POLICY ISSUE
(Information)

March 9, 2018 SECY-18-0037

FOR: The Commissioners

FROM: Marc L. Dapas, Director
Office of Nuclear Material Safety and Safeguards

SUBJECT: REVIEW OF THE EMERGING MEDICAL TECHNOLOGIES PROGRAM

PURPOSE:

The purpose of this paper is to provide the Commission with the results of the U.S. Nuclear Regulatory Commission (NRC) staff's review of the emerging medical technologies program. This includes a list of past, in process, and anticipated NRC staff reviews of emerging medical technologies and resource estimates for the reviews to include guidance development. This paper does not address any new commitments.

BACKGROUND:

On April 24, 2002, the U.S. Nuclear Regulatory Commission amended its regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 regarding the medical use of byproduct material and published a final rule in the *Federal Register* (67 FR 20250) which included a new section, "Subpart K – Other Medical Uses of Byproduct Material or Radiation From Byproduct Material." Part 35 Subpart K (10 CFR 35.1000) describes the process to obtain a license, or license amendment, for a new medical use of byproduct material or radiation from byproduct material, which is not addressed in other parts of Part 35 (i.e., an emerging medical technology).

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DISCUSSION:

Due to the growth in medical applications of radioisotopes and advancements in medical technologies for use in diagnosis, therapy, and medical research, it is anticipated that an increase in the number of emerging medical technologies licensed by the NRC will occur. To ensure that the NRC has the resources to conduct timely assessments of these technologies, the staff has reviewed its past and current efforts regarding emerging medical technologies to determine what resources are necessary to evaluate them. The enclosure (non-public) contains an estimate of when the staff expects to begin reviews of these emerging medical technologies and an estimate of the resources needed for this work based on past efforts.

As part of ongoing efforts to remain abreast of emerging medical technologies, the staff conducts outreach to a number of stakeholders. This includes routine engagement with the Advisory Committee on the Medical Uses of Isotopes (ACMUI), as well as interactions with professional societies involved with emerging medical technologies, the manufacturers of emerging medical technologies, the U.S. Food and Drug Administration, and the Agreement States. The staff coordinates internally with the Office of Nuclear Regulatory Research, the regions, and the Office of the General Counsel to determine whether the emerging medical technology is already included in the regulations in 10 CFR Part 35 Subparts D through H (10 CFR 35.100 to 35.600). In addition, the staff may have to assess other issues related to the emerging medical technology such as whether any special safety considerations or waste disposal options to meet 10 CFR Part 20 requirements are necessary. If the emerging medical technology is specifically addressed in 10 CFR Part 35 Subparts D through H, the staff may provide additional information to the regions via a memorandum to assist in licensing and inspection based on the specific risks associated with the technology.

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. The licensing guidance consists of general licensing considerations, specific radiation safety aspects of the emerging medical technology, and training and experience expectations for those authorized to use the technology. The licensing guidance may also be used to inform the development of specific license conditions that are considered necessary for the medical use of the material.

Below is a list of staff reviews that have been conducted in the past 5 years, reviews that are currently in process, and anticipated future reviews.

Summary of Past NRC Staff Reviews

In the past 5 years, the staff has reviewed the following emerging medical technologies and made the following determinations:

- **SalutarisMD® Manual Radionuclide Eye Applicator** – determined to be licensed under 10 CFR 35.400 in October 2017;
- **Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator** – determined to be licensed under 10 CFR 35.1000, developed licensing guidance in July 2017 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17075A488);

- **Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes** – determined to be licensed under 10 CFR 35.1000, updated existing licensing guidance in October 2016 (ADAMS Accession No. ML16197A568);
- **Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™** – determined to be licensed under 10 CFR 35.1000, updated existing licensing guidance to incorporate the Icon™ device in May 2016 (ADAMS Accession No. ML16109A208);
- **Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres®**– determined to be licensed under 10 CFR 35.1000, updated existing licensing guidance (Revision 9) in February 2016 (ADAMS Accession No. ML15350A099);
- **ViewRay™ System for Radiation Therapy** – determined to be licensed under 10 CFR 35.1000, developed licensing guidance in July 2013 (ADAMS Accession No. ML13179A287);
- **Radium-223 Dichloride** – determined to be licensed under 10 CFR 35.300, sent a memorandum to the regions regarding licensing decision in January 2013 (ADAMS Accession No. ML12341A253); and
- **NorthStar Medical Radioisotopes, LLC RadioGenix™ Molybdenum-99/ Technetium-99m Generator System** – determined to be licensed under 10 CFR 35.1000, developed licensing guidance in February 2018 (ADAMS Accession No. ML17338A449).

