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

August 29, 2024

ALL AGREEMENT STATES, CONNECTICUT, AND INDIANA

NOTIFICATION OF ISSUANCE OF AKESIS GALAXY RTi GAMMA STEREOTACTIC RADIOTHERAPY LICENSING GUIDANCE (STC-24-051)

Purpose: To inform the Agreement States, Connecticut, and Indiana that the U.S. Nuclear Regulatory Commission (NRC) issued the Akesis Galaxy® RTi Licensing Guidance.

Background: On March 5, 2021, the Akesis Galaxy® RTi received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for use as a non-invasive system utilizing thirty (30) Cobalt-60 (Co-60) sources to treat brain lesions. The Akesis Galaxy® RTi is a gamma stereotactic radiosurgery unit with many unique properties that merit radiation safety considerations other than those required by Title 10 of the Code of Federal Regulations (10 CFR) Part 35, Subpart H, "Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units." These unique properties include real-time image-guided radiation therapy (RT-IGRT) accomplished using cone-beam computed tomography. The unit has a selectable, isometrically-focused collimator with sizes as defined by the treatment plan which provides for sub-millimeter accuracy and reproducibility. The system automates the treatment delivery by moving the intra-cranial target to the focal point, while the patient's head is immobilized either with a stereotactic, rigid-fixation headframe or with a mask-based headframe which has been fitted prior to the commencement of treatment. As a result, use of Akesis Galaxy® RTi gamma stereotactic radiosurgery unit is regulated under 10 CFR 35.1000, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."

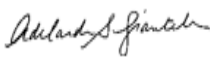
Enclosure 1 provides the final 10 CFR 35.1000 licensing guidance for Akesis Galaxy® RTi (ML24193A113). This guidance lists an approved set of regulations and licensing conditions specific to the Akesis Galaxy® RTi. This guidance should be used in concurrence with NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Material Licenses: Program-Specific Guidance about Medical Use Licenses," which provides overall licensing guidance for all medical uses of byproduct material. Enclosure 2 provides a supporting technical analysis table which includes a list of 10 CFR Part 35 regulations and conditions the NRC has deemed acceptable for the use of Akesis Galaxy® RTi. However, as stated in the licensing guidance, applicants may submit alternative list of regulations and specific conditions to be reviewed on a case-by-case basis.

The attached licensing guidance will be posted on NRC's public Web site (https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html).

If you have any questions regarding this correspondence, please contact me at (301) 415-3521 or the individual named below:

POINT OF CONTACT: Daniel Shaw E-MAIL: daniel.shaw@nrc.gov
TELEPHONE: (301) 415-3649

Sincerely,


Signed by Giantelli, Adelaide
on 08/29/24

Adelaide S. Giantelli, Branch Chief
State Agreement Liaison Programs Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosures:
1. Akesis Galaxy® RTi Licensing Guidance
2. Consolidated Technical Analysis

STC-24-051 NOTIFICATION OF ISSUANCE OF AKESIS GALAXY RTi GAMMA STEREOTACTIC RADIOTHERAPY LICENSING GUIDANCE DATE August 29, 2024

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Akesis Galaxy® RTi Licensing Guidance

August 23, 2024, Revision 0

U.S. Nuclear Regulatory Commission Contact
Daniel Shaw (301) 415-3649
MedicalQuestions.Resource@nrc.gov

Enclosure 1

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1. 10 CFR 35.1000 Use

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. As a result, the surrounding normal tissues will only receive a transient irradiation. The target spot is sometimes referred to as the “focal-spot” or “focus”. Before the treatment, the patient (with head frame or mask attached) will be positioned on the treatment couch. Based on the head frame or mask, CT-scans and/or MRI-scans, the target shape and patient position (X, Y, Z coordinates) will be confirmed. After the operator accepts the treatment parameters, the control system automatically executes the planned treatment. No further operator intervention is required during a normal treatment.

Note, Akesis uses the terms focus, focal-spot, target, and target-spot interchangeably to refer to the focal point.

Although the Akesis Galaxy® RTi is a GSR unit, the device includes several engineering changes that make the components and operation significantly different from the GSR units currently regulated in 10 CFR Part 35, Subpart H, “Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.” These engineering changes include the absence of helmets, relative helmet factors, helmet microswitches, hydraulic backups, trunnions, and a trunnion centricity point. In addition, Akesis Galaxy® RTi engineering changes include:

- A beam-collimating system for collimating, focusing and shielding the radiation beams. The system also consists of a shielding hemisphere, a tungsten-alloy shielding block, 30 rotating radiation sources, a source drawer, and a source carrier.

- A moveable (X, Y, Z) treatment couch that is used with the patient supine during the treatment process that moves the patient so that the target in the treatment plan coincides with the focal point of the device.

- As part of the IGS, the Akesis Galaxy® RTi includes the addition of an x-ray tube system mounted onto the unit to take cone beam computed tomography (CBCT) images to verify patient positioning using reference images.

