



U.S. NRC

UNITED STATES NUCLEAR REGULATORY COMMISSION

Protecting People and the Environment

NRC Licensing of Isotope Production Facilities

Marcus H. Voth

Office of Nuclear Reactor Regulation

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Overview

- Needs analysis
- Addressing Needs
- Regulatory Basis
- Utilization facility
- Production facility
- Guidance documentation
- Conclusion

Needs Analysis

- Production of bulk Mo-99
 - Activation
 - Fission
 - Accelerator
- Separation of fission-moly
- Processing for medical use of Tc-99m daughter of Mo-99
- Delivery to patients

Needs Analysis

- Activation
 - GE Vallecitos
 - Amend NPP license; do under NPR license
- Fission
 - Technologies
 - Conventional targets
 - Aqueous homogeneous reactor
 - Subcritical solution tank, accelerator-generated neutrons
 - Union Carbide / Cintichem
 - Separation may require a production facility
- Accelerator
 - Licensed under Agreement State Provisions

Addressing Needs: Mo-99 Working Group

- Nuclear Reactor Regulation
- Nuclear Material Safety and Safeguards
- Federal and State Materials and Environmental Management Programs
- General Counsel
- Nuclear Regulatory Research
- Nuclear Security and Incident Response
- International Programs
- Congressional Affairs
- Public Affairs
- Chief Financial Officer

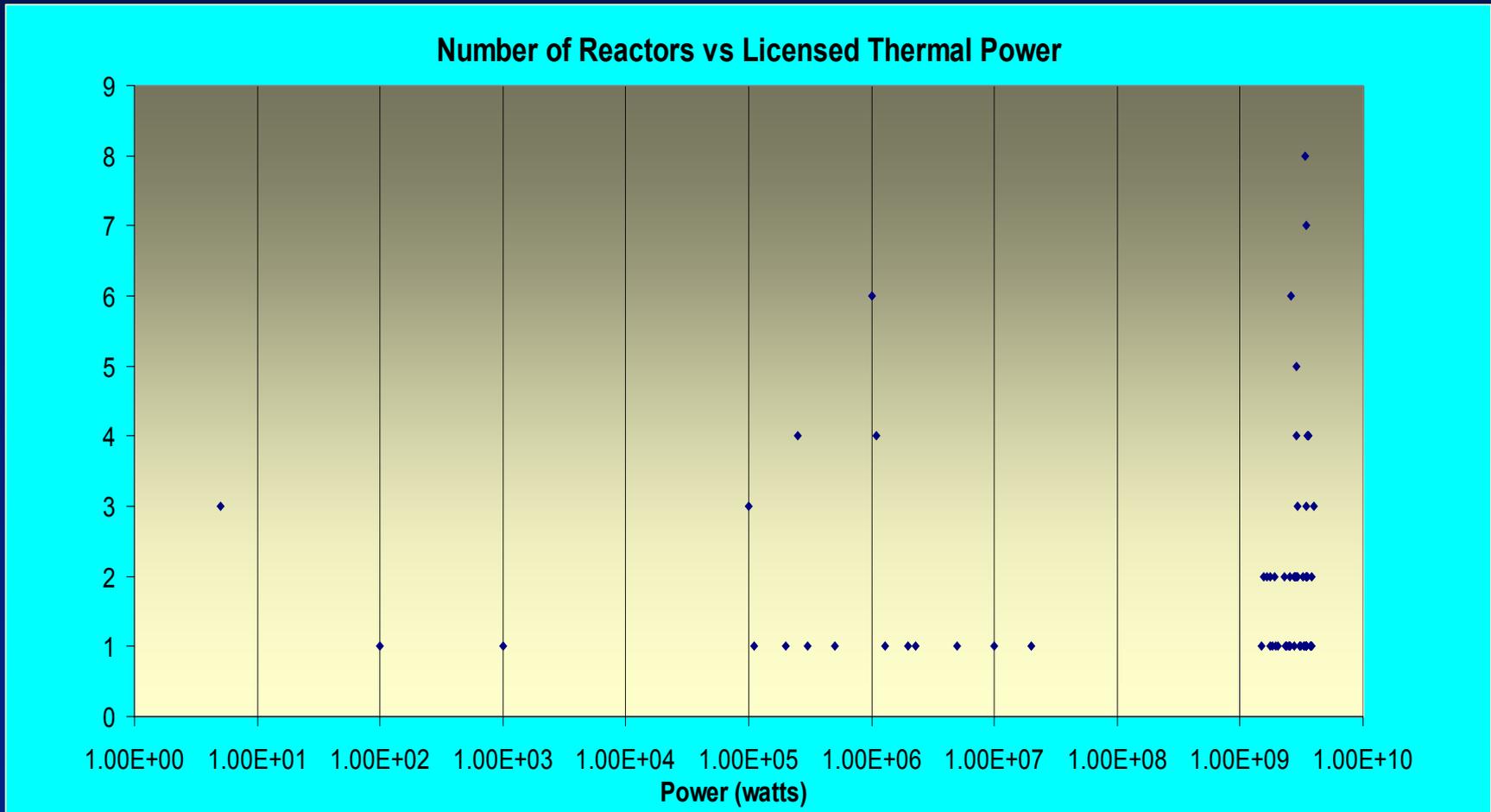
Regulatory Basis: Acts of Congress

- The Atomic Energy Act of 1954, as Amended
- The Energy Reorganization Act of 1974, as Amended
- The Energy Policy Act of 2005

Regulatory Basis: Title 10, Code of Federal Regulations

- Part 2 **Rules of practice**
- Part 20 Standards for protection against radiation
- Part 30 licensing of byproduct material
- Part 50 Domestic **licensing of production and utilization facilities**
- Part 51 Environmental protection regulations
- Part 55 Operators' licenses
- Part 70 Domestic **licensing of special nuclear material**
- Part 73 Physical protection of plants and materials
- Part 74 Material control and accounting of special nuclear material
- Part 150 **Agreement States**
- Part 170 Fees for regulatory services
- Part 171 Annual fees for reactor licenses and

The Fission (Utilization) Facility



The Production Facility: 10 CFR 50.2

- Definition: “(3) Any facility designed or used for the processing of irradiated materials containing special nuclear material, except”
 - Laboratory scale facility
 - Low fission product activity and Pu content
 - Process limited to 100 gm U-235 batch size
- No active Part 50 production facility is currently licensed by the NRC

Guidance Documentation: NUREGs

- NUREG-1537, Guidelines for Preparing and Reviewing Applications for the licensing of Non-Power Reactors, 1996.
 - Part 1, Format and Content
 - Part 2, Standard Review Plan and Acceptance Criteria
- NUREG-1520, Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility, Revision 1, May 2010.

Guidance Documentation: ISG

- NUREG-1537 Interim Staff Guidance (ISG)
 - Ch. 1-6 published for comment October 13, 2011
 - Ch. 7-18 publication date to be determined
- ISG objectives
 - Update references and regulations cited
 - Address aqueous homogeneous reactors and solution tank facilities, as applicable
 - Guidance for production a facility license application

Conclusions

- Existing regulations are adequate to license all anticipated facility designs
- Licensing processes are in place for potential applications
- Guidance is available to assist licensees in the preparation of quality license applications

QUESTIONS?