The full list of emerging medical technologies that have been reviewed by the NRC staff in the past and a link to corresponding documents is available on NRC's Medical Uses Licensee Toolkit Web site (https://www.nrc.gov/materials/miau/med-use-toolkit.html).

Summary of In Process NRC Staff Reviews

The staff is currently in the process of reviewing the following emerging medical technologies:

- **Lutetium-177 dotatate** – determined to be licensed under 10 CFR 35.300, developing a memorandum to the regions to clarify use and address waste issues with long-lived contaminant;
- **Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres®** – updating existing licensing guidance (Revision 10) and issued a draft for comment (ADAMS Accession No. ML17107A375) in the *Federal Register* (82 FR 51655) in November 2017; and
- **Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™** – updating existing licensing guidance (Revision 1) to address physical presence requirements.

Summary of Anticipated NRC Staff Reviews in Fiscal Year (FY) 2020 to FY 2023

Based on information received from various stakeholders, the staff anticipates the following emerging medical technologies to be reviewed by the NRC beginning in FY 2020:

- Phosphorus-32 OncoSil™ microparticles used in radiation therapy for advanced pancreatic cancer;
- Yttrium-90 Radiogel™ brachytherapy device for high-dose treatment of non-resectable tumors;
- MASEP Infini™ cobalt-60 stereotactic radiosurgery for treating brain tumors and lesions;
- GammaPod™ cobalt-60 stereotactic radiotherapy for treating breast cancer;

- Actinium Pharmaceuticals, Inc. Iodine-131 Iomab-B radiolabeled monoclonal antibody used to target white blood cells in preparation for hematopoietic stem cell transplantation in a number of blood cancer indications;
- Iodine-131 metaiodobenzylguanidine used for the diagnosis and treatment of neuroblastoma and some tumors of the adrenal glands;
- Areva Med thorium processing into lead-212 to be used in targeted alpha therapy;
- IRE ELiT Galli Eo® Germanium-68/Gallium-68 generator, which produces the radiochemical gallium-68 that will be used for the production of gallium-68 dotatate that will be used for clinical positron-emission tomography (PET) imaging;
- RadioMedix Germanium-68/Gallium-68 generator, which produces gallium-68 from germanium-68 for radiolabeling of PET tracers;
- Actinium-225 targeted alpha therapy used for treatment of prostate cancer;
- Flurpiridaz F-18 PET myocardial perfusion imaging radiopharmaceutical used to better evaluate certain types of heart disease;
- Radiolabeled nanotechnology (e.g., copper-64) for molecular imaging and internal radiotherapy applications targeting cancer;
- Alpha Tau Medical Radium-224 Alpha Diffusing Alpha Emitters Radiotherapy seeds for skin brachytherapy;
- Phosphorus-32 plaques for intraoperative radiation therapy of spinal tumors; and
- Bayer's Thorium-227 antibody therapy for treatment of lymph node, prostate, and breast cancer.

CONCLUSION:

The staff plans to continue its licensing activities for emerging medical technologies. In addition, the staff plans to include resources needed to review emerging medical technologies in the budget formulation for FY 2020.

RESOURCES:

An estimate of the resources necessary to evaluate emerging medical technologies are addressed in Enclosure 1, "Estimated Resources," which is not publicly available.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

/RA/

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Enclosure:
Estimated Resources

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OFFICE	MSTR	MSTR	MSTR	MSTR	Region I	Region III
NAME	I. Wu	L. Dimmick	D. Bollock	K. Williams	J. Nick for D. Lew	C. Lipa for S. West
DATE	12/28/17	1/2/18	1/8/18	1/23/18	2/2/18	1/26/18
OFFICE	Region IV	OCFO	OGC	MSTR	Tech Ed	NMSS
NAME	K. Kennedy by email	R. Allwein for M. Wylie	E. Houseman for M. Doane	K. Williams		M. Dapas
DATE	2/2/18	1/29/18	2/13/18	2/22/18	2/28/18	3/9/18

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