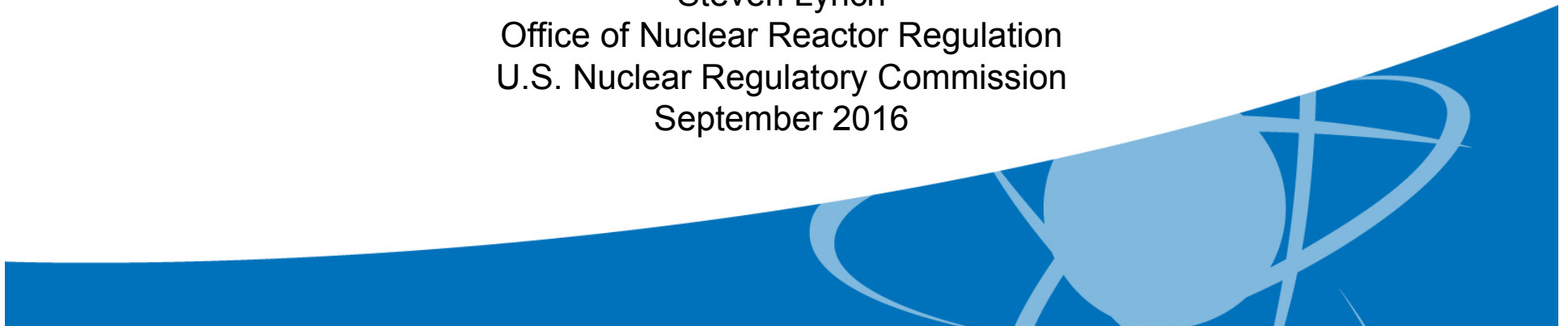


*Mo-99 2016 Topical Meeting on  
Molybdenum-99 Technological Development*

# U.S. Nuclear Regulatory Commission Licensing and Oversight Activities Related to Domestic Molybdenum-99 Production

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# Supporting Domestic $^{99}\text{Mo}$ Production

- NRC conducting reviews on applications submitted in accordance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR)
- 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 for low enriched uranium targets
- Medical uses of byproduct material
  - Generators for extracting technetium-99m ( $^{99m}\text{Tc}$ ) from molybdenum-99 ( $^{99}\text{Mo}$ )

# 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

# Recent, Current, and Anticipated Reviews

- Construction permit and operating license applications
  - SHINE Medical Technologies (SHINE)
    - Construction permit issued February 2016
    - Operating license application expected 2017
  - Northwest Medical Isotopes (NWMI)
    - Construction permit application under review
- License amendment issued to Oregon State University (OSU)
- License amendment request anticipated 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

# SHINE Medical Technologies, Inc.

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

# SHINE Irradiation Facility

- Irradiation facility houses eight subcritical irradiation units, which are comparable in power level and safety considerations to existing non-power reactors licensed under 10 CFR Part 50
- However, due to subcriticality, irradiation units did not meet the existing definition of utilization facility in 10 CFR 50.2 and could not be licensed under 10 CFR Part 70
- To align licensing process with potential hazards, NRC issued direct final rule modifying 10 CFR definition of utilization facility to include SHINE irradiation units
  - Published October 17, 2014
  - Effective December 31, 2014

# SHINE Radioisotope Production Facility

- Radioisotope Production Facility consists of three hot cells for  $^{99}\text{Mo}$  separation and purification
- Based on batch size (i.e., greater than 100 grams), facility meets the definition of a production facility as defined in 10 CFR 50.2, “Definitions”
- While NRC has historically licensed production facilities, no such facilities currently operating
- Few previously-licensed facilities have conducted similar activities as SHINE
  - Cintichem (licensed under 10 CFR Part 70)
  - West Valley (licensed as a reprocessing facility)



