



**SHINE Medical Technologies, LLC
(SHINE)
Operating License Application
Review Process
and
Environmental Scoping Meeting
December 12, 2019**

Purpose of Today's Meeting

- Provide an overview of the operating license application review process
 - Safety review
 - Environmental review
- Receive public input on the scope of the environmental review

Background

- Molybdenum-99 (^{99}Mo) decays to technetium-99m ($^{99\text{m}}\text{Tc}$) and is used for medical procedures
- Until recently, no domestically-produced ^{99}Mo supply since late 1980s
- Aging international reactors, dependence on foreign suppliers, and extended repairs jeopardize and disrupt international supply

Role of the NRC

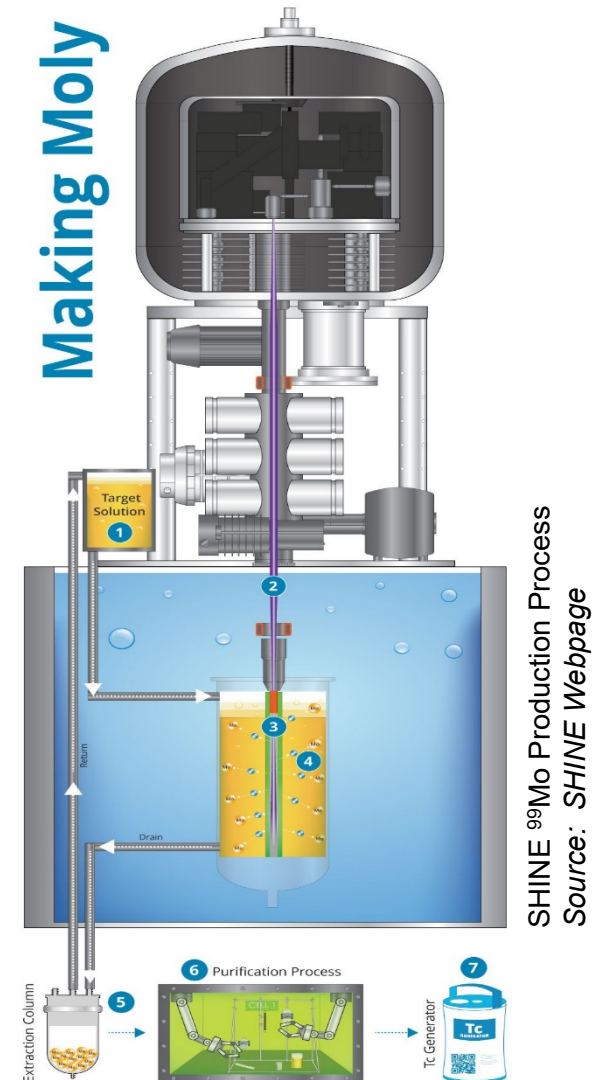
- Conduct reviews of applications for facilities proposing to manufacture, irradiate, and process low enriched uranium (LEU) and molybdenum targets
- Reviews support establishment of a domestically-available and reliable supply of ^{99}Mo

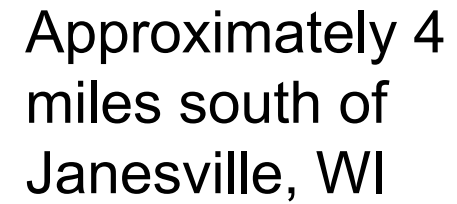
NRC Regulatory Oversight

- Governing Statutes
 - Atomic Energy Act of 1954, as amended
 - Energy Reorganization Act of 1974
- NRC's Mission Statement
 - Protect public health and safety
 - Promote common defense and security
 - Protect the environment

SHINE Technology

- SHINE proposes to fission an LEU target solution in 8 irradiation units licensed as *utilization facilities*
- ^{99}Mo recovered from irradiation solution in hot cells licensed as a *production facility*





Bordered by U.S.
Highway 51 and
the Southern
Wisconsin
Regional Airport

Construction Permit Application Review

- Application submitted in 2013
- Conducted safety and environmental reviews
 - Safety Evaluation Report
 - Environmental Impact Statement
- NRC issued Construction Permit No. CPMIF-001 to SHINE on February 29, 2016
- Construction activities began September 2019

