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

Licensing Novel Technologies within the Existing Regulatory Framework

Steven Lynch
Project Manager
June 7, 2016

Non-power Reactor Licensing

- Types of non-power reactor licenses
  - Research and test reactors
  - Commercial facilities
- Applicable regulatory requirements and guidance
- Licensing process
- Current reviews involving novel technologies

Classes of Non-Power Reactors

- Pursuant to the Atomic Energy Act (AEA), the NRC licenses production and utilization facilities
- All current reactors, both power and non-power, are licensed as utilization facilities
- Two primary classes of non-power reactor licenses:
  - Section 103 Commercial Licenses
  - Section 104 Medical Therapy and Research and Development Licenses

Section 104 Medical Therapy and Research and Development Licenses

- Three subsets of Section 104 licenses in AEA:
  - 104(a) – Medical therapy
  - 104(b) – Early industrial and commercial demonstration
  - 104(c) – Research and development
- All NRC-licensed research and test reactors licensed pursuant to Section 104(c) of the AEA
- One facility also holds a 104(a) license

Research and Test Reactors

- AEA directs Commission to impose minimum amount of regulation of 104(c) licensees necessary to fulfill Commission's obligations
- NRC licenses research and test reactors under regulations in Title 10 of the *Code of Federal Regulations,* Part 50, "Domestic Licensing of Production and Utilization Facilities"

Definitions

- *Research reactor:* a nuclear reactor licensed under subsection 104c of the AEA for operation at 10 megawatts or less, and is not a testing facility

- *Testing facility:* a nuclear reactor licensed under subsection 104c of the AEA for operation at:

  1) A thermal power level in excess of 10 megawatts; or

  2) A thermal power level in excess of 1 megawatt, if the reactor is to contain: (i) A circulating loop through the core for fuel experiments; or (ii) A liquid fuel loading; or (iii) An experimental facility in the core in excess of 16 square inches in cross-section

Section 103 Commercial Licenses

- A facility is deemed commercial if more than 50 percent of the annual cost of owning and operating is devoted to sale of materials, products, energy, or services
- Examples of non-power facilities licensed pursuant to Section 103 of the AEA
  - Medical radioisotope facilities proposing to produce molybdenum-99 (^{99}Mo)
  - Prototype plants

Licensing Comparison

- Test Reactors
  - Occupational dose requirements: 10 CFR 20.1201
  - Public dose requirements: 10 CFR 20.1301
  - Accident dose requirements: 10 CFR 100.11
  - Require Environmental Impact Statement (EIS), hearing, and ACRS Review
- Research Reactors
  - Occupational dose requirements: 10 CFR 20.1201
  - Public dose requirements: 10 CFR 20.1301
  - Accident dose guidance: NUREG-1537
  - No EIS, hearing, or ACRS review required