# SHINE Licensing Process

- SHINE facility will be licensed under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”
  - Target irradiation performed by *utilization facilities*
  - Fission product separation in *production facility*
- Special nuclear material will be licensed under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material”
- Byproduct material will be licensed under 10 CFR Part 30, “...Domestic Licensing of Byproduct Material”
- Source material will be licensed under 10 CFR Part 40, “Domestic Licensing of Source Material”

# Construction Permit Review Process

- Acceptance and docketing of application
- Parallel development of safety evaluation report and environmental impact statement (or environmental assessment)
- Request(s) for additional information, as needed
- Advisory Committee on Reactor Safeguards review
- Potential contested hearing; mandatory hearing (adequacy of staff safety and environmental review)
- Decision to grant or deny construction permit

# Construction Permit Regulatory Requirements

- Regulatory considerations for SHINE construction permit:
  - 10 CFR 50.22, Commercial and industrial facility licenses
  - 10 CFR 50.30, Environmental Report
  - 10 CFR 50.34(a), Preliminary safety analysis report
  - 10 CFR 20.1201, Occupational dose requirements
  - 10 CFR 20.1301, Public and accident dose requirements
  - 10 CFR 50.35, Issuance of construction permits
- Note: 10 CFR Part 50 Appendices A, “General Design Criteria...” and B, “Quality Assurance Criteria...” are only applicable to nuclear power reactors.
- 10 CFR Part 100, “Reactor Site Criteria,” siting and accident dose criteria are only applicable to nuclear power reactors

# Contents of Preliminary Safety Analysis Report

- Preliminary design of the facility, including principal design criteria, design bases, general arrangement, and approximate dimensions
- Preliminary analysis of structures, systems, and components, including ability to prevent and mitigate accidents
- Probable subjects of technical specifications
- Preliminary emergency plan
- Quality assurance program
- Research and development

# Regulatory Guidance and Acceptance Criteria

- NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors”
- Interim Staff Guidance Augmenting NUREG-1537
  - Radioisotope production facilities
  - Aqueous homogeneous reactors
  - Incorporates relevant non-reactor guidance from NUREG-1520, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility, Rev. 1”
- Other guidance (e.g., regulatory guides and ANSI/ANS standards) and engineering judgement used, as appropriate, to determine what is necessary for construction permit

# NUREG-1537 Review Areas

1. The Facility/Introduction
2. Site Characteristics
3. Design of Structures, Systems, and Components
4. Facility Description
5. Coolant Systems
6. Engineered Safety Features
7. Instrumentation and Control
8. Electrical Power Systems
9. Auxiliary Systems
10. Experimental Facilities\*
11. Radiation Protection and Waste Management
12. Conduct of Operations
13. Accident Analysis
14. Technical Specifications
15. Financial Qualifications
16. Other License Considerations\*
17. Decommissioning\*
18. Uranium Conversions\*
19. Environmental Review

\*Not applicable to the SHINE construction permit application

# NRC Review Methodology

- Since construction permit only allows construction, level of detail needed in application and staff's SER different than for combined operating license or operating license
- For the purposes of issuing a construction permit, the SHINE facility may be adequately described at a functional or conceptual level in the PSAR
- SHINE has deferred providing many design and analysis details until the submission of its final safety analysis report (FSAR) with its operating license application
- Staff's review tailored to unique and novel technology described in SHINE's construction permit application using appropriate regulatory guidance

# Resolving Technical Issues

- For technical areas requiring additional information, the staff has several options:
  - The staff may determine that such technical issues must be resolved prior to the issuance of a construction permit
  - The staff may determine that such information may be left until the submission of the FSAR
  - The staff may require that such technical issues be resolved prior to the completion of construction, but after the issuance of the construction permit
- In all cases, staff may issue requests for additional information
- In the second and third options, staff may track regulatory commitments or identify necessary license conditions



# Regulatory Basis for Construction Permit

- The following findings must be made to issue a construction permit, based on 10 CFR 50.35:
  - Facility has been described, including the principal architectural and engineering criteria for the design
  - Further technical or design information may be reasonably left for later consideration in the FSAR
  - Safety features or components requiring research and development have been identified
  - Safety questions will be resolved prior to the completion of construction and the proposed facility can be constructed without undue risk to the health and safety of the public
- Staff's conclusions also based on the considerations in 10 CFR 50.40 and 50.50