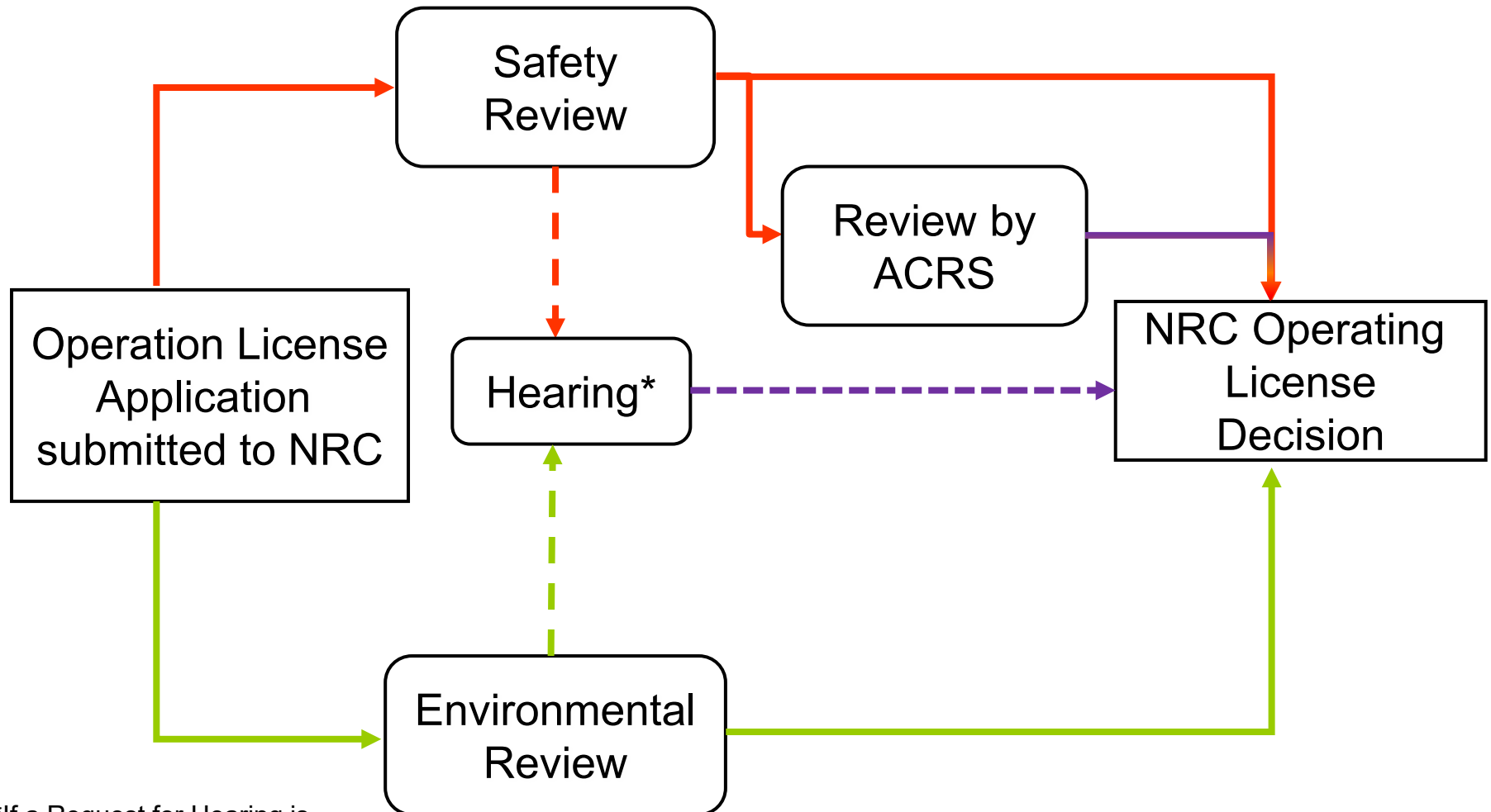
Operating License Application

- Operating license application submitted in July 2019
 - Final Safety Analysis Report (FSAR)
 - Environmental Report Supplement
- A notice of acceptance of the application for docketing was published in the *Federal Register* on October 15, 2019 (84 FR 55187)

Safety and Environmental Review Process

- Initial NRC staff review of the application
- Request(s) for additional information (RAI)
- Safety Evaluation Report (SER) and Environmental Impact Statement (EIS)
- Advisory Committee on Reactor Safeguards (ACRS)
- Potential for contested hearing
- Decision to grant or deny operating license

Operating License Application Review Process



*If a Request for Hearing is
Granted

Safety Review Methodology

- Review tailored to design and safety significance of technology
 - NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors”
 - Interim Staff Guidance Augmenting NUREG-1537
 - Other guidance and engineering judgement used, as appropriate

