

National Organization of Test, Research, and
Training Reactors

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

Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
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Today's Presentation will Cover...

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

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 (two received, one anticipated)
 - SHINE Medical Technologies (SHINE)
 - Northwest Medical Isotopes (NWMI)
- License amendment request from Oregon State University (OSU)
- Materials license request from Niowave
- Anticipated license amendment request from University of Missouri Research Reactor Center (MURR) in support of General Atomics
- Anticipated license application from Coqui RadioPharmaceuticals

Licensing Considerations

- Licensing determinations are facility- and technology-specific and made on a case-by-case basis
- Selection of appropriate licensing process(es) for a facility are based on the following considerations:
 - 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

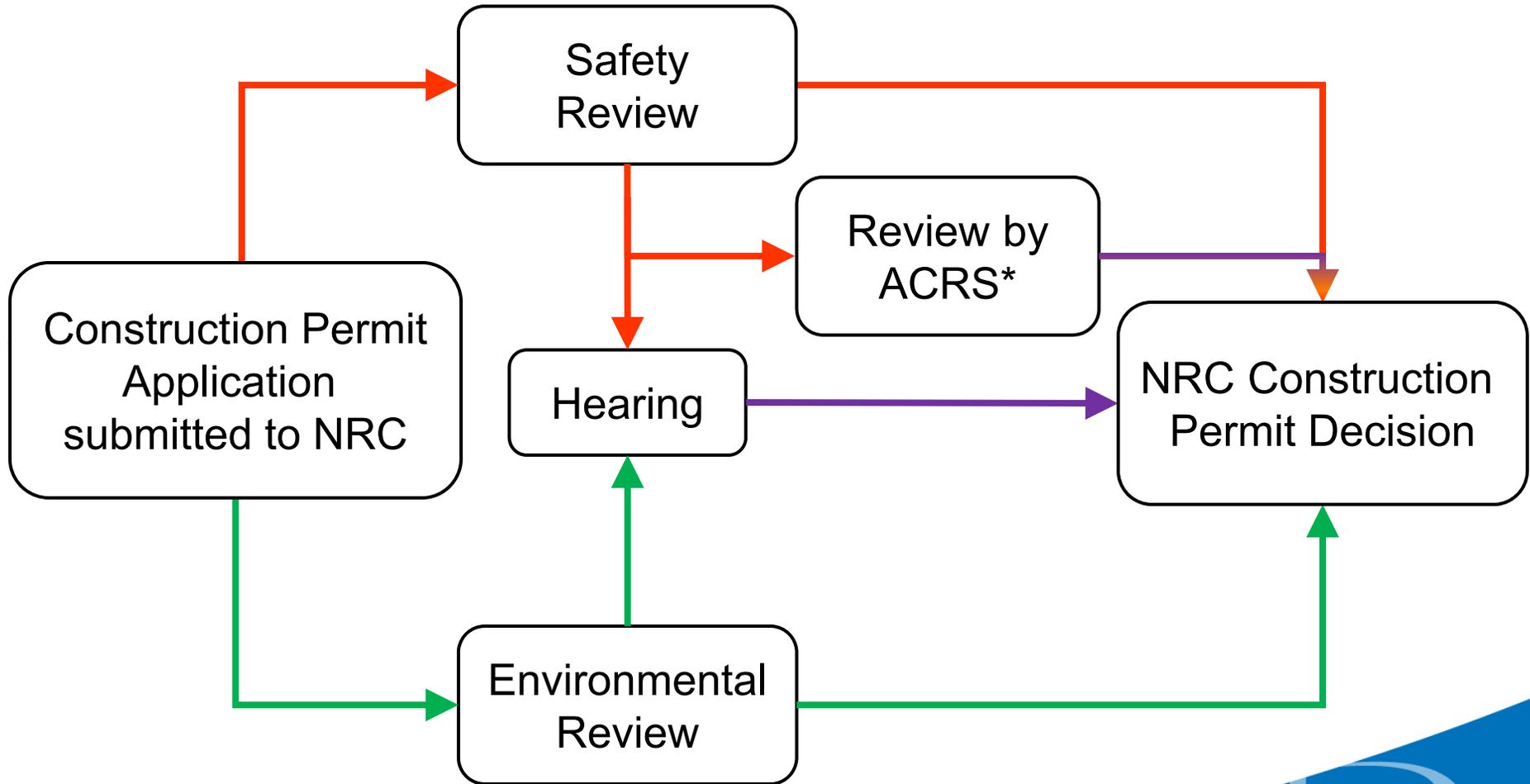
Licensing Requirements

- 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”