# Summary 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)
- Construction expected to begin in 2017
- Operating license application expected 2017

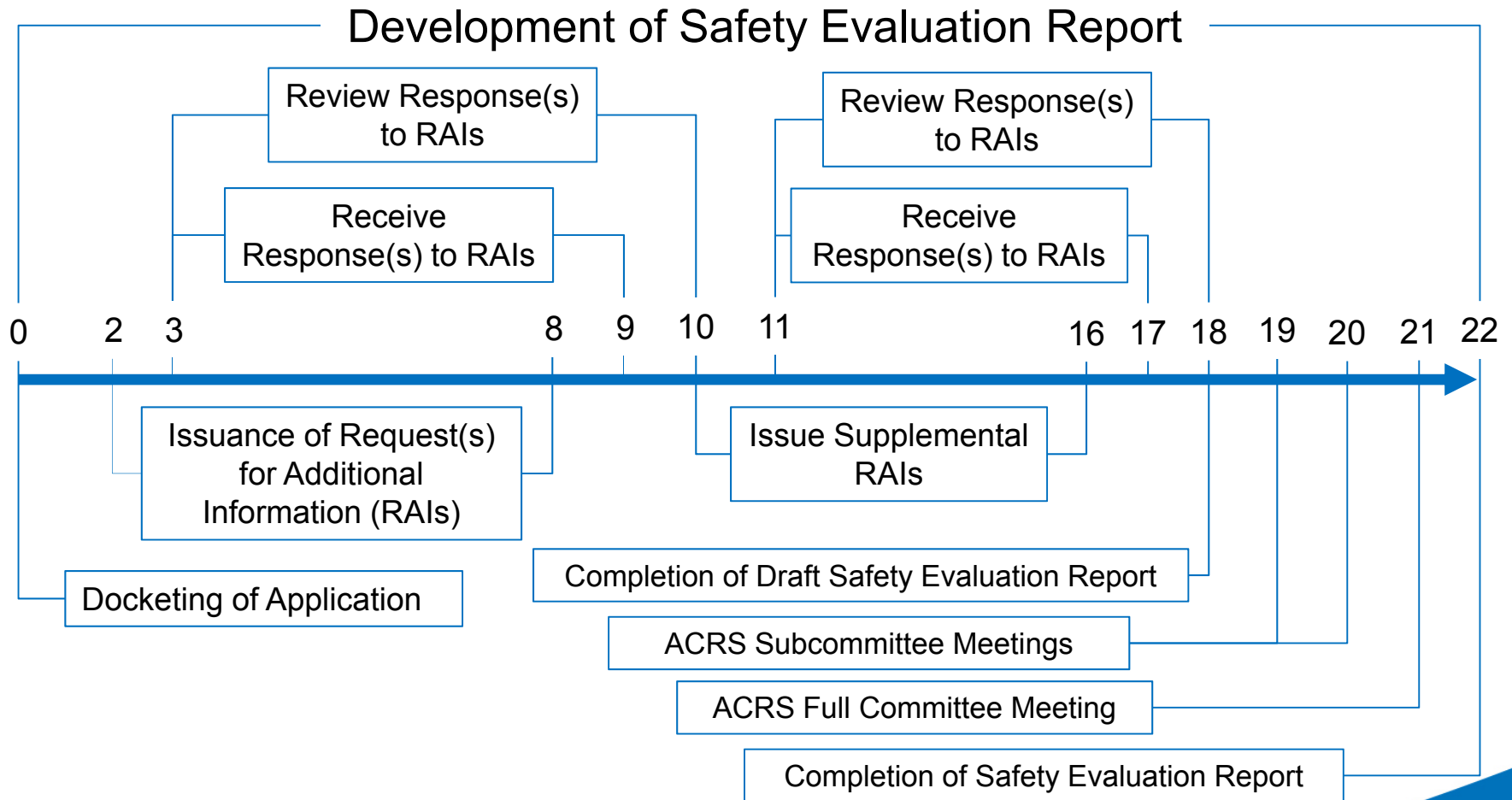
# Northwest Medical Isotopes

- 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 (MURR and OSU)
- $^{99}\text{Mo}$  recovered through processing of irradiated targets
- Proposed site: Columbia, MO