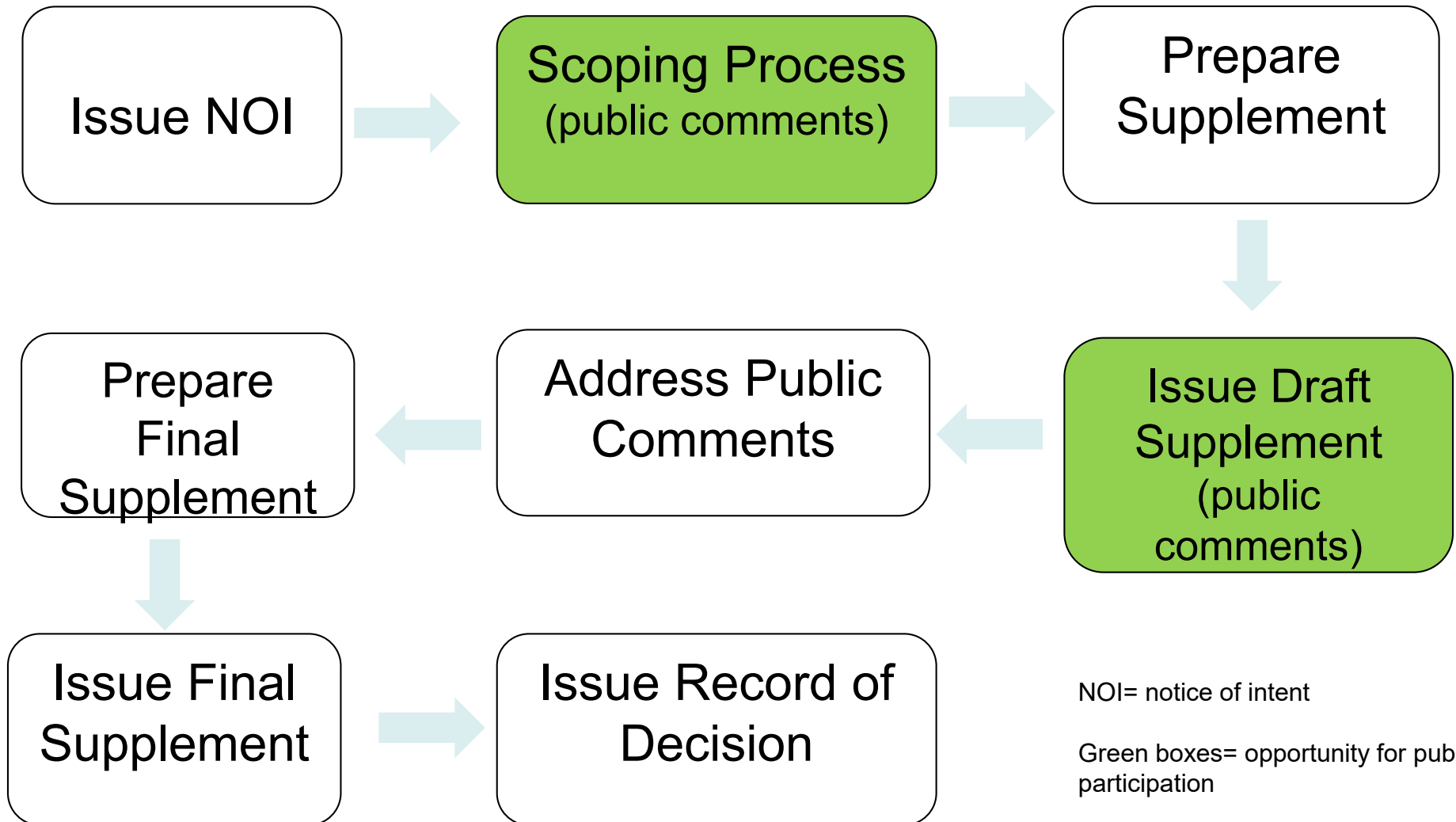
Environmental Review

- National Environmental Policy Act (NEPA)
 - Informs Federal decision making
 - Public disclosure of environmental impacts and other considerations
- NRC's environmental regulations are located at 10 CFR Part 51

Scope of Environmental Review

- Staff will prepare a supplement to the SHINE Final EIS (NUREG-2183)
- The supplement will only cover matters that differ from or reflect significant new information

Environmental Review



Supplement to the Final EIS

The supplement will:

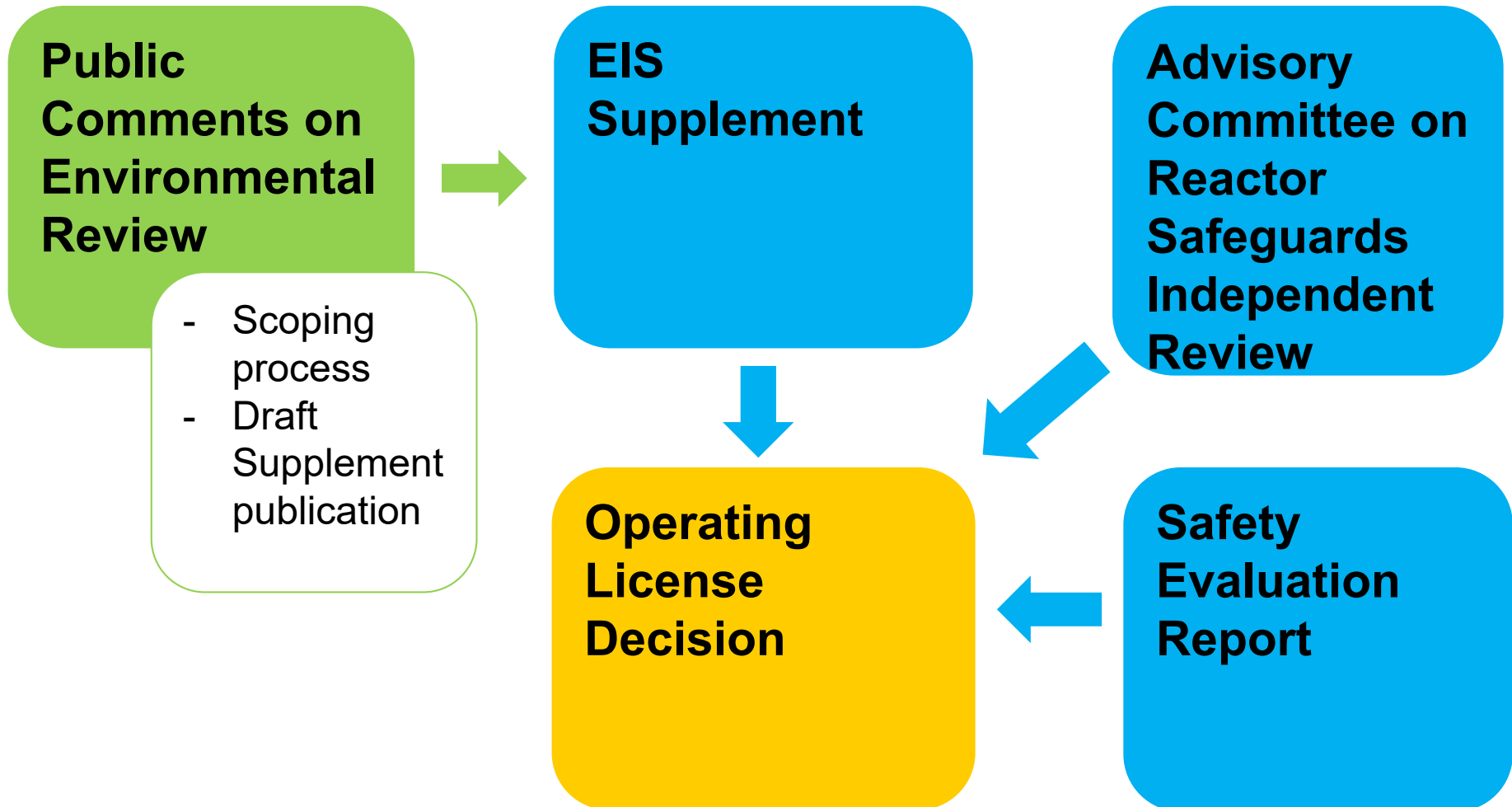
- Update the prior environmental review
- Describe matters that differ or reflect significant new information since publication of the EIS

Focus of Review

Changes to:

- Facility design (e.g., changes to building footprint)
- Facility operation (e.g., change in the number of workers)
- Natural or physical environment
- Regulatory environment (new permits)

Role of Public Comments on the Staff's Review



How to Submit Comments

- Today's meeting
- By mail (please reference SHINE operating license application review)

Office of Administration

ATTN: Program Management, Announcements and
Editing Staff

Mail Stop: TWFN-7-A60M

U.S. Nuclear Regulatory Commission

Washington, DC 20555-0001

How to Submit Comments (cont.)

- Online at <https://www.regulations.gov/>.
Enter ID: NRC-2019-0173
 - Please note that comments will not be edited to remove identifying information.
- Comments must be submitted by **January 13, 2020.**

Document Locations

- Hedberg Public Library
316 S Main St
Janesville, WI 53545
- NRC Agencywide Documents Access and Management System (ADAMS):
<https://www.nrc.gov/reading-rm/adams.html>
Enter Accession No. ML19211C139

Contact Information



Steven Lynch, Project Manager

Division of Advanced Reactors and Non-Power Production
and Utilization Facilities

Office of Nuclear Reactor Regulation

U.S. Nuclear Regulatory Commission

Email: Steven.Lynch@nrc.gov

Phone: [301-415-1524](tel:301-415-1524)

Jennifer Davis, Senior Project Manager

Division of Rulemaking, Environmental, & Financial Support

Office of Nuclear Material Safety and Safeguards

U.S. Nuclear Regulatory Commission

Email: Jennifer.Davis@nrc.gov

Phone: [301-415-3835](tel:301-415-3835)