Applications for Construction and Operation

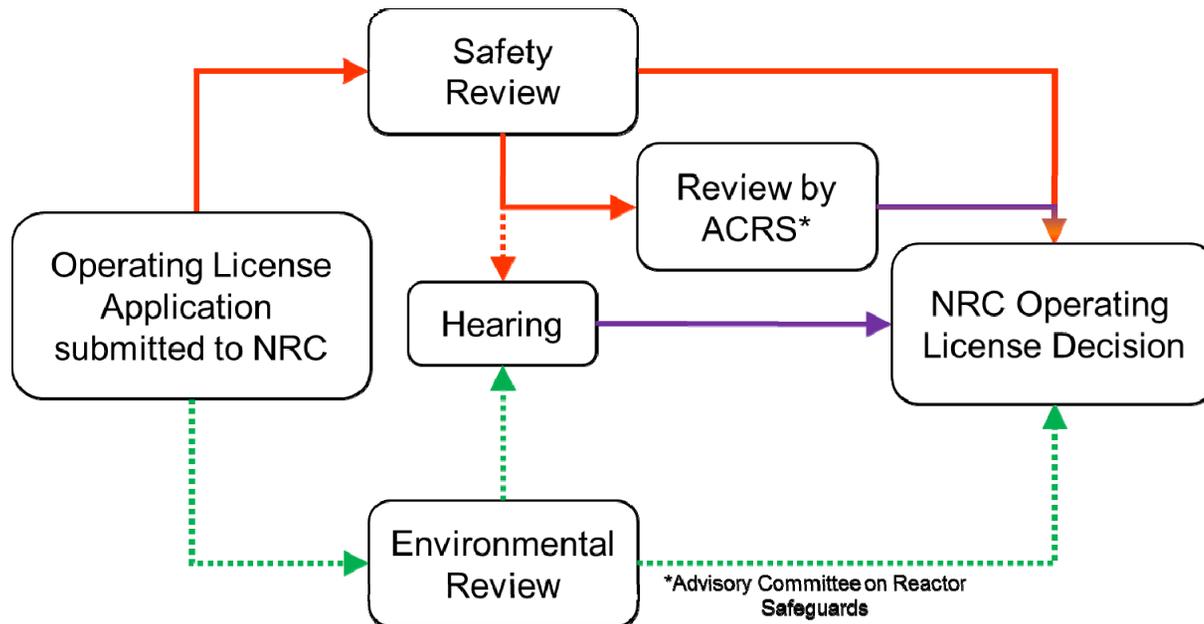
- Construction permit application
 - Environmental Report
 - Preliminary Safety Analysis Report
- Operating license application
 - Final Safety Analysis Report, including: plans for operation, emergencies, and technical specifications
 - Update to Environmental Report, as necessary
 - Physical Security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

Construction Permit Application Review



*Advisory Committee on Reactor Safeguards

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

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 in June, August, September and October 2015
- Final environmental impact statement and safety evaluation report scheduled for completion in October 2015
- Mandatory hearing on application scheduled for December 15, 2015
- Construction permit determination (winter 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

- NRC accepted part one of application for docketing (May 2015)
 - Currently determining whether to perform an environmental impact statement or environmental assessment
- Conducting acceptance review of part two of application
 - Appropriate licensing approach will be determined following acceptance
- Environmental site audit held September 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 request from OSU
 - Demonstration of ^{99}Mo production in small nuclear reactor with experimental uranium targets
 - Safety evaluation report under development
- Materials license issued to Niowave
 - Production of small amounts of ^{99}Mo through uranium fission using superconducting linacs for proof of concept
- Anticipated license amendment from MURR
 - General Atomics gaseous extraction technology to be used following uranium target irradiation
 - Public meeting held on April 27, 2015

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

Questions?