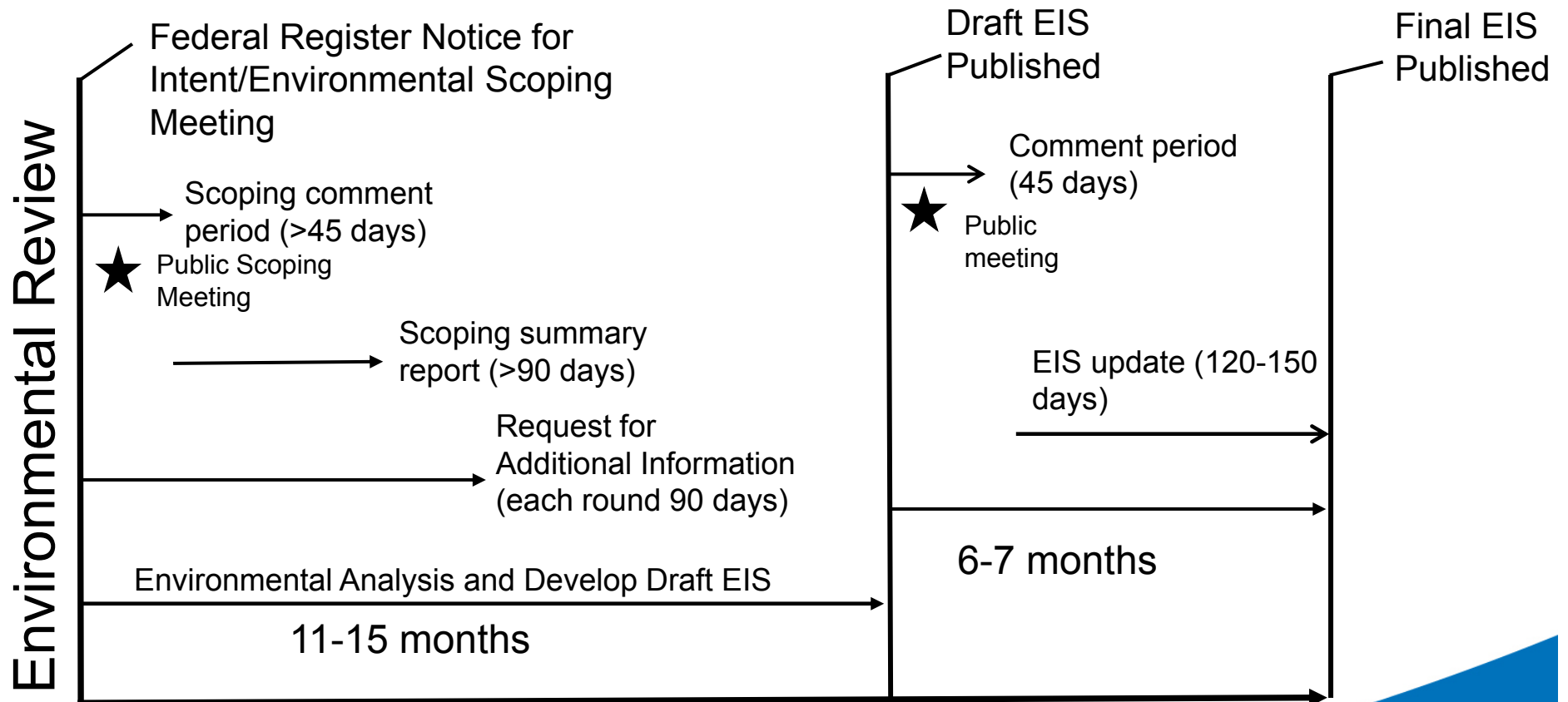
# NWMI Licensing Approach

- Hot cells licensed as *production facility* under 10 CFR Part 50
- Special nuclear material, including target manufacturing, will be licensed under 10 CFR Part 70
- NRC staff applying best practices from SHINE review:
  - Emphasis on most safety-significant technical aspects
  - Focused requests for additional information
  - Weekly status calls
  - Twenty-two month safety review schedule

# Sample 22-month Safety Review Timeline



# Sample Environmental Review Timeline



18-22 months\*

\*estimated time of review based on historical data. Actual time of review may vary based on complexity of application.

# Impacts to Review Schedule

- Quality of Application
  - Adherence to regulatory requirements
  - Technical completeness
  - Attention to detail (i.e., organization, format, etc.)
- Requests for Additional Information (RAIs)
  - Completeness, timeliness, and responsiveness to requests
  - Evaluation of new information
  - Number of requests for additional information
  - Number of rounds of RAIs
- Policy Questions
  - Commission involvement to resolve unique considerations
- Advisory Committee on Reactor Safeguards
  - Number of subcommittee meetings
  - Follow-up

# Other Scheduling Considerations

- Possible contested hearing(s)
- Mandatory hearing
  - Cannot hold mandatory hearing until completion of Safety Evaluation Report, Environmental Impact Statement, ACRS Review, and contested hearing(s)
- Commission decision to issue or deny construction permit
  - Decision on SHINE construction permit made 2 months following hearing
  - Decisions on combined operating licenses made 2 – 5 months following mandatory hearing



# Status of NWMI Review

- Part one of application accepted for docketing (May 2015)
- Environmental site audit (September 2015)
- Issued environmental requests for additional information (November 2015, with follow-up requests January, March, and June 2016)
- Environmental scoping meeting (December 2015)
- Part two of application accepted for docketing (December 2015)
- Issued safety requests for additional information (March 2016)
