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NRC Regulation of the Production of Byproduct Radionuclides

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NRC does not Regulate DOE or DOE Production of Isotopes

– Reactors 10 CFR 50.11, “Exceptions and exemptions from licensing requirements”

– Accelerators 10 CFR 30.12, “Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts”

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NRC Mission

To regulate the nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety, to promote the common defense and security, and to protect the environment.

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The NRC's regulatory mission covers three main areas:

- Reactors - Commercial reactors for generating electric power and research and test reactors used for research, testing, and training
- Materials - Uses of nuclear materials in medical, industrial, and academic settings, production of accelerator produced byproduct materials, and facilities that produce nuclear fuel
- Waste - Transportation, storage, and disposal of nuclear materials and waste, and decommissioning of nuclear facilities from service

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NRC Regulation of U.S. Produced Byproduct Radionuclides

Reactor Produced

- **Office of Nuclear Reactor (NRR)**
- **10 CFR Part 50**

Accelerator produced

- **Office of Federal and State Materials and Environmental Management Programs (FSME)**
- **10 CFR Part 30**

Reactor Production

- Class 103 licenses - a production or utilization facility;
  - that transfers or receives in interstate commerce, manufactures, produces, transfers, acquires, possesses, or uses for industrial or commercial purposes;
  - or if useful in the conduct of research and development activities, however, if to be used so that more than 50 percent of the annual cost of owning and operating the facility is devoted to the production of materials, products, or energy for sale or commercial distribution, or to the sale of services, other than research and development or education or training (10 CFR 50.22).

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Reactor Production

- Class 104 a licenses - utilization facility
  - for use in medical therapy (10 CFR 21.a)
- Class 104 b licenses - production or utilization facility
  - for industrial or commercial purposes under Cooperative Power Reactor Demonstration Program or by other specific law (10 CFR 21.b)
- Class 104 c licenses - production or utilization facility
  - which is useful in the conduct of research and development activities, and is not a class 103 facility as specified in the previous slide (10 CFR 50.21.c)

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Reactor Production

- Definitions from 10 CFR 50.2
  - *Non-power reactor* means a research or test reactor licensed under 10 CFR 50.21(c) or 50.22 for research and development.
  - *Research and development* means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

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Reactor Production

- Definitions from 10 CFR 50.2 (cont.)
  - Testing facility means a nuclear reactor which is of a type described in 10 CFR 50.21(c) for which an application has been filed for a license authorizing 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 in which the applicant proposes to conduct 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

Reactor Production

- NRC licensed non-power reactors
  - Research reactors
    - 32 facilities with operating licenses
    - Power levels from 5W to 10 MW
  - One test reactor- National Institute of Science and Technology (NIST) operates at 20 MW
  - All have class 104 c licenses (10 CFR 21.c)
  - One facility is also licensed for medical therapy and has a class 104 a license in addition to the class 104 c license. (10 CFR 21.a)

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Reactor Production

NRC non-power licensing guidance

NUREG-1537, Vol. 1&2, "Guidance for the Preparing and Reviewing Applications for the Licensing of Non-Power Reactors"

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Reactor Production

- Challenges
  - Isotope production typically under Part 50 license then used either under the Part 50 or transferred to a byproduct material license (NRC or Agreement State license)
  - Even though most non-power reactors produce isotopes for research and some for commerce large scale production may require a class 103 license (10 CFR 50.22)

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Accelerator production of Isotopes:

- New authorization in the Energy Policy Act of 2005
- Staggered effective date of the implementing "NARM Rule" from October 2007 to August 2009
- First new license expected October 2008

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Expected Producers:

- Non-Positron Emission Tomography (PET) Isotope Producers –

  Common Isotopes - Commercial producers for industrial, research and development, and medical users

  Exotic isotopes – Universities and Non-DOE Federal Facilities for research and development uses

- Pet Isotope Producers

  Commercial Nuclear Pharmacies

  Hospitals

  Universities

  Non-DOE Federal Facilities

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Agreement States

- 35 States have signed Agreements w/ NRC to regulate nuclear materials.
- Pennsylvania became the 35th Agreement State on March 31, 2008.
- States regulate 80% of the US nuclear materials users. NRC: 20%.