- The Akesis Galaxy® RTi unit can immobilize the patient’s head with either a rigid-fixation stereotactic head frame or with a mask positioning system. The immobilization of the patient’s head is achieved via the headframe interface system that includes a frame-locking interface assembly (U-Frame) and adapter (L-Frame). The U-frame is permanently fixed to the treatment couch and provides a fixed reference of table position to beam center. When mated to the patient’s headframe, the specified positional accuracy of the beam is achieved by precise table movements. Either an independently 510(k) cleared and compatible mask-based or a rigid-fixation head frame must be properly attached to the head frame interface.

- The Akesis Galaxy® RTi will use the real-time image-guided radiation therapy (RT-IGRT) system to monitor movements of the patient during setup and treatment while immobilized by the head frame interface.

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]

2. Licensing Guidance

This guidance provides applicants with an acceptable means of satisfying the requirements for a license for the use of the Akesis Galaxy® RTi, however, it is not intended to be the only means of satisfying requirements for a license. The applicant must submit the information required by 10 CFR 30.33 and 10 CFR 35.12 as described below. The applicant must submit additional information and commitments requested below or, unless the information is specifically required by regulation, may submit alternative commitments for review by the U.S. Nuclear Regulatory Commission (NRC) staff to determine whether the regulatory requirements are met. The licensee commitments will be incorporated into the applicant's license by license conditions and will be reviewed during routine inspections. If an applicant commits to the guidance provided below, the applicant must follow commitments described with the use of the word "should." This guidance may be revised as additional experience is gained regarding the medical use of the Akesis Galaxy® RTi.

The Akesis Galaxy® RTi makes use of an integrated CBCT imaging system (i.e. the IGS) to ensure the patient is properly positioned for and during treatment. The specific license issued by the NRC does not authorize the licensee to possess and use the CBCT imaging system. This authorization must be obtained from the applicable state agency having jurisdiction over computed tomography scanning equipment. However, because the CBCT is critical to verifying the accuracy of the patient positioning, NRC will require licensees to commit to certain quality assurance (QA) measurements as outlined in the section titled, "Specific Information on Radiation Safety Precautions and Instructions."

Applicants are reminded that licenses issued pursuant to 10 CFR 35.1000[1] must still meet the general requirements in 10 CFR Part 35, Subparts A, B, C, H, L, M and N, except as specified in this guidance. The enclosed consolidated technical analysis table provides guidance on applicable requirements in 10 CFR Part 35. Additionally, applicants must meet applicable requirements of 10 CFR Parts 19, 20, 30, 37 and 71.

Applicants may refer to NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Material Licenses: Program-Specific Guidance About Medical Use Licenses," as it provides overall licensing guidance for all medical uses of byproduct material, including information on how to submit a facility's address and description and applicable model procedures for audits, occupational dose monitoring programs, and surveys.

3. General

[1] Medical uses of byproduct material licensed under 10 CFR 35.1000 are designated as Compatibility Category D. Agreement States are not required to adopt these regulations for purposes of compatibility.

3.1. Sensitive Security-Related Information

Certain sensitive security-related information such as quantities and locations of radioactive materials at licensed facilities are no longer released to the public. Submission of this type of information in an application should be marked as specified in Regulatory Issue Summary 2005-31, Revision 1, "NRC Regulatory Issue Summary 2005-31, Control of Security Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material."

Additional information on procedures handling and marking security-related information and any updates are available at https://www.nrc.gov/reading-rm/sensitive-info.html.

3.2. 10 CFR Part 37

Applicants requesting authorization for the Akesis Galaxy® RTi unit must comply with 10 CFR Part 37 before installing sources for this unit.

Individuals who have not been granted unescorted access in accordance with 10 CFR Part 37 must be escorted at all times, such as individuals who service the CBCT component or are inspecting (i.e., NRC or Agreement State inspectors) the Akesis Galaxy® RTi must be escorted at all times unless they fall under the relief granted under 10 CFR 37.29. For more information, see NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses;" NUREG-2155, "Implementation Guidance for 10 CFR Part 37, 'Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material;'" and NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

3.3. Radionuclides, Form, Possession Limits, and Purpose of Use

Per the requirements of 10 CFR 35.12, the applicant shall identify the radionuclides, chemical/physical form, requested maximum possession limit, and purpose of use. For guidance to meet the requirement, refer to NUREG 1556, Volume 9, Revision 3 "Contents of and Application" additional information. NRC Form 313, "Application for Materials License" may be used to submit this information. The information in the table below provides the suggested format and information for completing Item 5 (Radioactive Material) and Item 6 (Purpose of Use) on the NRC Form 313, "Application for Materials License."

