



Construction Permit Application Review SHINE Medical Technologies

Overview

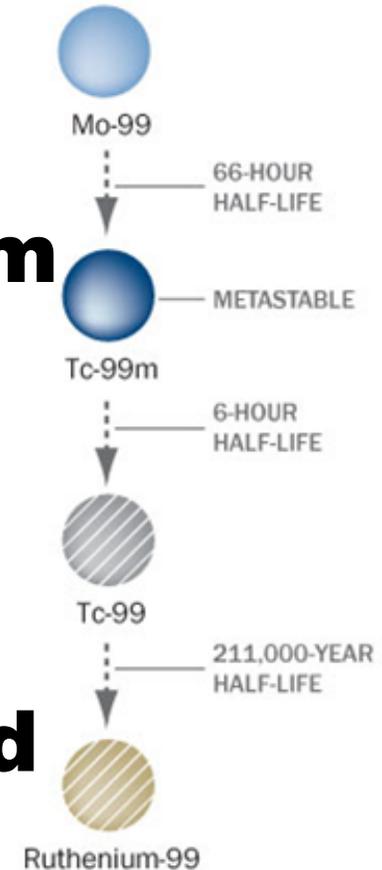
December 15, 2015

Panelists

- **William Dean** - **Director, NRR**
- **Mirela Gavrilas** - **Deputy Director, NRR/DPR**
- **Jane Marshall** - **Deputy Director, NRR/DLR**
- **Marissa Bailey** - **Director, NMSS/FCSE**

Introduction to Molybdenum-99

- **Molybdenum-99 (^{99}Mo) decays to technetium-99m**
 - **Effective diagnosis**
 - **Minimal exposure**
- **50,000 procedures daily**
- **No domestically-produced supply**



Establishing a Domestic Supply

- **National policy objectives support domestic production capabilities**
- **Cost-sharing agreements encourage commercial partners**
- **SHINE proposes to produce ^{99}Mo through uranium fission**

