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

January 24, 2020

ALL AGREEMENT STATES

NOTIFICATION OF ISSUANCE OF XCISION® GAMMAPOD™ LICENSING GUIDANCE (STC-20-007)

Purpose: To inform the Agreement States that the Xcision® GammaPod Licensing Guidance was published on January 22, 2020.

Background: On December 22, 2017, the GammaPod™ received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for use as a non-invasive stereotactic radiotherapy system utilizing 36 or 25 Cobalt-60 (Co-60) sources to treat breast cancer. The GammaPod™ system is different from traditional gamma stereotactic radiosurgery units as it uses a vacuum-assisted breast cup immobilization and stereotactic localization system, rotating source and collimator carriers, and table motion during treatment.

A joint Organization of Agreement States and U.S. Nuclear Regulatory Commission (NRC) working group was created to: (1) confirm the need to license the Xcision® GammaPod under Title 10 *Code of Federal Regulations* (CFR) 35.1000 rather than 10 CFR 35, Subpart H, and (2) develop an associated 10 CFR 35.1000 licensing guidance document if necessary.

Discussion: Although GammaPod™ is a gamma stereotactic radiosurgery device, the working group concluded that it includes several engineering changes that make its components and operation significantly different from the gamma stereotactic radiosurgery units currently regulated in 10 CFR 35, Subpart H. These engineering changes include the elimination of helmets, relative helmet factors, helmet microswitches, hydraulic backups, trunnions, and a trunnion centricity point, all of which are described in 10 CFR 35, Subpart H. In addition, the GammaPod's several new engineering features described above were not included in 10 CFR 35, Subpart H. As a result, the working group concluded the Gammapod will need to be licensed under 10 CFR Part 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material," and developed associated licensing guidance.

This licensing guidance is available at http://www.nrc.gov/materials/miau/med-use-toolkit.html.

If you have any questions regarding this correspondence, please contact me at 301-415-0324 or the individual named below:

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State, and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Xcision® GammaPod Licensing
Guidance

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