Radionuclides NRC Form 313, Section 5.a.)	Cobalt-60
Chemical/Physical Form (NRC Form 313, Section 5.b.)	Sealed sources (Manufacturer and Model Number, e.g., Nordion (Canada) Inc., Model C-374)
Maximum Possession Limit (NRC Form 313, Section 5.c.)	220 curies per source not to exceed 6600 curies total (or 10000 curies during source exchange)
Authorized Use (NRC Form 313, Section 6)	For 10 CFR 35.1000 medical use in the Akesis Galaxy® RTi gamma stereotactic radiosurgery unit

3.4. Facility Address and Description [10 CFR 30.33(a)(2) and 10 CFR 35.12(b)(1)]

Provide an address of use, submit a facility diagram, and description of the location where the Akesis Galaxy® RTi GSR unit will be used or stored.

4. Training and Experience

4.1. Authorized Individuals [10 CFR 30.33(a)(3); 10 CFR 35.12(b)(1); 35.50; 35.51; and 35.690]

Licensees must have at least one Authorized User (AU), one Authorized Medical Physicist (AMP), and one Radiation Safety Officer (RSO) for medical use of the Akesis Galaxy® RTi to be added to the license. The NRC has determined that individuals meeting the guidance provided below will be considered qualified and authorized for the Akesis Galaxy® RTi GSR unit. Applicants may also submit alternative training and experience commitments to be reviewed on a case-by-case basis by the NRC staff. The alternative information should include an explanation of why the applicant believes the alternative information demonstrates that the individuals are qualified to be authorized individuals.

Because there are minimal Akesis Galaxy RTi units approved for medical use in the United States at the time this licensing guidance is initially being published, there are a limited number of preceptors available to sign attestations. Therefore, the NRC is postponing requiring a written attestation for three years from the publication of this guidance, until August 23, 2027. At that time, attestations will be required for individuals who do not hold certification by a recognized specialty board or are not already authorized for use of other GSR units. The NRC will continue to review the availability of preceptors and may revise this guidance if it determines that sufficient preceptors have not become available. In addition, all individuals seeking authorization for use of the Akesis Galaxy® RTi must submit documentation of successful completion of required device-specific training.

4.1.1. Authorized User

Applicants and licensees should identify each authorized user (AU) of the Akesis Galaxy® RTi GSR unit and provide documentation of their training and experience in the use of the unit. The NRC Form 313A (AUS), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]," or other formats may be used to document this training and experience. The physician will be considered qualified for use of the Akesis Galaxy® RTi GSR unit if the individual meets the following:

1) Is listed on an NRC or Agreement State license (or NRC Master Materials License permit)as an AU for 10 CFR 35.600 medical use of a GSR unit; an AU for 10 CFR 35.1000 medical use of the Akesis Galaxy® RTi; or is board certified by a recognized board listed on the NRC's Web site "Specialty Board Certifications Recognized by NRC Under 10 CFR Part 35" under section 10 CFR 35.690, "Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units," or meets the criteria in 10 CFR 35.690(b)(1) and (2) for GSR unit use;

AND

2) Received documented training in hands-on device operation, safety procedures, and clinical use which includes headframe or mask fitment for the Akesis Galaxy® RTi GSR

unit. If the individual is already an AU for another GSR unit, in accordance with 10 CFR 35.690(c), this training must also include the differences in the device operation, safety procedures, and clinical use of the Galaxy RTi and the other GSR unit(s) that the individual is authorized to use. This training requirement may be satisfied by satisfactory completion of a training program provided by the Akesis vendor or by receiving training supervised by an AU or authorized medical physicist (AMP), as appropriate, who is authorized for the Akesis Galaxy® RTi use;

AND

3) Obtain a written attestation that the individual has satisfactorily completed the above training and is able to independently fulfill the radiation safety related duties as an AU for the Akesis Galaxy RTi unit. The written attestation must be signed by a preceptor AU who is authorized for the Akesis Galaxy® RTi unit. The written attestation is not required for individuals who hold certification by a recognized specialty board or are already authorized for other GSR units.

4.1.2. Authorized Medical Physicists

Identify each AMP for the Akesis Galaxy® RTi GSR unit and provide documentation of his/her training and experience in the use of the unit. The NRC Form 313A (AMP), "Authorized Medical Physicist Training and Experience and Preceptor Attestation [10 CFR 35.51]," or other formats may be used to document this training and experience. The medical physicist shall be considered qualified for use of the Akesis Galaxy® RTi GSR unit, if the individual meets the following:

1) Is listed on an NRC or Agreement State license (or NRC Master Materials License permit) as an AMP for GSR unit use; or is board certified by a board listed on the NRC's Web site "Specialty Board Certifications Recognized by NRC Under 10 CFR Part 35" under section 10 CFR 35.51, "Training for an Authorized Medical Physicist;" or meets the criteria in 35.51(b)(1) and (2) for GSR unit use;

AND

2) Received documented training in hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system for the Akesis Galaxy® RTi unit. If the individual is already an AMP for a GSR unit, in accordance with 10 CFR 35.51(c), this training must also include the differences in the device operation, safety procedures, clinical use, and the operation of a treatment planning system of the Akesis Galaxy® RTi and other GSR units for which the individual is authorized. In order to function independently as an AMP, the individual shall have demonstrated familiarity with the treatment using both a headframe and mask positioning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the Akesis vendor or by training supervised by an AMP authorized for Akesis Galaxy® RTi use;

AND

3) Obtained a written attestation that the individual has satisfactorily completed the above training and is able to independently fulfill the radiation safety-related duties as an AMP for the Akesis Galaxy® RTi unit. The written attestation must be signed by a preceptor

AMP authorized for the Galaxy RTi unit. The written attestation is not required for individuals who hold certification by a recognized specialty board or are already authorized for other GSR units.