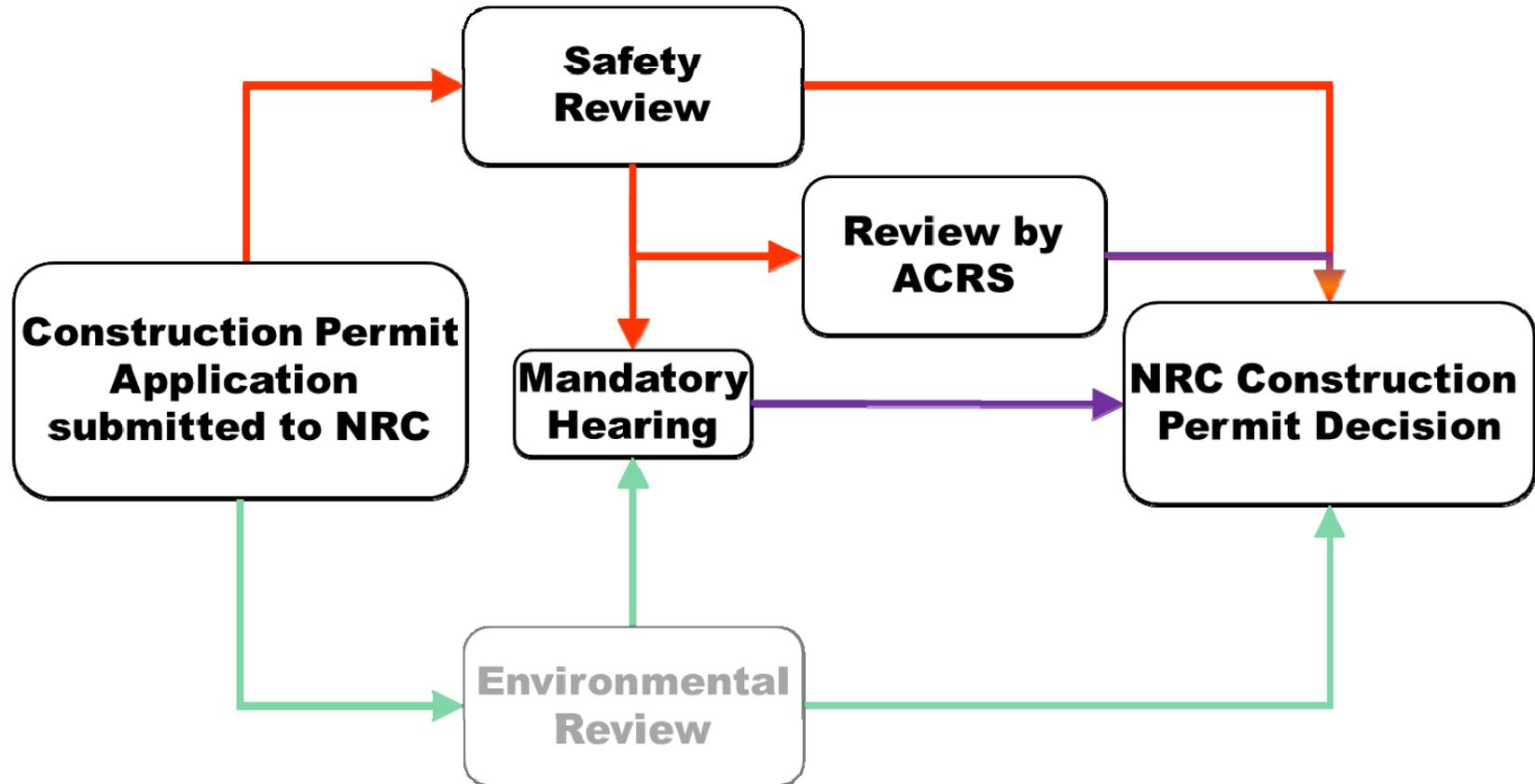
Preparing for SHINE Review

- **Interoffice working group contributed diverse expertise**
- **Public meetings engaged stakeholders**
- **Review coordinated with Federal, State, and local governments**

Allowing Construction

- **SHINE application only seeks construction authorization**
- **Design details may be left for operating license application**
- **Review assessed preliminary design and analysis**

Conducting the Safety Review



Tailoring Review Methodology

- **Review accommodated unique technology**
- **Staff used existing guidance**
- **Staff determined whether reasonable assurance that final design will conform to design bases**

