

Regulatory Activities Related to Licensing Medical Radioisotope Production Facilities

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Supporting Domestic Mo-99 Production

Consistent with statutory responsibilities under the Atomic Energy Act of 1954, as amended, NRC is prepared to conduct reviews on all medical radioisotope production related license applications submitted in accordance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR)

Regulatory Authority and Mission Statement

- Statutes
 - Atomic Energy Act of 1954, as amended
 - National Environmental Policy Act
- Mission
 - The NRC licenses and regulates the Nation's civilian use of radioactive materials to protect public health and safety, promote the common defense and security, and protect the environment

Outreach and Communication

- RIS 2013-03, “Pre-application Communication and Scheduling for Medical Radioisotope Facilities intending to produce Molybdenum-99”
- Public meetings
 - Technical aspects of design and regulatory approach
 - Environmental scoping meetings and site audit
- 26th Annual Regulatory Information Conference
 - Technical session on medical radioisotope production
 - Panel discussed establishing domestic Mo-99 supply without the use of highly enriched uranium (HEU)

Interest in Mo-99 Production

- Letters of Intent
 - Babcock and Wilcox Technical Services Group
 - Coqui Radiopharmaceuticals
 - Eden Radioisotopes
 - Flibe Energy
 - General Electric Hitachi Nuclear Energy
 - Northwest Medical Isotopes, LLC
 - Precision Engineering Consultants, Inc.
 - SHINE Medical Technologies, Inc. (SHINE)
 - University of Missouri-Columbia
- Amendment Request
 - Oregon State University (OSU)

Regulatory Activities: Exemptions from Requirements

- Any interested person may apply for a specific exemption from regulatory requirements
- Approved two exemptions from 10 CFR 2.101(a)(5) to allow submission of a construction permit application in two parts

Regulatory Activities: Clarifications of Regulations

- Encourage discussion of applicant's proposed licensing approach in pre-application public meetings to help clarify regulatory requirements
- Further clarification of regulatory requirements may be obtained through a written request to the NRC
- Content of NRC response depends on quality and detail of information accompanying the request
 - Requestor's proposed approach or position
 - All supporting technical details

Regulatory Activities: SHINE

- Received two-part construction permit application
 - Environmental Report (March 2013)
 - Preliminary Safety Analysis Report (May 2013)
- Application accepted for docketing (December 2013)
- Application proposes to:
 - Produce Mo-99 from uranium fission
 - Construct facility in Janesville, WI

Regulatory Activities: SHINE (cont.)

- Staff is reviewing SHINE construction permit application
 - Drafting requests for additional information
 - Drafting environmental impact statement
- NRC staff is coordinating environmental review with the Department of Energy, in accordance with the American Medical Isotopes Production Act of 2012

Regulatory Activities: OSU

- Received license amendment application (April 2012)
- Application proposes to irradiate uniquely designed targets at OSU TRIGA® reactor to demonstrate Mo-99 production in small reactors
- Following two requests for additional information, the staff is continuing to review the OSU application

Conclusion

- NRC staff encourages frequent and early communication through updated responses to RIS and public meetings
- NRC staff regulatory activities are consistent with the NRC's statutory responsibilities under the Atomic Energy Act of 1954, as amended
- NRC is prepared to review applications related to the national initiative to establish a domestic supply of Mo-99 without the use of HEU

Questions?