4.2. Radiation Safety Officer

Identify the Radiation Safety Officer (RSO) with responsibility for the Akesis Galaxy® RTi GSR unit and provide documentation of his/her training and experience in radiation safety for the unit. NRC Form 313A (RSO), "Radiation Safety Officer Training and Experience and Preceptor Attestation [10 CFR 35.50]," or other formats may be used to document this training and experience. The NRC recognizes that some applicants with new installations could have an individual who will have RSO responsibilities for the Akesis Galaxy® RTi unit but may not have access to an operational unit at the time of the radiation safety, regulatory issues, and emergency procedures training. For this reason, the applicant may commit that the individual will complete supplemental hands-on radiation safety and emergency procedure training before first patient treatment using the GSR unit. The individual shall be considered qualified to be the RSO for the Akesis Galaxy® RTi GSR unit if the individual meets the following:

1) Is listed as an RSO on an NRC or Agreement State license (or NRC Master Materials License permit) authorizing GSR unit medical use, or is board certified by a board listed on the NRC's Web site "Specialty Board Certifications Recognized by NRC Under 10 CFR Part 35" under section 10 CFR 35.50, "Training for Radiation Safety Officer," or meets the criteria 35.50(b)(1), or 35.50(c)(1) or (2) for GSR unit use;

AND

2) Received documented training in the radiation safety, regulatory issues, and emergency procedures for the Akesis Galaxy® RTi GSR unit. If the individual already has RSO responsibilities for a GSR unit, in accordance with 10 CFR 35.50(e), the training must also include instruction in the differences in the radiation safety, regulatory issues, and emergency procedures of the Akesis Galaxy® RTi unit and other GSR units for which the individual has RSO responsibility. This training requirement may be satisfied by completing training that is provided by the Akesis vendor or supervised by an individual (RSO or AMP or AU) that is authorized for the Galaxy RTi unit. The individual should complete or commit to complete supplemental hands-on radiation safety and emergency procedures training on an operational Akesis unit before first use of the unit for patient treatment;

AND

3) Obtained a written attestation that the individual has satisfactorily completed the above training and is able to independently fulfill the radiation safety-related duties as a RSO for the medical use of the Akesis Galaxy® RTi GSR unit. The written attestation must be signed by a preceptor RSO, AMP, or AU authorized for the Akesis unit. The written attestation is not required for individuals who hold certification by a recognized specialty board or are already authorized for use of another GSR unit licensed under 10 CFR 35.600 or 10 CFR 35.1000.

5. Licensing Commitments

5.1. Written Directive: [10 CFR 35.40]

The Akesis Galaxy® RTi stereotactic radiosurgery unit delivers a therapeutic dose of radiation from byproduct material and under 10 CFR 35.40 requires a written directive. Calculation of the dose to the treatment site is dependent on the shaping of the radiation field at the focal point by selection of different collimators. Therefore, to assure the dose is delivered in accordance with the AU's direction, the written directive should include the collimator specifications, the treatment plan of the single shot or the multi-shot irradiation according to the position and coordinates of the target. The applicant should provide the following commitment:

> "For the Akesis Galaxy® RTi GSR unit use, the written directive will contain the patient or human research subject's name; the total dose; the treatment site; dose per fraction; number of fractions; and the X, Y, Z target coordinate values; gamma angle; beam rotation start and stop angle and collimator size for each treatment shot within an anatomically distinct treatment site."

When a written directive is needed, licensees are required under 10 CFR 35.41(a)(2) to have procedures that provide high confidence that each administration is in accordance with the written directive. Under 10 CFR 35.41(b)(4) these procedures are required to address, among other things, verification that any computer-generated dose calculations are correctly transferred into the control system of GSR units authorized by 10 CFR 35.600. This verification is also applicable to GSR units regulated under 10 CFR 35.1000. For the Akesis Galaxy® RTi GSR unit, the computer-generated dose calculations for each shot (i.e., each set of target coordinates) should also include the collimator settings for that shot. For this reason, the applicant should provide the following commitment:

> "For the Akesis Galaxy® RTi GSR unit, procedures that provide high confidence that each administration is in accordance with the written directive will address verification that any computer-generated dose calculations are correctly transferred into the Akesis Galaxy® RTi control system."