- Completion of review anticipated by September 2017
- Application supported by license amendments for existing research reactors
  - Prototypical target irradiation (OSU), issued
  - Commercial target irradiation (OSU, MURR), anticipated

# Reactor License Amendments

- License amendment issued to OSU in 2016
  - Demonstration of  $^{99}\text{Mo}$  production in small nuclear reactor with experimental uranium targets
  - Additional amendment expected to support commercial target irradiation for NWMU
- Anticipated licensing requests from MURR
  - General Atomics gaseous extraction technology to be used following uranium target irradiation
  - Additional amendment expected to support commercial target irradiation for NWMU

# Materials and Medical Use Licenses

- Materials license issued to Niowave in 2015
  - Production of small amounts of  $^{99}\text{Mo}$  through uranium fission using superconducting linacs for proof of concept
  - NRC staff considering amendment request to increase LEU possession limit
- NorthStar Medical Radioisotopes
  - Proposes to produce  $^{99}\text{Mo}$  from enriched molybdenum target irradiation
  - Developed RadioGenix  $^{99\text{m}}\text{Tc}$  generator system compatible with lower specific activity  $^{99}\text{Mo}$
  - NRC staff developing licensing guidance for medical use applicants and licensees that possess RadioGenix system

# Oversight, Infrastructure, and Support Activities

- Developing construction and operation inspection programs
- Reviewing regulations and guidance
- Coordinating 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, Department of Homeland Security)
  - State and local governments
  - Public
- Providing updates on public website:
  - <http://www.nrc.gov/reactors/medical-radioisotopes.html>

# Summary of 2016 Licensing Activities

- Issued SHINE construction permit
- Reviewing NWMI construction permit application
- Issued license amendment to Oregon State University
- Anticipate receiving additional applications within the next year
  - Prepared to review additional applications
  - Encourage early and frequent communication with potential producers

# Questions?

