 - Solid clad and aqueous solution targets
 - New and existing facilities
 - Hot cells for separation of fission products
- NRC may also license some accelerator-based technologies involving natural molybdenum if not under Agreement State jurisdiction

Similarities to Non-power Reactors

- Thermal power levels comparable non-power reactors typically licensed under 10 CFR Part 50
- Consequently, the safety considerations are similar with regard to:
 - Fission heat removal
 - Decay heat generation
 - Reactivity feedback mechanisms
 - Fission gas release
 - Radiolytic decomposition of water
 - Fission product buildup
 - Accident scenarios

Licensing Approach

- Anticipate licensing most facilities under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”
- May license certain facilities under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material” or 10 CFR Part 30, “...Domestic Licensing of Byproduct Material”

Pre-application Preparation

- Outreach and communication
 - Regulatory Issue Summaries
 - Public meetings
- Establishment of inter-office ⁹⁹Mo working group
- Development of licensing guidance for applicants and NRC reviewers
- Identification of applicable regulations

Inter-Office Working Group

- Representatives from across the agency, including:
 - Office of Nuclear Reactor Regulation
 - Office Nuclear Material Safety and Safeguards
 - Office of Federal and State Materials and Environmental Management Programs
 - Office of Nuclear Regulatory Research
 - Office of Nuclear Security and Incident Response
 - Office of New Reactors
 - Regions II and III

Licensing Guidance

- NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors”
 - Part 1, Format and Content
 - Part 2, Standard Review Plan
- NUREG-1520, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility, Rev. 1”

Licensing Guidance

- Interim Staff Guidance Augmenting NUREG-1537
 - Published October 2012
 - Radioisotope production facilities
 - Aqueous homogeneous reactors
 - Incorporates relevant non-reactor guidance

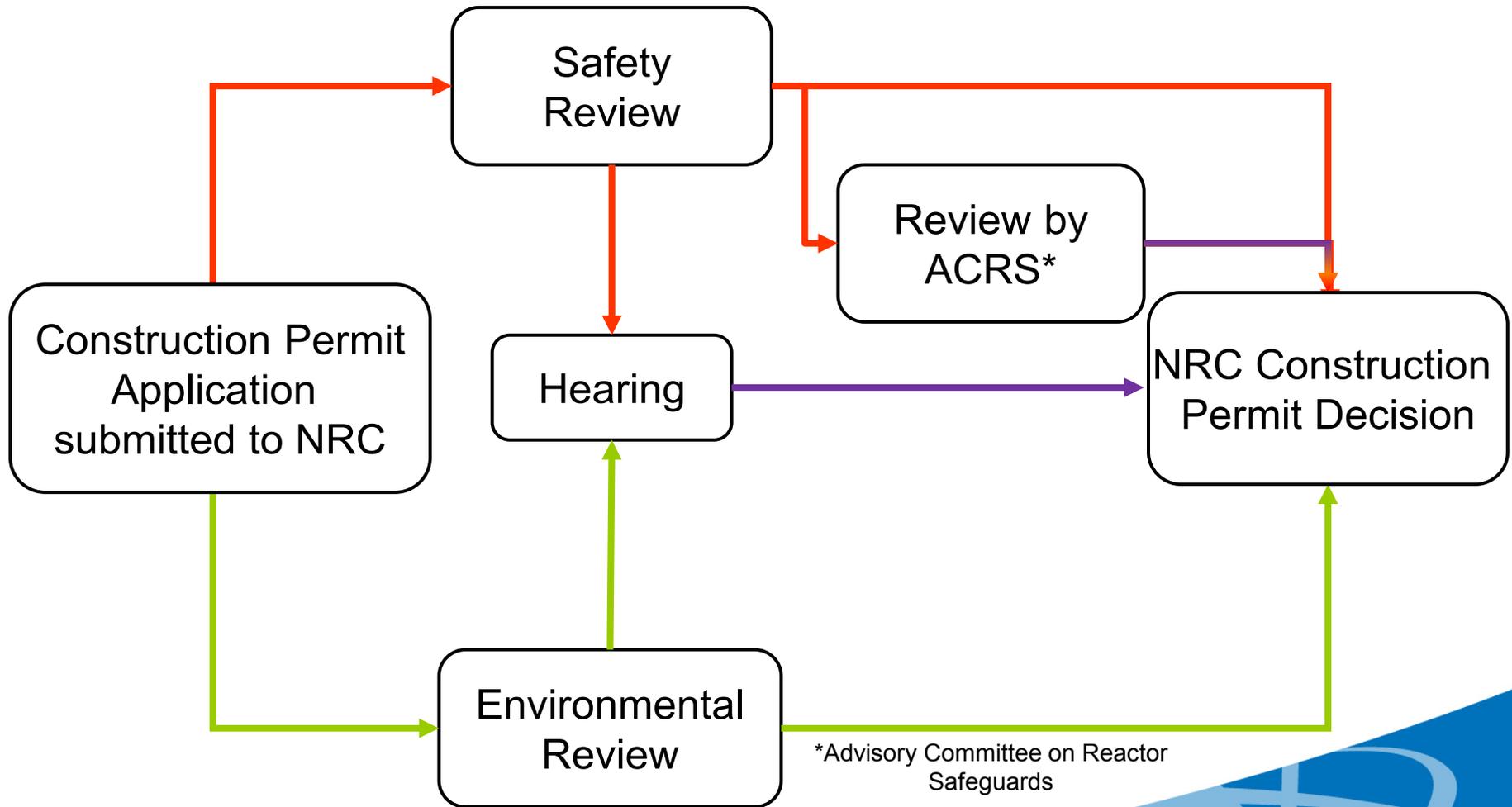
Applicable Regulations

- Other relevant regulations:
 - Part 20, “...Protection Against Radiation”
 - Part 30, “...Licensing of Byproduct Material”
 - Part 51, “Environmental Protection Regulations for Domestic Licensing...”
 - Part 55, “Operators’ Licenses”
 - Part 73, “Physical Protection of Plants and Materials”

