U.S. Nuclear Regulatory Commission
Advisory Committee on the Medical Use of Isotopes

Subcommittee Review and Comments on

Akesis Galaxy® RTi Draft Licensing Guidance

Draft Report

Submitted on March 6, 2024

Subcommittee Members:

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Background:

The Subcommittee and its Chair were appointed by Advisory Committee on the Medical Uses of Isotopes (ACMUI) Chair, Darlene Metter, on December 8, 2023. The subcommittee charge was to review and comment on the U.S. Nuclear Regulatory Commission (NRC) staff's draft Akesis Galaxy® RTi Licensing Guidance.

Introduction:

The Akesis Galaxy® RTi is a gamma stereotactic radiosurgery (GSR) unit that contains thirty Cobalt-60 sources with approximately 6000 curies (Ci) total initial source activity. The unit is paired with an Image Guidance System (IGS) that uses reference images to move the treatment couch to the correct target position for lesion treatment. During treatment, the radiation sources will be aligned with the user selected secondary collimators. The source and the collimating structures rotate simultaneously during treatment to form thirty non-overlapping convergent 360° gamma ray arcs. All thirty beams are directed towards the target to deliver the desired prescribed dose. The NRC staff has determined that the Akesis Galaxy® RTi is regulated under 10 CFR Part 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation From Byproduct Material." [10 CFR 35.1000].

Discussion:

The subcommittee reviewed the licensing guidance (LG) and provided the following significant comments.

- Section 1. The committee discussed the determination for why the device was licensed under 35.1000. “As a result…” was removed from the last paragraph of the working draft as it’s misleading to indicate the engineering changes were the driver.

- Section 4.1.1, paragraph 2. The subcommittee decided to remove “preparing treatment plans and calculating treatment doses and times” from the Authorized User (AU) training and experience (T&E) requirements.

- Section 4.1.2, paragraph 2. The subcommittee suggested that the statement “In order to function independently as an Authorized Medical Physicist (AMP), the individual shall have demonstrated familiarity with the treatment using both a stereotactic frame and the patient immobilization system which is a frameless system” be added as an AMP T&E requirement. This statement is consistent with Leksell Gamma Kinfe® Perfexion and Leksell Gamma Kinfe® Icon licensing guidance.

- Section 4.2, paragraph 3. The subcommittee recommended that the statement “The written attestation is not required for individuals who hold certification by a recognized specialty board or are not already authorized for use of another Akesis® model or other gamma stereotactic radiosurgery units licensed under 10 CFR 35.600” be added to the attestation for the Radiation Safety Officer (RSO) to be consistent with Leksell Gamma Kinfe® Perfexion and Leksell Gamma Kinfe® Icon licensing guidance.

- Section 5.2. The Subcommittee asked that the following requirement be added as follows “The spot test and full calibration test, *completed and reviewed per 10 CFR 35.645…”*

The Subcommittee discussed the availability of the Sealed Source and Device (SS&D) certificate. The NRC staff indicated that the SS&D was not yet published by California Department of Public Health (CDPH). CDPH has provided NRC’s Medical Safety and Events Assessment Branch (MSEB) a draft of the SS&D during an October 2023 meeting, but that document cannot be shared with the public. It was further stated that the NRC staff would share the SS&D as soon as it was published.

The Subcommittee also discussed the following coming action items:

- Draft Report for Subcommittee Review and Comments on Draft Akesis Galaxy® RTi

- ACMUI Presentation Report for the Akesis Galaxy® RTi Draft Licensing Guidance

Respectfully submitted on March 6, 2024,
Subcommittee on Akesis Galaxy® RTi Guidance
Advisory Committee on the Medical Uses of Isotopes
Nuclear Regulatory Commission