U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

American Pharmacists Association
2016 Annual Meeting & Exposition

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

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March 2016

Learning Objectives

- Role of U.S. Nuclear Regulatory Commission (NRC)
- NRC initial licensing process
- Status of reviews
- Ongoing infrastructure and support activities

Which of the following is a necessary part of a construction permit?

A. Quality assurance program

B. Security plan

C. Technical specifications

D. Emergency plan

Which of the following is not part of the NRC's construction permit application review?

A. Independent review by the Advisory Committee on Reactor Safeguards

B. Site vulnerability assessment

C. Parallel safety and environmental reviews

D. Mandatory hearing

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* (10 CFR)
- NRC is coordinating environmental review work with the Department of Energy (DOE), in accordance with American Medical Isotopes Production Act
- NRC is supporting the Department of Homeland Security's (DHS) site vulnerability assessments for utilization facilities, in accordance with the provisions of Section 657 of the Energy Policy Act of 2005

Current and Anticipated Licensing Reviews

- Construction permit applications
  - SHINE Medical Technologies (SHINE), issued
  - Northwest Medical Isotopes (NWMI), under review
  - Coqui Radiopharmaceuticals (Coqui), anticipated
- License amendment issued to Oregon State University (OSU)
- License amendment request from University of Missouri Research Reactor Center (MURR) in support of General Atomics
- Additional license amendment requests anticipated from OSU and MURR in support of NWMI project
- Materials license issued to Niowave

Licensing Considerations

- Licensing determinations are facility- and technology-specific and made on a case-by-case basis
- Selection of licensing process for a facility based on:
  - Type and quantities of material on site (e.g., low enriched uranium or natural molybdenum targets)
  - Type(s) of activities performed at facility (e.g., target manufacturing, irradiation, and/or processing)
  - Method of irradiation (e.g., nuclear reactor, accelerator)
  - Method of target processing, including batch size
  - New or existing facility

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 targets if not under Agreement State jurisdiction

Licensing Requirements

- Anticipate licensing most facilities under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”
  - Target irradiation performed by *utilization facilities*
  - Fission product separation in *production 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”