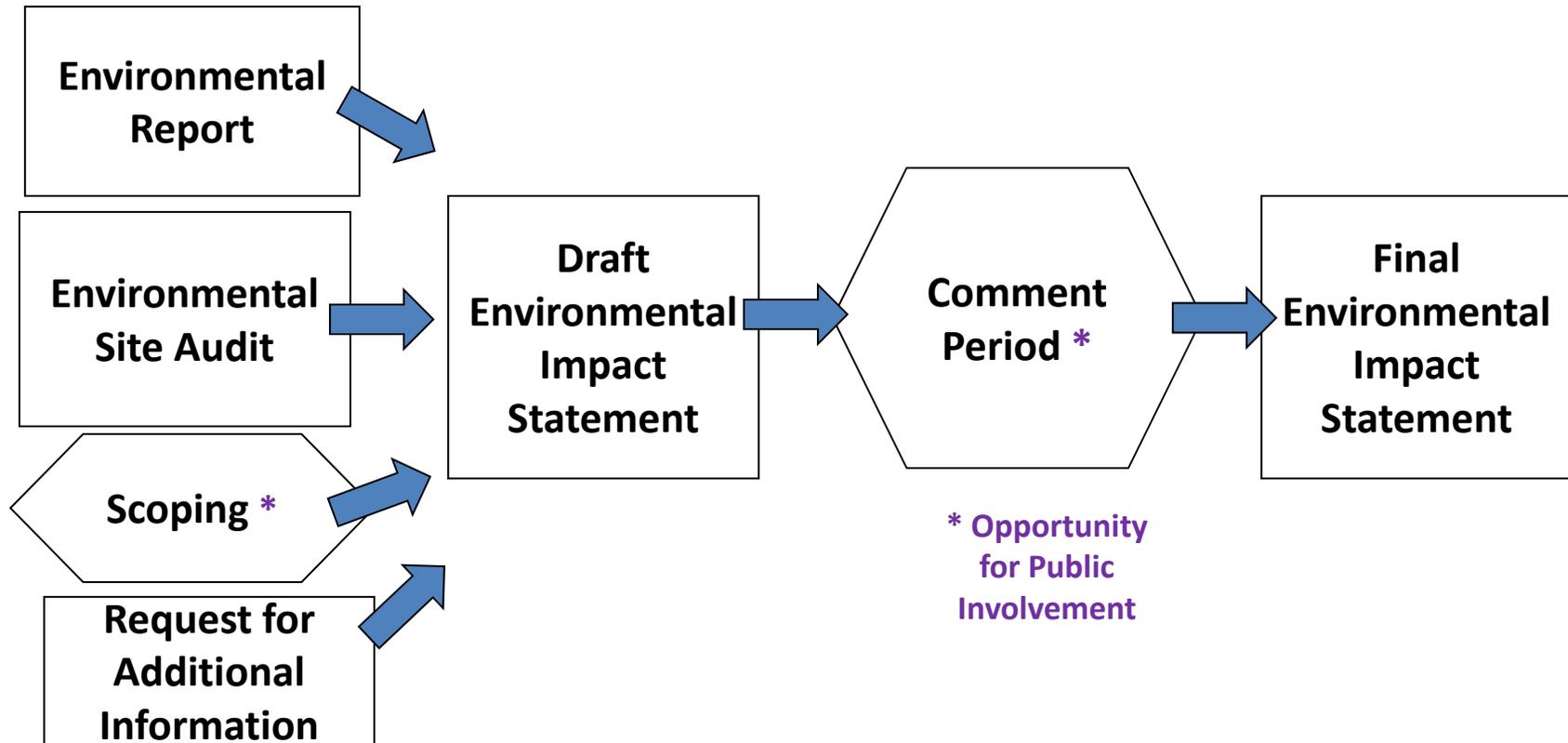
Additional Information

- **Review supported by additional information**
- **In some cases, permit conditions necessary**
- **Regulatory commitments track items for resolution in final safety analysis report (FSAR)**

Environmental Regulations

- **National Environmental Policy Act**
 - **Informs Federal decision making**
 - **Public disclosure**
- **NRC's environmental regulations**
 - **Title 10 of the *Code of Federal Regulations* (10 CFR) Part 51**

Environmental Review Process



Proposed Janesville Site



- **Agricultural fields**
- **Previously disturbed**
- **No surface water features**
- **No threatened or endangered species**
- **No historical or cultural resources**

Regulatory Basis

- **Commission authorized by Atomic Energy Act, Section 103**
- **Review primarily based on 10 CFR Parts 20, 50, and 51**
- **Review also considered 10 CFR Part 70 performance requirements**

Construction Permit Issuance

- **Preliminary design described**
- **Further technical or design information may be left for FSAR**
- **Ongoing research and development has been identified**
- **Facility can be constructed and operated without undue risk**

Permit Considerations

- **Construction will not endanger public health and safety**
- **SHINE technically and financially qualified**
- **Environmental requirements satisfied**

Introducing Review Panels

Panel Number	Discussion Topics	Evaluation Areas
Safety Panel 1	Licensing Considerations	Safety Evaluation Report Chapters 1 and 4
Safety Panel 2	Accident Analysis	Safety Evaluation Report Chapter 13
Environmental Panel	<ul style="list-style-type: none">• Final Environmental Impact Statement Process• Analysis of Alternatives• Summary of Conclusions and Recommendations	Final Environmental Impact Statement

Acronyms

- **FCSE – Division of Fuel Cycle Safety, Safeguards, and Environmental Review**
- **DLR – Division of License Renewal**
- **DPR – Division of Policy and Rulemaking**

Acronyms

- **NMSS – Office of Nuclear Material Safety and Safeguards**
- **NRR – Office of Nuclear Reactor Regulation**