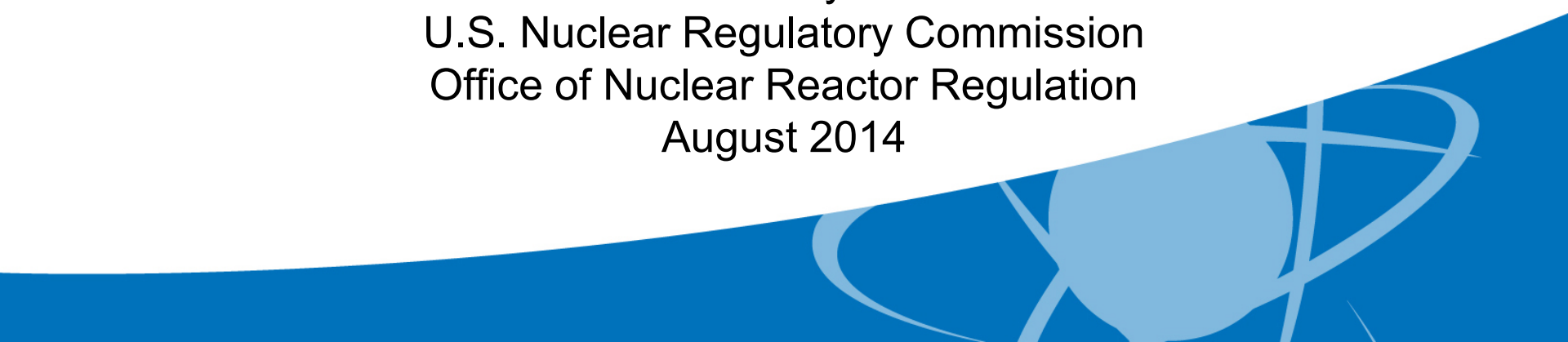


2014 National Organization of Test, Research, and Training Reactors Conference

Licensing Medical Radioisotope Production Facilities

Steven Lynch
U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation
August 2014

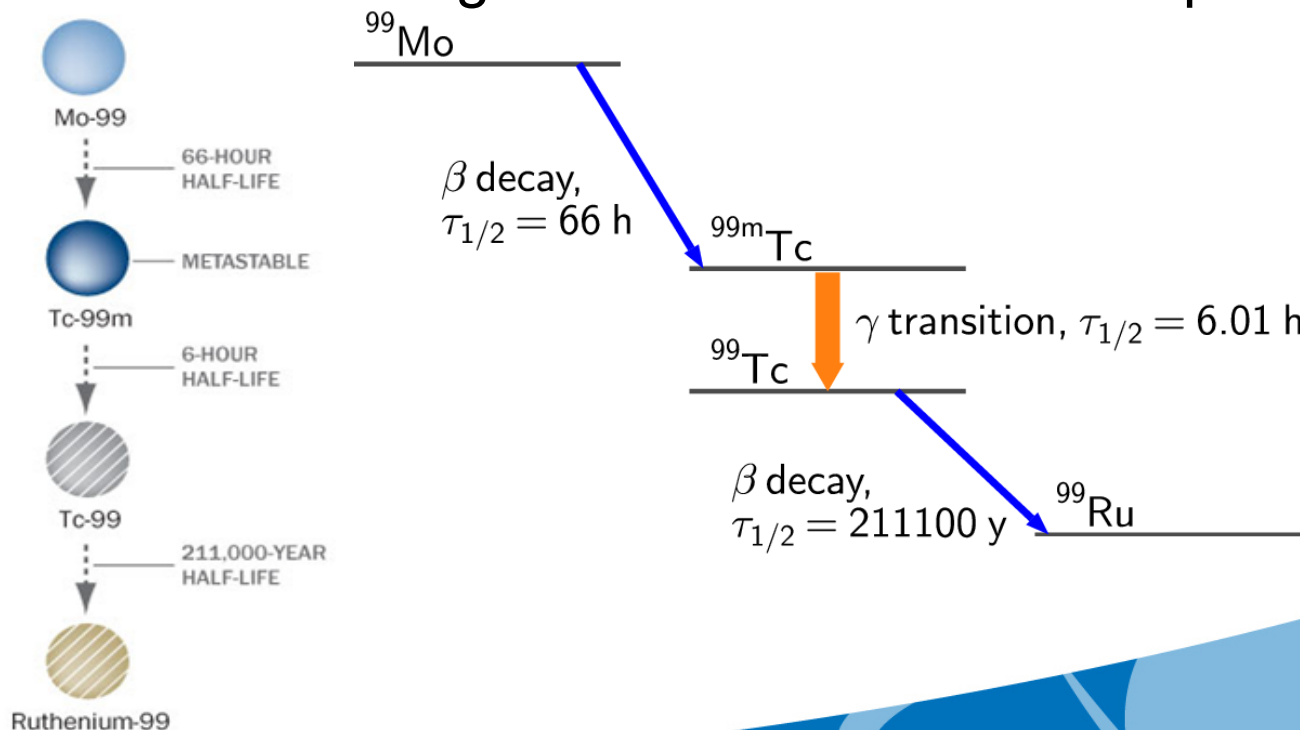


Today's Presentation will Cover...

