

# Licensing of Ac-225/227 at NRC

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# Outline

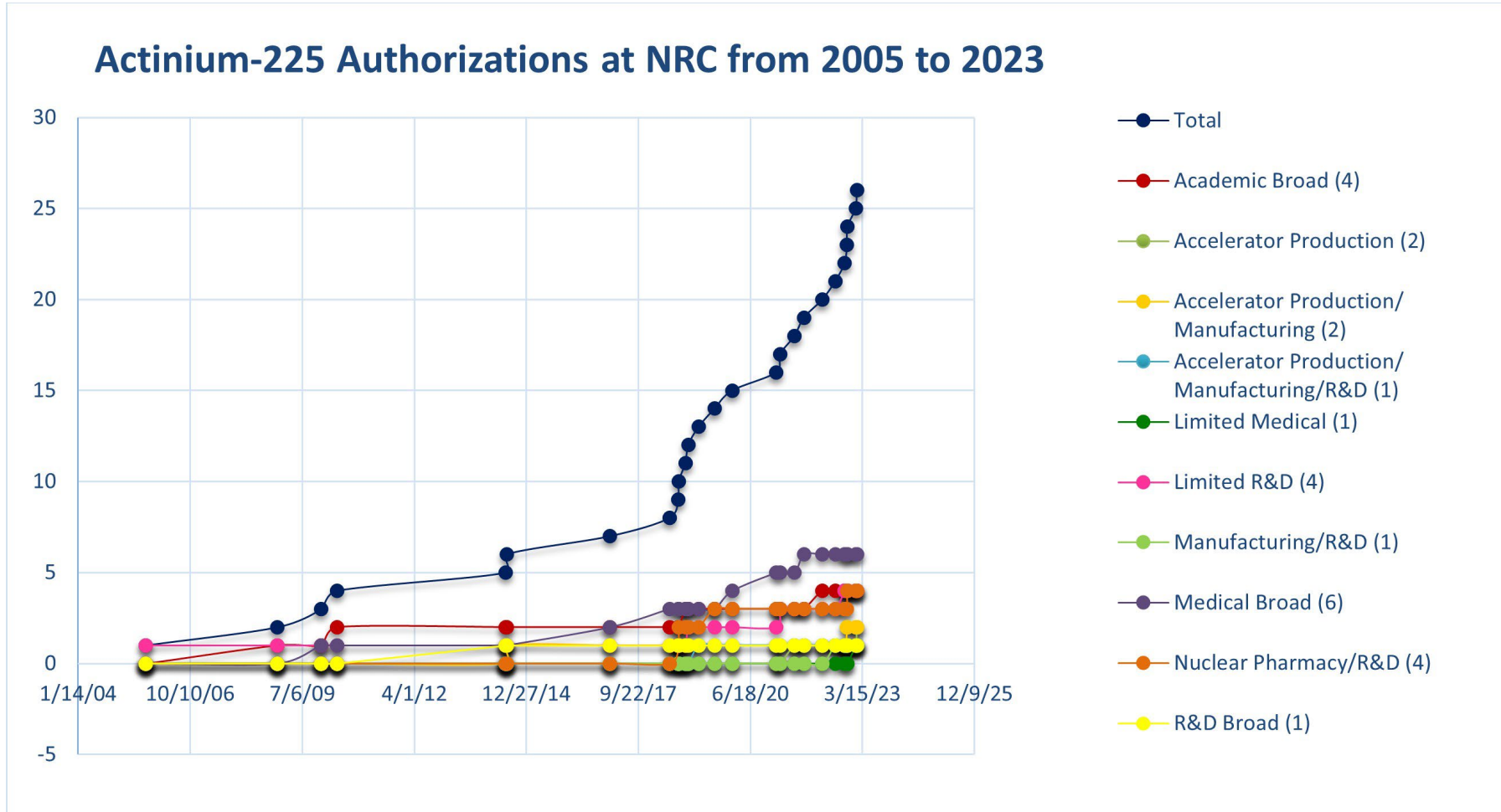
- Licensing Experience at NRC
- Licensing Considerations
  - Decommissioning Financial Assurance
  - Emergency Plan
  - Radiation Safety Program
  - Licensing Conditions

