UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 26, 2019

MEMORANDUM TO: Donna Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

Patty Pelke, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety
Region III

Heather Gepford, Chief
Licensing and Decommissioning Branch
Division of Nuclear Materials Safety
Region IV

FROM: Chris Einberg, Chief ***/RA/***
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Division of Materials Safety, Security, State and Tribal Programs
Office of Nuclear Materials Safety and Safeguards

SUBJECT: LICENSING FOR MEDICAL TECHNOLOGIES GAMMATILE

On July 6, 2018, the GammaTile™ received 510(k) clearance from the U.S. Food and Drug Administration for use as a radionuclide brachytherapy source. GammaTile™ is a collagen-based tile, preloaded by the manufacturer with Cesium-131 (Cs-131) brachytherapy seeds. The tiles are used for treatment of recurrent brain tumors by being implanted into the brain immediately following surgical resection. The tiles are placed by a neurosurgeon under supervision of an Authorized User. Due to the physical characteristics of the collagen-based tile, the U.S. Nuclear Regulatory Commission (NRC) staff reviewed the safety aspects of the medical use of the Cs-131 brachytherapy seeds contained inside the GammaTile™ to determine if this use should be licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, Subpart F, “Manual Brachytherapy” or 10 CFR Part 35, Subpart K, “Other Medical uses of Byproduct Material or Radiation From Byproduct Material.”

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Through its evaluation, the NRC staff determined the radiation safety concerns associated with use of the GammaTile™ are similar to other sutured applicators used in manual brachytherapy. Therefore, the GammaTile™ can be licensed under 10 CFR 35.400. In accordance with 10 CFR 35.400, the Cs-131 sources contained in the GammaTile™ must be listed on an Sealed Source and Device Registry (SSDR) for manual brachytherapy and used in accordance with the radiation safety conditions and limitations described in that SSDR or in research under an active Investigational Device Exemption as described in 10 CFR 35.400(b).

According to the manufacturer, GammaTile™ is placed into the brain by a neurosurgeon, who are generally not authorized users. Therefore, the neurosurgeon must use the material under the supervision of a physician authorized for under 35.400 in accordance with 10 CFR 35.27, "Supervision." As required by 10 CFR 35.27, the authorized user must instruct the neurosurgeon in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material. The neurosurgeon is required to follow authorized user's radiation safety instructions and written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of byproduct material. In addition, the authorized user must complete the written directive in accordance with 10 CFR 35.40.

As the NRC staff concluded the device can be licensed under 10 CFR 35.400, physicians authorized for the use of byproduct material for manual brachytherapy under 10 CFR 35.490, "Training for use of manual brachytherapy sources" are authorized to use, or supervise the use, of the GammaTile™ containing Cs-131 sources for manual brachytherapy. As the tiles become pre-loaded by the manufacturer, the licensee must verify that the Cs-131 sources have been calibrated by the manufacturer in accordance with 10 CFR 35.432, "Calibration measurements of brachytherapy sources."

If the NRC becomes aware of future developments related to the production, distribution, or medical use of the GammaTile™ that may negatively impact radiation safety, the NRC staff will revisit this licensing decision for any additional actions.

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DATED: AUGUST 26, 2019

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