- 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

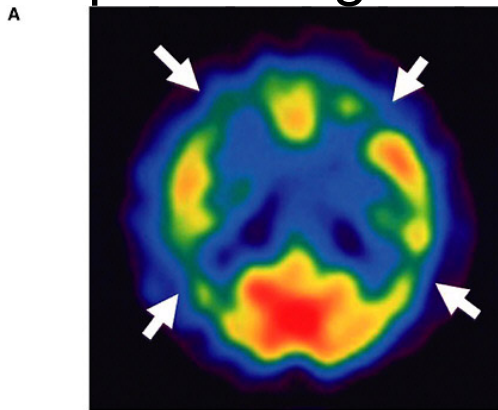
Purpose of ^{99}Mo is to Produce Technetium-99m

- 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

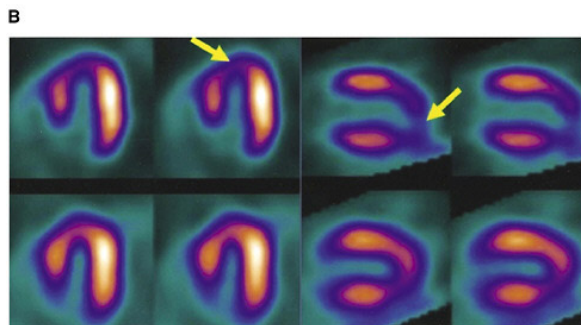


^{99m}Tc Diagnostic Imaging

- 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

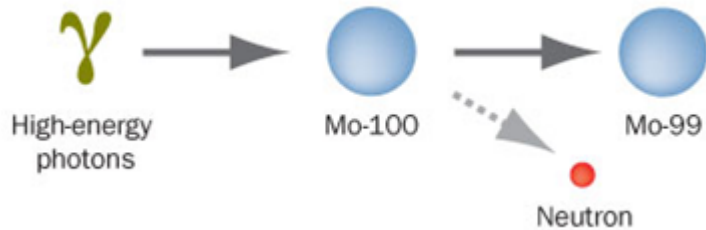


Cardiac perfusion SPECT study at stress and rest using a ^{99m}Tc radiotracer

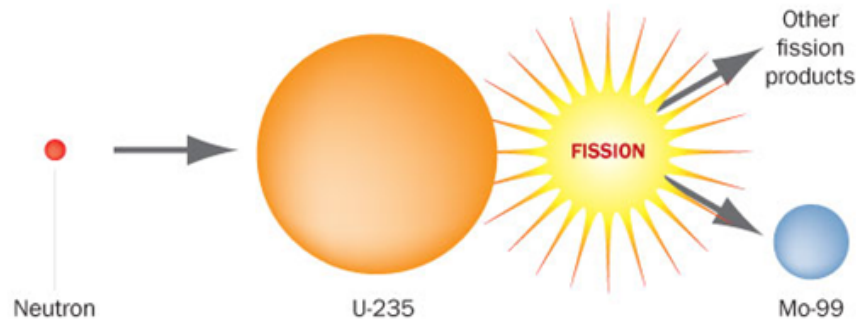