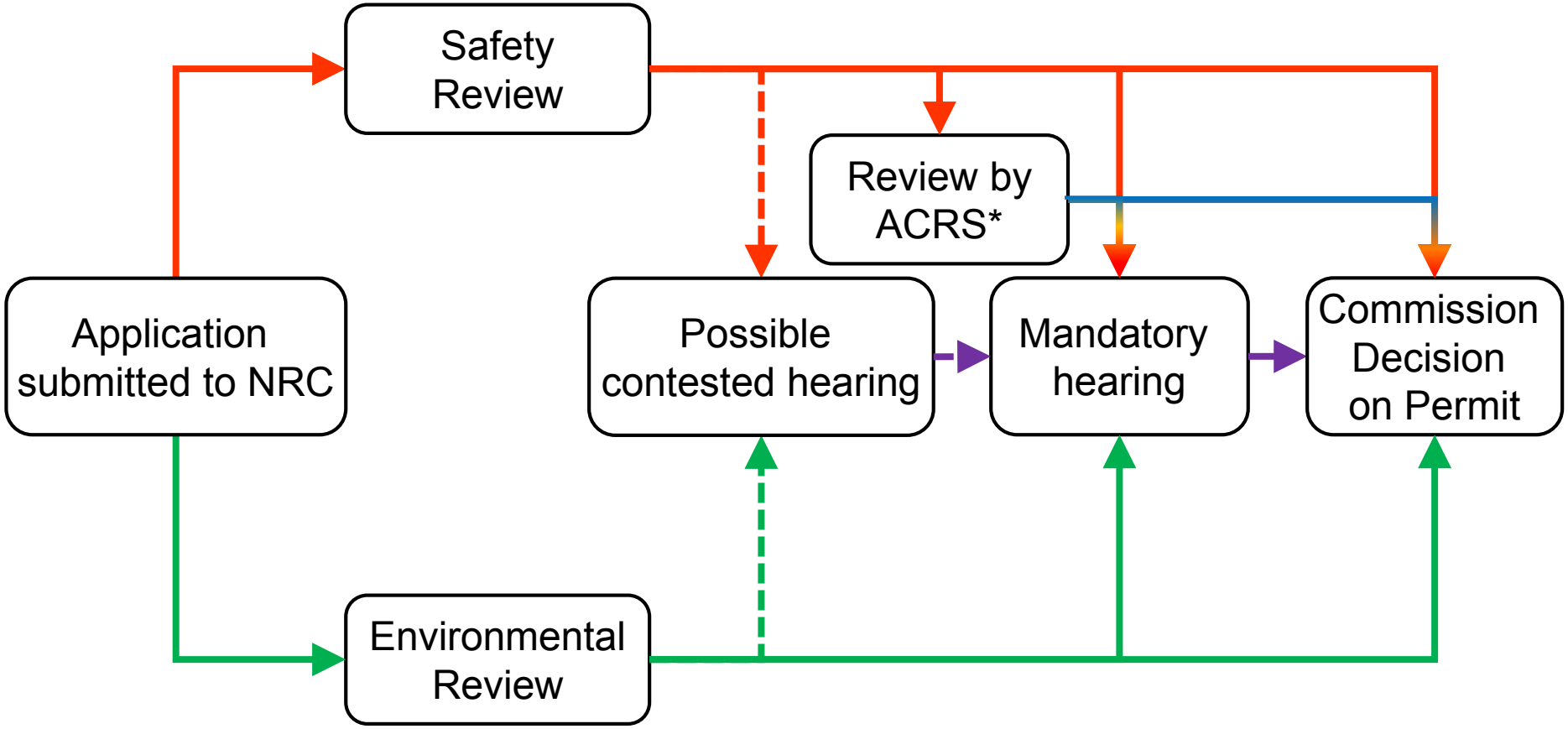
Applicable Regulatory Guidance

- NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors”
- Regulatory Guides
  - Division 2, “Research and Test Reactors”
  - Division 5, “Materials and Plant Protection”
  - Guidance on technical specification development, quality assurance program requirements, and emergency planning
- ANS/ANSI Research Reactor Standards ANS 15 Series (15.1, 15.2, 15.4, 15.8, 15.11, 15.16) referenced by guidance