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# Authorizations of Ac-225 at NRC

- **2005 through 2017: 6 licensees**, all have Decommissioning Financial Assurance – Academic, Medical & R&D Broad Scope; also Academic-based limited R&D or Accelerator Production
- **November 2017: 1 medical broadscope licensee** not subject to Financial Assurance added
- **2018 through 2020: 8 additional licensees** including 2 nuclear pharmacy/limited R&D licensees and 1 limited R&D not subject to Financial Assurance authorized
- **2021 through 2023: 11 additional licensees** including 1 limited medical and 1 limited R&D not subject to Financial Assurance authorized

# Expanding Ac-225/227 Authorizations at NRC



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# Licenses that May Authorize Ac-225 or Ac-227

- Ac-225 & Ac-227 both listed: **7** licensees
- Ac-225 not Ac-227: **16** licensees
- Ac-227 not Ac-225: **3** licensees
- 10 CFR 35.200 & 10 CFR 35.300: **632 & 290** licensees
- Any byproduct material with Atomic Numbers including for AN 89 (Actinium): ~ **100** licensees

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# Decommissioning Financial Assurance

- Actinium-227 on the license: When Possession Limit exceeds 10  $\mu\text{Ci}$  ( $10^3$  \* 0.01  $\mu\text{Ci}$ ): At time of licensing, **Financial Assurance is Required**.
  - Atomic Number 1 through 104, or subset thereof (not limited to half-life of less than or equal to 120 days): At Licensing, Require EITHER
    - **Financial Assurance** is Submitted OR
    - **License Condition** limits Possession
  - 10 CFR 35.200 or 10 CFR 35.300: Limit Possession by Condition
  - 10 CFR 30.35: Absent exemption, FA Requirements always apply.
  - Ac-225 on the license: Consider whether impurities exceed FA limits.
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# Emergency Plan

- **10 CFR 30.32(i)(1)**: Applies **When Possession Exceeds 10 CFR 30.72 limits**.
- **10 CFR 30.72 Table**: Ac-225 and Ac-227 are **not Listed**.
  - Default Value for **alpha-emitters**: **2 Curies**
  - Default Value for **beta-emitters**: **10,000 Curies**
- **Requires**:
  - (i)(1)(i): **Evaluation** shows Max Offsite Dose below limits OR
  - (i)(1)(ii): **Emergency Plan** for Responding to Release

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# Radiation Safety Program Considerations

- Dosimetry, Instrumentation, and Alarms: Description
- Ventilation, Air Monitoring, and Release: Description, Assumptions, Parameters, and Adequacy Analysis
- Shielding: Adequacy
- Materials Accountability: Receiving Waste from Customers
- Labeling: As needed
- Other: As needed



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# Decay-in-Storage Waste Program Requirements

- For Medical Use Licensees: 10 CFR 35.92 Specifies
- For Other Licensees: License Condition Specifies
- Limited to Short Half-Lived Materials:
  - Less than or equal to 120 days
  - Exemptions (10 CFR 20.2301)
    - Authorized by Law + No Undue Hazard to Life or Property
- Requires:
  - Radioactivity: Indistinguishable from Background
  - Labels: Removed or Obliterated

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# Other Considerations

- Materials – Authorizations & Impurities
- Personnel – Authorized Individuals & Training Program
- Facilities and Equipment – Locations & Instruments
- Distribution Requirements – Medical vs. Non-medical
- Licensing Site Visits & Initial Inspections
- Other Regulatory Authorities (DOT, FDA, etc.)

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## NRC Regulatory Resources

- NUREG 1556 Series Volumes:
  - (7) Research & Development (including for animal use)
  - (9) Medical (for 10 CFR 35.200, 10 CFR 35.300, etc.)
  - (11) Broad Scope (including Academic, R&D, and Medical)
  - (12) Manufacturing (typically non-medical)
  - (13) Radiopharmacy
  - (21) Accelerator Production
- NUREG 1757 Volume 3: Decommissioning Financial Assurance
- Other

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# Questions

- Questions? Email to:  
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