Applications for Construction and Operation

- Construction permit application
 - Environmental report
 - Preliminary safety analysis report
- Operating license application
 - Final Safety Analysis Report, including: plans for operation, emergencies, and technical specifications
 - Update to Environmental Report, as necessary
 - Physical Security Plan
- 18 – 24-month review of each application

Construction Permit Application Review



Docketing of Application

- Acceptance/sufficiency review
 - Summary description of the facility
 - Preliminary design of the facility
 - Preliminary analysis and evaluation of design
 - Environmental Report
- Decision to docket

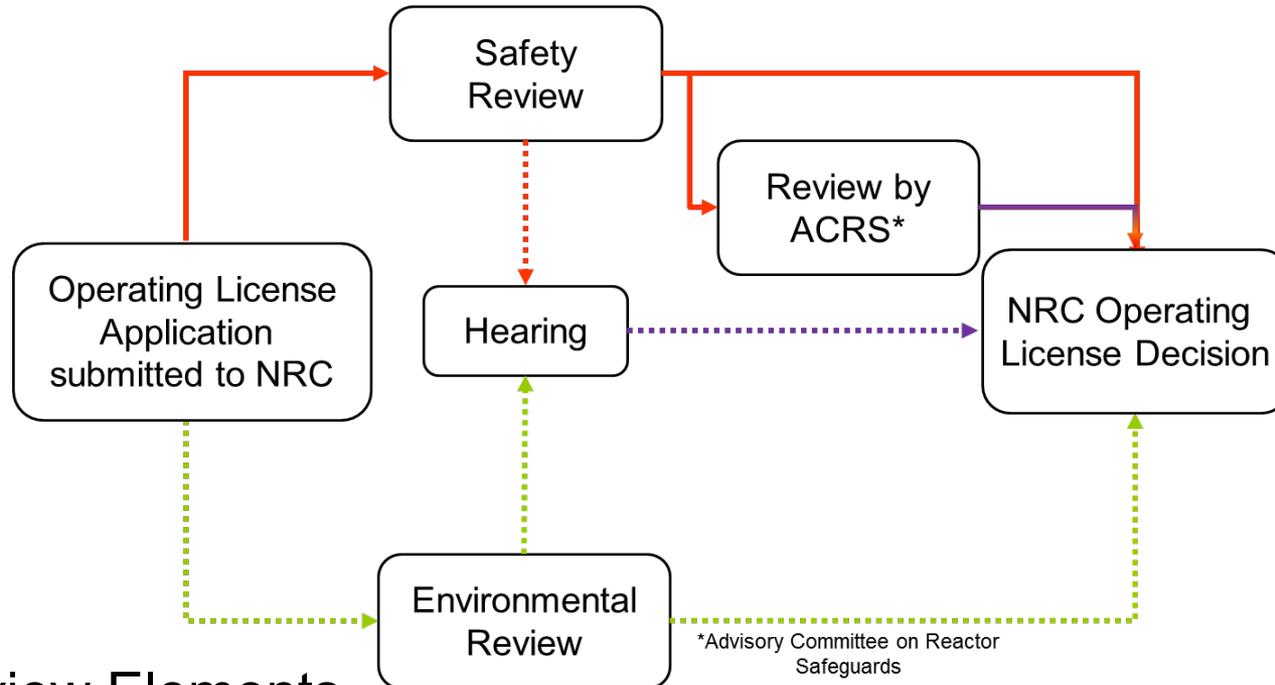
Safety Review

- NRC staff review of the application
- Request(s) for additional information, as needed
- Safety Evaluation Report
- Advisory Committee on Reactor Safeguards
- Hearing
- Decision to grant or deny construction permit

Environmental Review

- National Environmental Policy Act
 - NRC Environmental regulations (10 CFR Part 51)
- Environmental scoping meeting
- Site audit
- Draft Environmental Impact Statement
- Environmental Impact Statement
- Review coordination with DOE, as necessary

Operating License Application Review



- Review Elements

- Safety Evaluation Report
- No hearing, unless petition granted
- Advisory Committee on Reactor Safeguards
- Decision to grant or deny license

Current Licensing Activities

- Received two-part SHINE construction permit application
 - Environmental Report (March 26, 2013)
 - Preliminary Safety Analysis Report (May 31, 2013)
- Application fully docketed December 2, 2013
- Proposes to produce ^{99}Mo from uranium fission
 - Irradiation Facility
 - Radioisotope Production Facility
- Proposes to construct facility in Janesville, WI

Current Licensing Activities

- Received license amendment application from Oregon State University (April 2012)
- Application proposes to irradiate targets at Oregon State University TRIGA® reactor to demonstrate Mo-99 production in small reactors
- Applicant has been issued requests for additional information in support of the staff's review of the application

Looking Forward

- Actively reviewing SHINE construction permit application and Oregon State University amendment application
- Anticipate receiving 1 - 2 additional applications within the next year
 - Prepared to review additional applications
 - Encourage early and frequent communication with other potential producers

Questions?