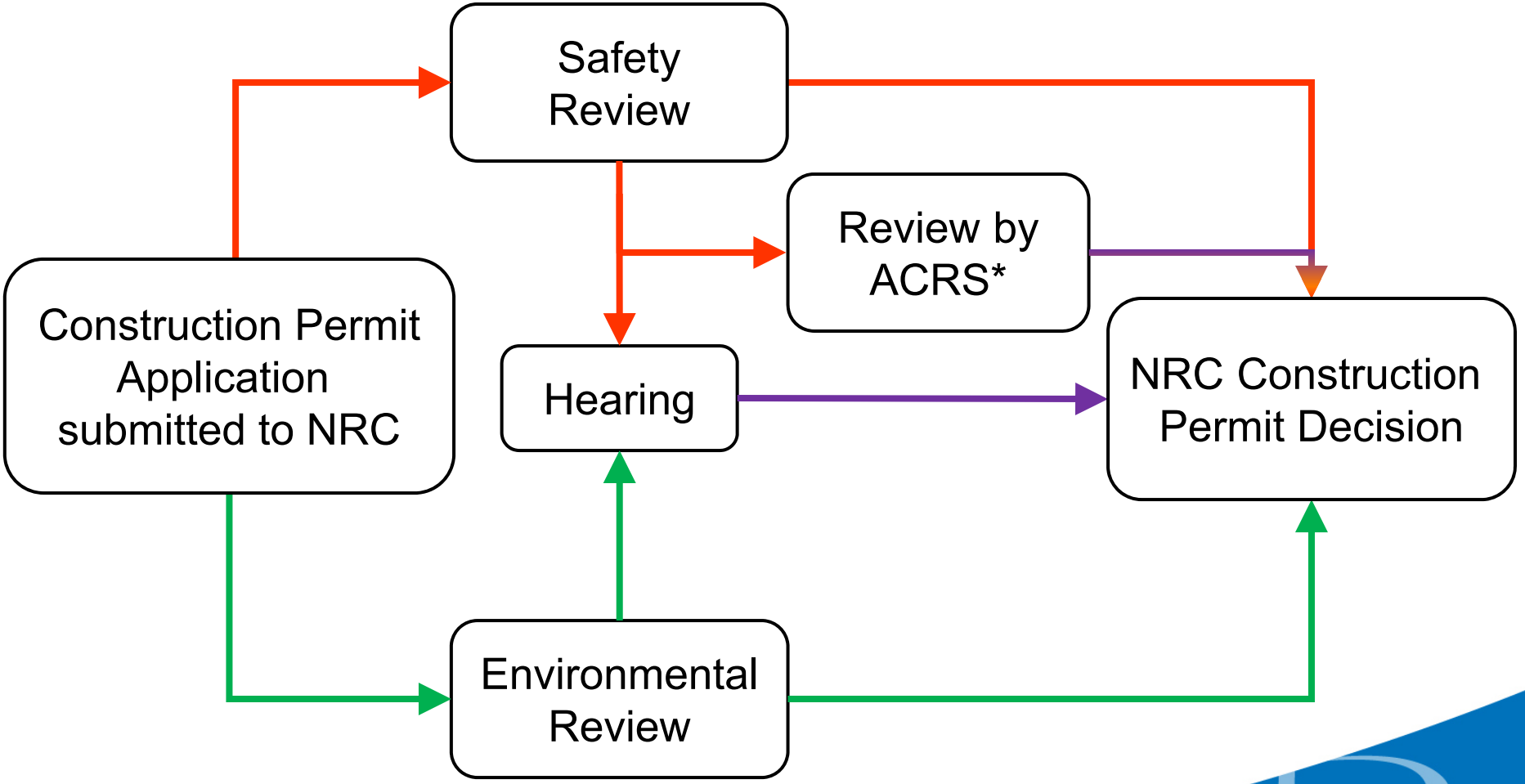
Initiating the Licensing Process

- Letters of intent
  - Indicate applicant's level of interest
  - Provide anticipated application submission schedule
  - Introduce proposed technology
- Public Meetings
  - Promote engagement between NRC and applicants
  - Support the development of high-quality applications
  - Allow for appropriate budgeting and resource allocation
  - Keep public informed of NRC licensing actions

Applications for Construction and Operation

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

Construction Permit Application Review



*Advisory Committee on Reactor Safeguards

Construction Permit Safety Review

- Acceptance review of PSAR
- Docketing of application
- Development of safety evaluation report
- Request(s) for additional information, as needed
- Advisory Committee on Reactor Safeguards
- Potential contested hearing
- Mandatory hearing (adequacy of staff safety and environmental review)
- Decision to grant or deny construction permit

Construction Permit Environmental Review

- National Environmental Policy Act
  - NRC environmental regulations (10 CFR Part 51)
- Environmental scoping meeting
- Site audit
- Draft Environmental Impact Statement (or environmental assessment)
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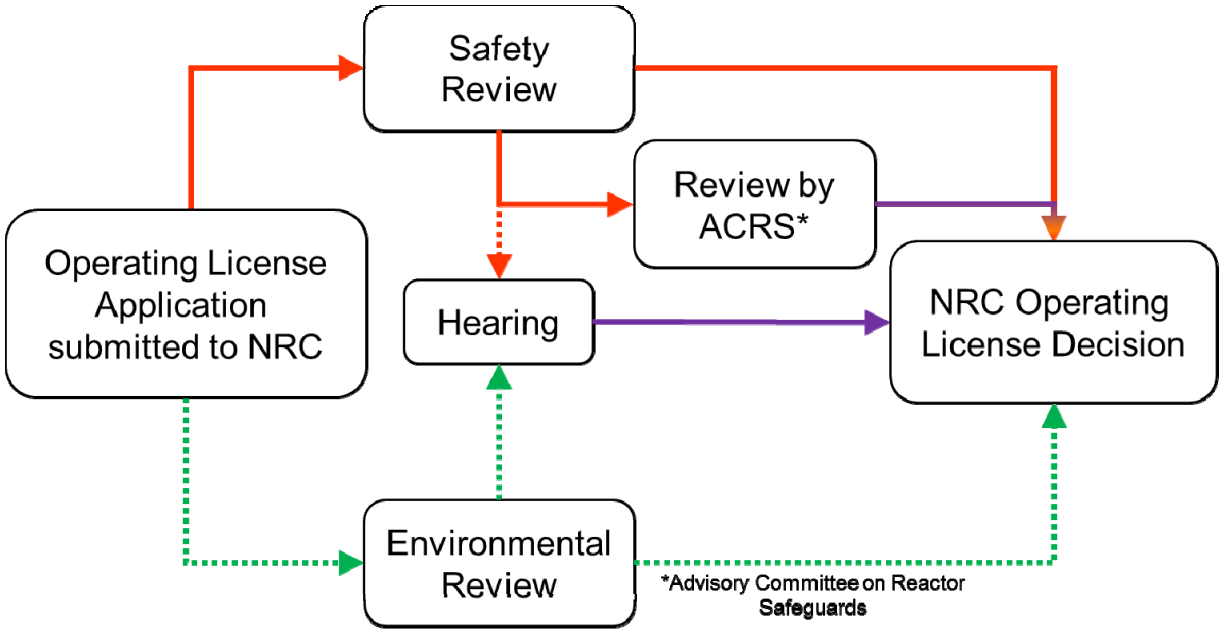
Operating License Application Review