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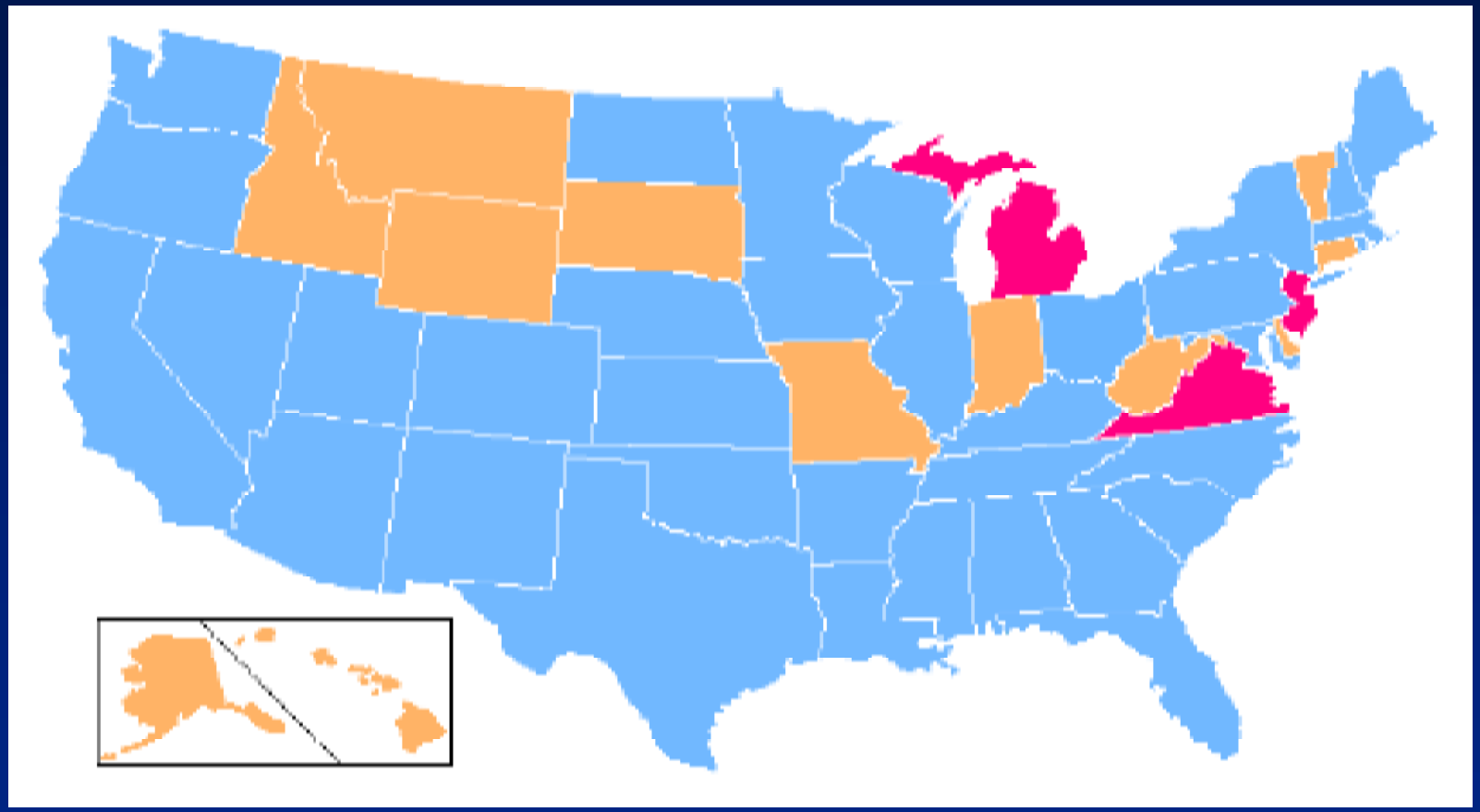
Agreement State Map



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NRC licensing guidance for Accelerator Production of Isotopes

NUREG-1556, Vol. 21, "Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator,"

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