Emerging Medical Technologies

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Subpart K – Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

If the emerging medical technology is not specifically addressed in 10 CFR Part 35 Subparts D through H, the staff will form a joint NRC/Agreement State working group to develop licensing guidance describing an acceptable approach for meeting NRC regulations.

If the emerging medical technology is specifically addressed in 10 CFR Part 35 Subparts D through H, the staff may provide additional information to assist in licensing and inspection based on the specific risks associated with the technology.
Examples of Past Reviews

- NorthStar Medical Radioisotopes, LLC RadioGenixTM Molybdenum-99/ Technetium-99m Generator System developed licensing guidance in February 2018
- Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator developed licensing guidance in July 2017
- Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes updated existing licensing guidance in October 2016
- Leksell Gamma Knife® PerfexionTM and Leksell Gamma Knife® IconTM updated existing licensing guidance to incorporate the IconTM device in May 2016
- Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® updated existing licensing guidance (Revision 9) in February 2016
Examples of Past Reviews not 35.1000

Å Lutetium-177 dotatate determined to be licensed under 10 CFR 35.300 in June 2018

Å SalutarisMD® Manual Radionuclide Eye Applicator determined to be licensed under 10 CFR 35.400 in October 2017

Å Radium-223 Dichloride determined to be licensed under 10 CFR 35.300 in January 2013
Examples of In Process Reviews

- **MASEP Infini™** cobalt-60 stereotactic radiosurgery for treating brain tumors and lesions
- **GammaPod™** cobalt-60 stereotactic radiotherapy for treating breast cancer

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- **Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres®** — updating existing licensing guidance (Revision 10)
- **Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™** — updating existing licensing guidance (Revision 1) to address physical presence requirements.
MASEP Infini™

This system is a dedicated external beam irradiation system designed for the non-invasive stereotactic delivery of radiation dose to the head. The system includes a radioactive source body, collimator body, rotating mechanism, shield body, pair of shield doors, and patient couch. The source body houses thirty Co-60 sources, with five sources positioned along each of six helical lines separated by 60 degrees, which rotate via a shaft that rests on a pair of bearings supported by the external shield body. The collimator body houses four sets of differently-sized collimators which are positioned along helical lines separated by 15 degrees and can be rotated with or independently of the source body.
GammaPod™

This system is a dedicated external beam irradiation system designed for the non-invasive stereotactic delivery of radiation dose to the breast. The system includes a radiation treatment delivery unit, the patient immobilization and localization device, treatment control system with a control console, and a treatment planning system. The radiation treatment delivery unit places 36 or 25 Cobalt-60 (Co-60) sources, on a hemispherical structure, to generate either 36 or 25 collimated beams aimed at the common isocenter.
Examples of Anticipated Reviews

Å Phosphorus-32 OncoSil™ microparticles for advanced pancreatic cancer
Examples of Anticipated Reviews

Å Thorium-227 antibody therapy for treatment of lymph node, prostate, and breast cancer
Example of a New Drug and Device Inquiry

Å N-13 Amonia for myocardial perfusion PET Imaging

I Ionetix ION-12SC is a 12 MeV, 10 μA self-shielded superconducting cyclotron.
Thank you!

For more information on emerging medical technologies

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