U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

NRC PERSPECTIVES ON EMERGING RADIONUCLIDES

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PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

- Subparts A-C – general information, administrative requirements, and technical requirements
- Subparts D-H – specific requirements for specific uses (training and experience requirements, health and safety procedures)
  - D (35.100, 35.200) – unsealed material, no written directive required
  - **E (35.300) – unsealed material, written directive required**
  - F (35.400) – manual brachytherapy
  - G (35.500) – sealed sources for diagnosis
  - H (35.600) – afterloader, teletherapy, gamma stereotactic radiosurgery
- **Subpart K (35.1000) – new and emerging technology**
- Subpart L – Records
- Subpart M – Reports
- Subpart N - Enforcement

MEDICAL USE AUTHORIZATION

10 CFR 35.390(b)(1)(ii)(G)

(3) Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and…

RADIATION SAFETY AND REGULATORY ASPECTS

- Radionuclide and progeny emissions;
- Radiation detection, monitoring measurements;
- Authorized user training and experience needs;
- Patient administration;
- Patient release considerations;
- Dosage measurement;
- Dose delivery, handling;
- Waste disposal.

RECENT EXPERIENCE

- Radium-223 Dichloride
  - Licensed under 35.300, January 2013
  - Issues: dose calibrator, survey meter, and well counter measurements; long-lived contaminants.

- Lutetium-177 radiopharmaceuticals
  - Licensed under 35.300, June 2018
  - Issues: presence of metastable Lu-177 (half-life of 161 days) exceeds decay in storage criteria.

OTHER CONSIDERATIONS FOR EMERGING RADIONUCLIDES

- Patient dosimetry
  - medical physics involvement
- Extravasation
  - injection quality
- Long-lived contaminants
  - contribution to patient dose
  - waste disposal concern

Questions?

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