A number of medical events with earlier models of GSR units resulted from movement of the head frame or head frame pins during coughing and other patient movement. As part of its program to provide high confidence that the administration is in accordance with the written directive, the applicant should develop written procedures for the following: (1) pausing treatment and checking the patient set-up if a patient is observed to move during the course of a treatment shot and (2) visually checking the patient set up each time the gamma angle is changed or at the end of the treatment run, whichever comes first.

The applicant should confirm the following for the Akesis Galaxy® RTi:

> "In order to provide high confidence that the administration is in accordance with the written directive our program will include written procedures for: (1) verification of the integrity of the fixation before starting the treatment (2) pausing treatment and checking the patient set-up if a patient is observed to move during the course of a treatment and every time the RT-IGRT system pauses the system due to patient movement outside the set limit and (3) visually checking the patient set up each time the gamma angle is changed or at the end of the treatment run, whichever comes first."

5.2. Specific Information on Radiation Safety Precautions and Instructions: [10 CFR 35.12(d)(3)(i)]

The applicant must submit the information required by 10 CFR 35.12(d). Because the Akesis Galaxy® RTi unit is a GSR unit, the applicant may simplify its submission by confirming the following:

> "For use of the Akesis Galaxy® RTi , we will meet the following requirements for a GSR unit in 10 CFR Part 35, Subpart H:
>
> Section 35.600,
>
> Section 35.605 (and retain records of the information described in Section 35.2605 for 3 years),
>
> Section 35.610 (and retain procedures described in Sections 35.610(a)(4) and (d)(2) for the retention period stated in Section 35.2610, and retain instructions described in 35.610(d) for the retention period stated in Section 35.2310.
>
> Section 35.615 (a) through (d), 35.615(f)(4), and 35.615(g)
>
> Section 35.615(f)(3) (with the modifications listed below),
>
> Section 35.630 (and retain a copy of the information described in Section 35.2630 for the duration of the license),
>
> Section 35.635 (with modifications discussed below and retain a copy of the information described in Section 35.2632 with modifications discussed below for the retention period of 3 years),
>
> Section 35.645 (with modifications discussed below and retain a copy of the information described in Section 35.2645 with modifications discussed below for 3 years),
>
> Section 35.652 (with modifications discussed below and retain a copy of the information described in Section 35.2652 with modifications discussed below for the duration of the use of the unit),
>
> Section 35.655, (and retain records of the inspection as described in Section 35.2655), and
>
> Section 35.657.

Unlike earlier GSR units, the sources in the Akesis Galaxy® RTi unit are in a movable source drawer. Therefore, radiation surveys required in 10 CFR 35.652(b) will be required following any repairs to the source driving unit or to other electronic or mechanical component that could expose the source, reduce the shielding around the sources, or compromise the radiation safety of the unit or the sources. The driving unit includes a motor and gearbox for the outer, primary collimator (source carrier), a motor and gearbox for the inner, secondary collimator, feedback encoders for both, secondary feedback encoders, a position indicator, tensioners, timing belts, and two electromagnetic clutch brakes. The system determines the relative position of the

secondary collimator and the source carrier through the position information feedback from the motor encoders. The system compares the information from the motor encoders to determine whether the rotating hemispheres' relative position is consistent with the treatment plan and to trigger an interlock should an inconsistency occur. The tensioners are designed to adjust the tension of the timing belts. The manufacturer states that the timing belts must be replaced annually by Akesis service personnel.

The spot test and full calibration test, completed and reviewed per 10 CFR 35.645, should include assessing whether the patient docking systems function correctly to place the mechanical center) of the stereotactic frame at the radiation focal point, to know the size of the radiation focal point by confirming the collimator sizes, and to test the precision with which the treatment site could be placed at the radiation focal-spot and the accuracy of the dose calculations. New tests should be performed as part of the revised spot test and full calibration test to assess these basic properties for the Akesis Galaxy® RTi unit.

Some of the calibration measurements required under 10 CFR 35.635 and 35.645 cannot be performed and the results of such determinations and tests cannot be recorded as described in 10 CFR 35.2632 or 35.2645 because the components specified in those regulatory provisions do not exist in the Akesis Galaxy® RTi unit. For example, for treatment with the Akesis Galaxy® RTi unit, the patient's head is either immobilized with the aid of a stereotactic head frame or with the aid of a double shell mask that is uniquely shaped to each patient. Regardless of the method of immobilization, the patient's head is attached in an "immovable" position to the treatment couch, and the treatment couch itself is moved (X, Y, and Z directions) over small distances to center the treatment site at the radiation focal-spot.