10 CFR Part 50 Licensing Process

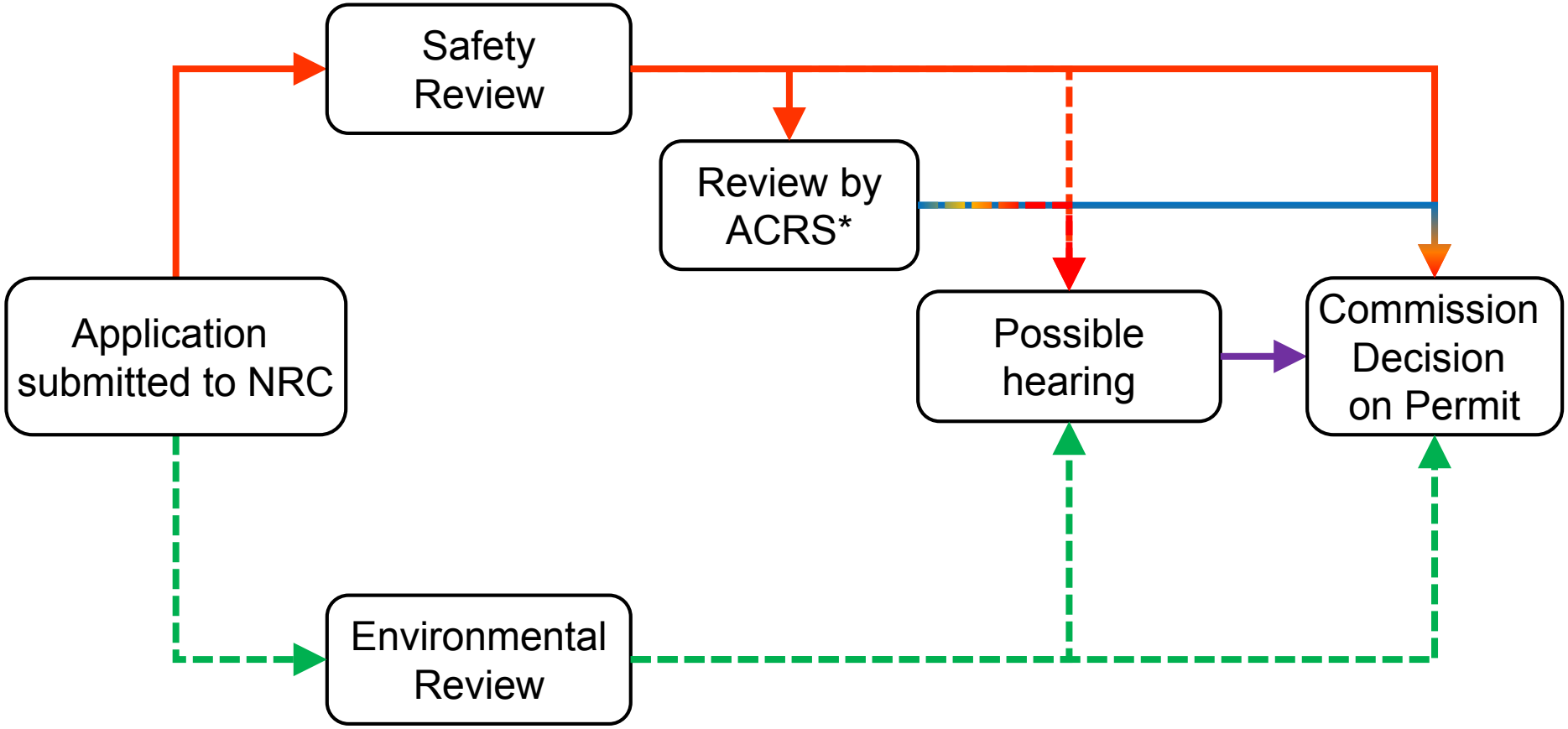
- Applications contain both general and technical information
- Construction permit application
  - Environmental report
  - Preliminary safety analysis report (PSAR)
- Operating license application
  - Update to environmental report, as necessary
  - Final safety analysis report (FSAR)
  - Physical security plan
  - Safeguards contingency plan
  - Protection against unauthorized disclosure
- May submit applications separately or together
- Testing facilities and commercial facilities may request limited work authorization to allow certain construction activities prior to the issuance of a construction permit

Test Reactor Construction Permit Review



* Advisory Committee on Reactor Safeguards

Test Reactor Operating License Review



* Advisory Committee on Reactor Safeguards

Medical Isotope Licensing Reviews

- 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
- Most facilities licensed under 10 CFR Part 50
  - Target irradiation performed by *utilization facilities*
  - Fission product separation in *production facilities*

Addressing Novel Technology Through Regulatory Guidance

- Interim Staff Guidance (ISG) 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”

SHINE Medical Technologies, Inc.

- Proposes to produce ^{99}Mo from fission of low enriched uranium target solution in 8 irradiation units
- ^{99}Mo recovered through irradiated target solution processing in 3 hot cells
- Direct final rule issued modifying definition of *utilization facility* to include SHINE irradiation units
- Construction permit issued in February 2016
  - 22-month application review from time of docketing

Northwest Medical Isotopes, LLC

- Proposes to manufacture low enriched uranium targets for irradiation at existing research reactors
- ^{99}Mo recovered through hot cell processing of irradiated targets
- Target irradiations performed by existing research reactors
- Construction permit application review ongoing

Ongoing ^{99}Mo 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
  - State and local governments
  - Public

Getting Started: Pre-Application Interactions

- For novel technologies, early interaction supports efficient application processing and review
- Public Meetings
  - Promote engagement between NRC and potential applicant
  - Inform the development of high-quality applications
  - Inform budgeting and resource allocation
  - Inform public of NRC process