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

SHINE Medical Technologies

- NRC received two-part construction permit application
  - Environmental Report (March 26, 2013)
  - Preliminary Safety Analysis Report (May 31, 2013)
- SHINE proposes to produce ^{99}Mo from fission of low enriched uranium target solution in Irradiation Facility consisting of 8 irradiation units
- ^{99}Mo recovered through irradiated target solution processing in Radioisotope Production Facility consisting of 3 hot cells
- Proposed site: Janesville, WI

SHINE Licensing Approach

- SHINE facility licensed under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities"
  - Irradiation units licensed as *utilization facilities*
  - Hot cells licensed as *production facility*
- Special nuclear material will be licensed under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"

Status of SHINE Review

- Issued requests for additional information (September 2014, with follow-up requests in January, March, April, and September 2015)
- Issued direct final rule modifying definition of *utilization facility* to include SHINE irradiation units (issued October 2014, effective December 2014)
- Published draft environmental impact statement (May 2015)
- Meetings with ACRS (June, August, September, and October 2015)
- Final environmental impact statement and safety evaluation report completed (October 2015)
- Mandatory hearing on application (December 2015)
- Construction permit issued (February 2016)

Northwest Medical Isotopes

- NRC received two-part construction permit application
  - Environmental Report (February 2015)
  - Preliminary Safety Analysis Report (July 2015)
- NWMI proposes to manufacture low enriched uranium targets for irradiation at existing research reactors
  - University of Missouri – Columbia (MURR)
  - Oregon State University (OSU)
- ^{99}Mo recovered through processing of irradiated targets
- Proposed site: Columbia, MO

Status of NWMI Review

- Part one of application accepted for docketing (May 2015)
- Environmental site audit (September 2015)
- Issued request for additional information (November 2015)
- Environmental scoping meeting (December 2015)
- Part two of application accepted (December 2015)
- Application supported by license amendments for existing research reactors
  - Prototypical target irradiation (OSU)
  - Commercial target irradiation (OSU, MURR)

License Amendments and Materials Licenses

- License amendment issued to OSU
  - Demonstration of ^{99}Mo production in small nuclear reactor with experimental uranium targets
- Materials license issued to Niowave
  - Production of small amounts of ^{99}Mo through uranium fission using superconducting linacs for proof of concept
- Anticipated licensing request from MURR
  - General Atomics gaseous extraction technology to be used following uranium target irradiation

Ongoing Infrastructure and Support Activities

- Developing construction and operation inspection programs
- Continuing analysis of applicability of regulations and guidance
- Maintaining and expanding technical and licensing expertise through inter-office working group
- Maintaining communication with stakeholders
  - Federal government (Office of Science and Technology Policy, National Nuclear Security Administration, DHS)
  - State and local governments
  - Public

Key Points

- Issued a construction permit application to SHINE
- Actively reviewing the Northwest Medical Isotopes construction permit applications
- Anticipate receiving additional applications within the next year
  - Prepared to review additional applications
  - Encourage early and frequent communication with other potential producers

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Questions?