The individual removable collimator helmets in earlier GSR units have been replaced by one collimator body which consists of 4 different size collimators and they all rotate together. The sources, housed in a source drawer, and the collimating structures rotate simultaneously during treatment to form thirty non-overlapping convergent 360° gamma ray arcs. The collimator system contains four different sets of fixed collimator apertures (4 mm, 8 mm, 14 mm, and 18 mm) as well as shielded position (Beam-off). The collimator aperture is set so that the focal point remains constant independent of the collimator used. Therefore, the location and function of the collimators, the patient bed, the docking device, the frame adapter, the mask adapter, and the source exposure indicator light on the device are critical to the safe use and proper functioning of the Akesis unit and should be tested as part of the spot-checks (referred to as QA checks in the operator's manual) and full calibration test. Also, the condition and function of the clearance test tool and QA test tool are critical to determine the location of the radiation focal point, table location, and frame adapter function. For Akesis unit, the verification of the accuracy of the patient positioning with the CBCT is critical and therefore the QA measurements described in the vendor-supplied Instructions for Use shall be performed exactly as stated.

The Akesis Galaxy® RTi will use the real-time IGS to monitor movements of the patient during setup and treatment while immobilized by the mask. The imaging focus of IGS coincides with the focal-spot of the treatment device. The equipped IGS can register the acquired images with the reference images in the treatment plan and send the position deviation to the Recording and Verification System (RVS). According to the position deviation sent by IGS, the control system moves the treatment couch to the correct target position, and then treatment can be performed. The RVS will pause the patient treatment in the event that the treatment couch position is out of tolerance during the irradiation process by ±0.5 mm in X, Y, and Z directions.

The applicant should confirm the following for the Akesis Galaxy:

“We will follow the survey requirements of 10 CFR 35.652 and make the surveys at installation of a new source and following repairs to the driving unit or other electronic or mechanical component that could expose the source, reduce the shielding around the sources, or compromise the radiation safety of the unit or the sources. The driving unit includes a motor and gearbox for collimating structure, a motor and gearbox for the source carrier, position indicating device, a tensioner, and two clutch brakes. The two driving devices are used to drive the collimating structure and source carrier, respectively. We will retain information described in Section 35.2652 for the period stated in Section 35.2652.”

“We will follow the applicable full calibration requirements of 10 CFR 35.635 and the spot-check requirements in 10 CFR 35.645 and retain the information described in 10 CFR 35.2632 for each full calibration and 10 CFR 35.2645 for each check except for those involving helmets, helmet factors, helmet micro-switches, trunnions, and hydraulic backup of the treatment table retraction system. We will keep each record of the full calibration and spot-checks for 3 years.”

“Before the first use of the Akesis Galaxy® RTi unit each day, we will confirm that the docking device is securely mounted to the treatment couch (table) and that the frame adapter can be correctly docked in the docking device. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Akesis Galaxy® RTi unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.”

“Before each patient use, and when the patient is immobilized with the stereotactic U-frame, we will confirm that the L-frame adapter is functioning correctly and can be attached correctly to the coordinate frame. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Akesis Galaxy® RTi unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.”

“Before each patient use, and when the patient is immobilized with a mask, we will confirm that the mask fits the patient’s head, the mask adapter is functioning correctly and can be attached correctly to the docking device. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Akesis unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.”

“Before each patient use of the Akesis Galaxy® RTi unit, we will confirm that the Image Guidance System (IGS) is working properly. This is done by verifying that a IGS starts real-time image guidance through use of the Akesis provided phantom. The test will also be performed during the full calibration measurements of the Akesis Galaxy® RTi unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.”

“Before the first use of the Akesis unit each day, when using the cone beam computed tomography (CBCT) system during patient setup, we will confirm that the precision of the CBCT system is within the specifications provided by the manufacturer. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Akesis unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.”

“On a monthly basis, we will confirm that the location of the radiation focal point (isocenter accuracy), with respect to the treatment couch position, is within the specifications provided by the manufacturer. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Akesis Galaxy® RTi unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.”

“On a monthly basis, we will confirm that the location of the treatment couch at a number of off-center positions is within the collision specifications provided by the manufacturer. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Akesis Galaxy® RTi unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.”

“On a monthly basis, we will confirm that the CBCT image quality is satisfactory. The description of the test and the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Akesis Galaxy® RTi unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.”

“Approximately every six months (with exact date subject to vendor service availability), we will confirm that the beam collimating system is within appropriate tolerance limits. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Akesis Galaxy® RTi unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.”

“During installation and approximately every six months (with exact date subject to vendor service availability, i.e., planned maintenance), we will confirm that the vendor will verify that the location of the radiation focal point, with respect to the treatment couch, is within the specifications using measurements conducted in an off-centered position. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Akesis Galaxy® RTi unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.”

“Every year, we will have the timing belt replaced by Akesis service personnel.”

“We confirm that if the frame adapter or mask adapter fails to perform as designed, we will remove it from service until repaired.”

"We confirm that if the source carrier or treatment couch positioning fail to perform as designed, we will lock the control console in the off position and not use the unit except as necessary to repair, replace, or check the malfunctioning system."

