

Regulatory Requirements for Ac-225/227

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Outline

- Radiation Safety Challenges
- Regulatory Considerations
 - Decommissioning Financial Assurance
 - Licensing
 - Waste
 - Other

Radiation Safety Challenges

Accelerator-produced Ac-225 may contain Ac-227 impurity which can cause substantial challenges:

- Ac-227 impurity can be as high as 2%
- Ac-227 has a long half-life of 21.8 years
 - Waste and Decommissioning Financial Assurance requirements

Regulatory Considerations

- Decommissioning Financial Assurance/Funding Plan
- Licensing
- Waste Disposal

Decommissioning Financial Assurance (DFA)

10 CFR 30.35

- Decommissioning Financial Assurance (DFA) provides reasonable assurance of the availability of funds for decommissioning.
- A decommissioning funding plan (DFP) is a financial assurance requirement that is based on a site-specific detailed cost estimate for decommissioning the licensed facility.
- Financial Assurance is required for licensees authorized to possess byproduct material with half-lives greater than 120 days and in excess of the limits in 10 CFR 30.35, “Financial Assurance and Recordkeeping for Decommissioning.”

Decommissioning Financial Assurance (continued)

For alpha-emitters, such as Ac-227, that are not listed in Part 30 Appendix B, the default quantity of 0.01 microcuries (μCi) is used:

- For \$225,000 financial assurance, the Appendix B value is multiplied by 10^3 :
 $0.01 \mu\text{Ci} \times 10^3 = 10 \mu\text{Ci}$
- For \$1,125,000 financial assurance, the Appendix B value is multiplied by 10^4 :
 $0.01 \mu\text{Ci} \times 10^4 = 100 \mu\text{Ci}$
- For DFP, the Appendix B value is multiplied by 10^5 :
 $0.01 \mu\text{Ci} \times 10^5 = 1 \text{ mCi}$
- Assuming a 2% impurity, financial assurance is required at 0.5 mCi of Ac-225
 $10 \mu\text{Ci Ac-227} / 0.02 = 500 \mu\text{Ci Ac-225}$

Decommissioning Financial Assurance (continued)

- A DFP may be submitted in support of financial assurance amount. In some cases , the financial assurance required for a DFP may be significantly lower than the \$225,000 minimum in financial assurance. This may address some of the concerns raised by small businesses.
- A DFP must cover all areas where radionuclides are used under the same license; not just the area(s) where Ac-225/227 is used.
- Rulemaking underway to revise the Appendix B values – threshold for DFA/DFP would decrease 10-fold.

Licensing Considerations

- Possession Limit
 - Maximum amount licensee may possess at any one time
 - Consider the amount of activity per treatment and stored on site
- Radioactive impurities and decay chain daughter products are not listed on licenses
- Differences from Lu-177m (impurity of Lu-177)
 - Lu-177m (160 day half-life) is a minor contributor
 - Beta-emitter – default value is higher

Waste Disposal

- Waste with a half-life greater than 120 days must be disposed of as low-level radioactive waste. Waste may not be held for decay-in-storage.
- Includes chemical and biological waste contaminated with the long-lived Ac-227 material
 - PPE, absorbent pads, needles, syringes, tubing, infusion equipment, vials, etc.
 - Contamination of equipment or patient treatment spaces?
- Some suppliers or radiopharmacies will allow customers to return waste for disposal.
- Ac-227 is a complex mixture of radionuclides.

Other Considerations

- Agreement State Compatibility
- Options for DFA/DFP
 - Reducing possession limit to below 10 CFR 30.35 limits
 - DFP instead of DFA
 - Exemption (10 CFR 30.11)

Questions

- Questions? Email to:
MedicalQuestions.Resource@nrc.gov