Methods of ^{99}Mo Production



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

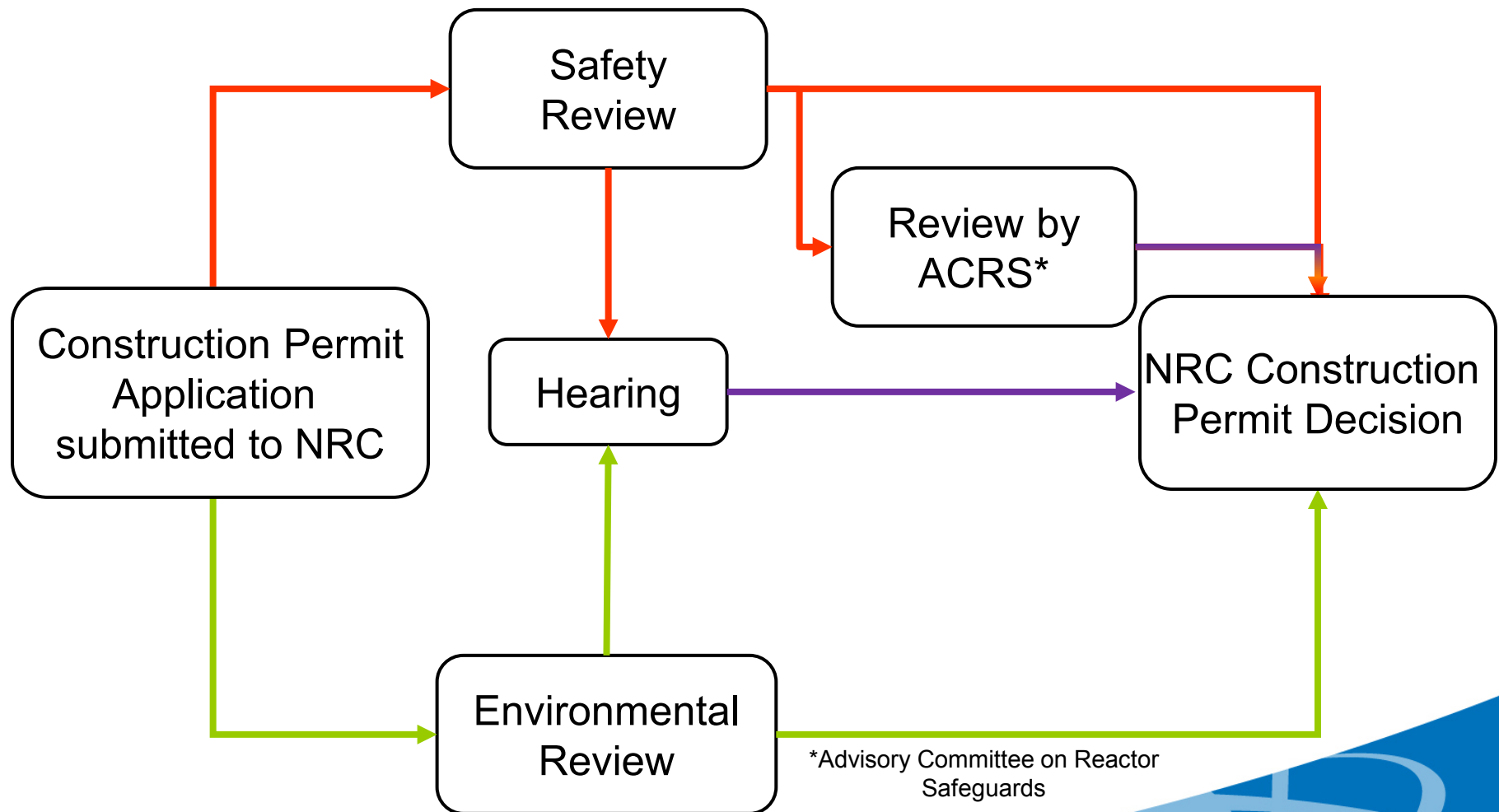
Applicable Regulations

- 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

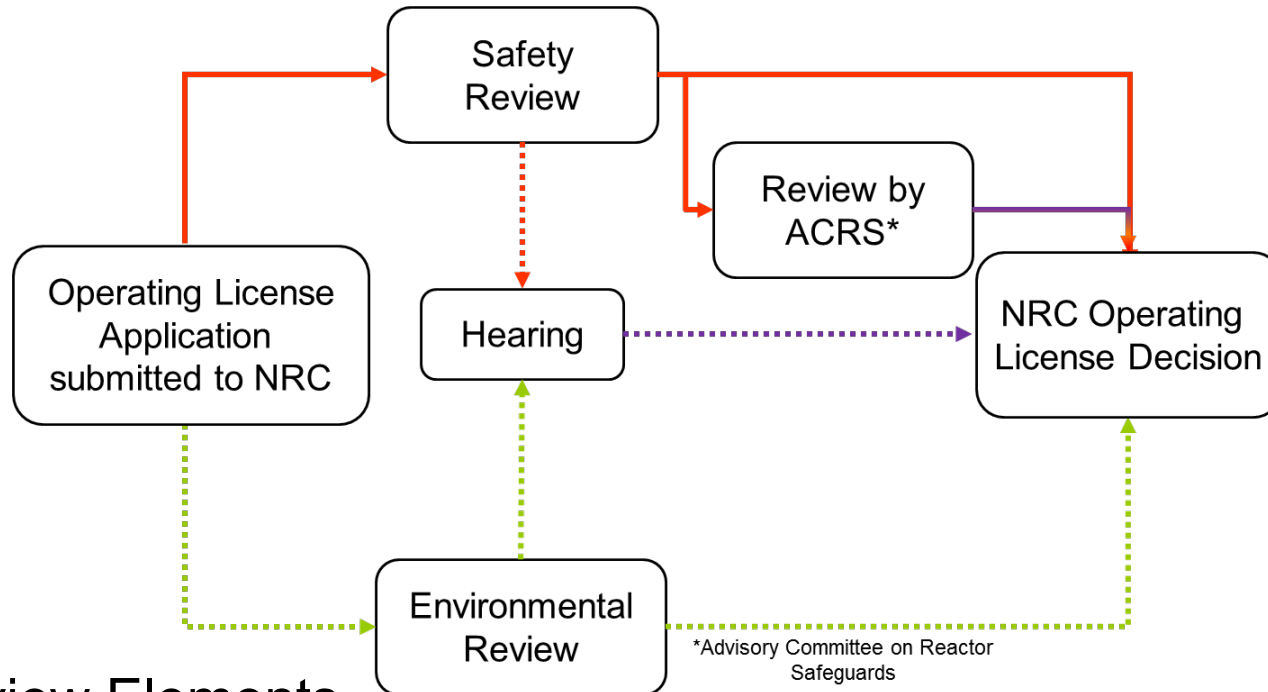
Safety Review

- 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
- Advisory Committee on Reactor Safeguards
- No hearing, unless petition granted
- 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?