"We confirm that removal or major repair of the components associated with the source carrier and collimator assemblies will be considered a major repair of the source assembly and will require full calibration."

"We confirm that if the CBCT-system and/or the IGS system fails to function as specified by the manufacturer, we will have the system(s) repaired or replaced before the next patient treatment requiring the proper function of these system."

5.3. Physical Presence Required by 35.615(f)(3)

As stated in 10 CFR 35.615(f)(3), an AU and an AMP are required to be physically present throughout all patient treatments involving GSR units. However, the Akesis Galaxy® RTi unit has additional safety functions and utilizes a completely automated treatment system to deliver dose to the patient. Internal collimation alleviates the need to change collimator helmets and patients are positioned as required by the treatment plan by moving the treatment couch. The CBCT and IGS ensure the patient is properly positioned prior to treatment and any movement during treatment causes the sources to move to the "blocked" position. An auto dry-run test is accomplished prior to patient treatments. The Akesis Galaxy® RTi has twenty-two (22) independent interlocks to ensure patient safety during the treatment. These interlocks ensure the room is safe, the patient is in the proper position and secure, and that the beam and collimators are in position and indicated per TPS. As such, the physical presence of the AU throughout all patient treatments is unnecessary for the Akesis Galaxy® RTi unit, provided an AMP and a physician, under the supervision of an AU, are present throughout the duration of all treatments.

Therefore, Akesis Galaxy® RTi unit licensees should confirm they are meeting the requirements in 10 CFR 35.615(f)(3) or the following:

1) An AU and an AMP will be physically present during the initiation of all patient treatments involving the Akesis Galaxy® RTi unit;

2) An AMP and either an AU or a physician, under the supervision of an AU, who has been trained in the operation and emergency response for the unit, will be physically present during continuation of all patient treatments involving the Akesis Galaxy® RTi unit; and

3) An AU will return to the Akesis unit console if there is an interruption of treatment to evaluate the patient, to review any information related to an abnormal situation, and to ensure that the treatment is being delivered in accordance with the treatment plan and written directive prior to re-initiation of the treatment.

5.4. Procedures required by 10 CFR 35.610 and 35.645 [10 CFR 30.33(a)(3) and 10 CFR 35.12(b)(2)]

The applicant is required by 10 CFR 35.12(b)(2) to provide the procedures in 10 CFR 35.610, 35.642, 35.643, and 35.645, as applicable. For the Akesis Galaxy® RTi radiation safety program only the procedures in 10 CFR 35.610 and 35.645 are appropriate.

The Akesis Galaxy RTi unit does not have helmet microswitches or trunnion centricity. Therefore, the applicant will not be required to provide spot-check procedures for those particular components. However, the applicant should provide additional daily spot-check procedures for proper operation of the frame adapter or mask adapter docking device, additional monthly spot-check procedures for the location of the radiation focal point with respect to the treatment couch position, and collision table location, and a six month spot-check procedure (with exact date subject to vendor service availability) for verification of correct sector movement and location.

The applicant must provide a copy of:

- Safety procedures and instruction for the Akesis Galaxy® RTi unit, and
- Spot-check procedures for unit.

5.5. Published Protocols Accepted by Nationally Recognized Bodies

Full calibration measurement procedures for GSR units are required by 10 CFR 35.635(d) to be performed in accordance with published protocols accepted by nationally recognized bodies. However, the Akesis Galaxy® RTi unit contains components and features that are not addressed in the full calibration procedures accepted and published by nationally recognized bodies. In this case, the applicant may use procedures developed by the manufacturer.

The applicant should confirm the following:

> "We will perform full calibration measurement procedures in accordance with published protocols accepted by nationally recognized bodies, except when nationally recognized bodies have not published required full calibration procedures for components and features of the Akesis Galaxy® RTi unit. In the absence of published protocols for the Akesis Galaxy® RTi unit accepted by nationally recognized bodies, we will use procedures developed by the manufacturer."

5.6. Full Inspection and Service of the Akesis Galaxy® RTi Unit [10 CFR 35.655]

The NRC requires the full inspection and servicing of GSR units to assure proper functioning of the source exposure mechanism and other safety components. While a number of systems external to the radiation vault can be inspected and serviced prior to source replacement, areas inside the vault can only be inspected and serviced in the absence of the sources. Therefore, the full inspection and service of the Akesis Galaxy® RTi unit can only be performed at source exchange.

The applicant should confirm the following:

> "We will commit to have each Akesis Galaxy® RTi GSR unit fully inspected and serviced during source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed 7 years for each unit."
>
> This inspection and servicing will only be performed by persons specifically licensed and authorized to do so by the Commission or an Agreement State.

We will retain records of the information described in Section 10 CFR 35.2655 for the duration of use of the unit."

6. Notes to Licensees

6.1. Alterations to the Akesis Galaxy® RTi

This licensing guidance is based on the sealed source and device (SS&D) safety evaluation in registration certificate CA-1511-D-101-S. Modification of the sources, the device (including the CBCT approved in the SS&D certificate), or the source-device combination, will require an amended SS&D certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use and safety of the modified Akesis unit.

6.2. Changes in Physical Conditions of Use

If the physical conditions of use exceed those reported in the SS&D certificate, the limited specific medical use licensee should request an amendment for the new conditions, and a broad scope licensee should perform its own engineering and radiation safety evaluation addressing those differences.

6.3. Notification for AUs and AMPs

The NRC recognizes that if an AU or AMP satisfies the training and experience listed in the NRC's licensing guidance for the Akesis Galaxy® RTi unit and is currently listed on a Commission or Agreement State medical use license or permit for the GSR unit, the AU or AMP should be allowed to work under a different license for the medical use of the Akesis Galaxy® RTi unit. A limited specific medical use applicant initially applying for authorization for the medical use of the Akesis Galaxy® RTi unit or an existing licensee applying for an amendment may request authorization to notify the NRC in the future that it has permitted an AU to work at its facility without the need to request an additional license amendment, provided the following conditions are met:

1) The AU or AMP meets the training and experience criteria listed in NRC's licensing guidance for the Akesis Galaxy® RTi unit;

2) The AU or AMP is currently listed for the Akesis Galaxy® RTi unit use on a Commission or Agreement State license, a permit issued by a Commission master material license, a permit issued by a Commission or Agreement State licensee of a broad scope, or a permit issued by a Commission master material license broad scope permittee;

3) The licensee provides NRC a copy of the license or permit on which the AU or AMP was originally listed for the Akesis Galaxy® RTi unit; and

4) The licensee provides documentation to NRC for each AU or AMP of the above listed conditions no later than 30 days after the date that the licensee allows the AU or AMP to work as an AU or AMP for the Akesis Galaxy® RTi unit.

If this authorization is approved, these notification conditions will be incorporated as license conditions in the licensee's license.

6.4. Revisions to Existing Akesis Galaxy® RTi Radiation Safety Programs to Conform to Future Changes in Licensing Guidance and Additional Safety Recommendations from the Manufacturer

Requesting authorization in accordance with this guidance will permit a licensee to make certain changes under 10 CFR 35.26, "Radiation protection program changes," to the Akesis Galaxy® RTi GSR unit safety program that might otherwise require a license amendment.

This licensing guidance and safety recommendations from the manufacturer may be revised as the regulator and manufacturer gain additional experience regarding medical use of the Akesis Galaxy® RTi GSR unit. Therefore, in contrast to 10 CFR 35.26, a licensee already authorized to use the Akesis Galaxy® RTi GSR unit and committed by license condition to follow the provisions in this guidance and the operators' manual existing at the time of commitment must apply for and receive an amendment to its license prior to making changes to conform to the revised guidance and additional radiation safety recommendations.

An applicant initially applying for authorization for medical use of the Akesis Galaxy® RTi GSR unit (or a licensee applying for an amendment to conform with this revision of the guidance) may request authorization to allow future changes to its radiation safety program, provided the following conditions are met:

1. The revision is in compliance with the regulations of the NRC or Agreement State;

2. The revision is based upon NRC's current guidance for the Akesis Galaxy® RTi GSR unit medical use under 35.1000 use posted on the NRC web site or the current operators' manual and additional safety recommendations from the manufacturer;

3. The revision has been reviewed and approved by the licensee's RSO and management;

4. The affected individuals are instructed on the revised program before the change is implemented;

5. The licensee will retain a record of each change for 5 years; and

6. The record will include a copy of the appropriate licensing guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee's management representative who reviewed and approved the change.

If the NRC approves this authorization, these conditions will be incorporated as license conditions in the licensee's license. This may be done by incorporating the commitments in the tie down condition.

7. Note to Regulators

7.1. Inspection Frequency

Licenses authorizing Akesis Galaxy® RTi units should be inspected every two years. Per Enclosure 1 to Inspection Manual Chapter 2800, licenses authorizing emerging technology in

10 CFR 35.1000 are assigned a Priority 2 inspection code.

7.2. Program Code

The NRC regions should use program code 02240.

8. Paperwork Reduction Act Statement

The information collections contained in this guidance are covered by the requirements of 10 CFR Parts 30, 32 and 35, which were approved by the Office of Management and Budget (OMB), approval numbers 3150-0017, 3150-0001, and 3150-0010, as well as, 3150- 0120 for filling out the NRC Form 313.

9. Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement, unless the requesting document displays a currently valid OMB control number.

Appendix

Consolidated Technical Analysis

The following table provides a list of 10 CFR Part 35 regulations and conditions the NRC has determined are applicable for use of Akesis Galaxy RTi. Licensees shall comply with all regulations which address use of Akesis Galaxy RTi. The table also provides specific regulations and conditions which the NRC has determined are necessary for the medical use of Akesis Galaxy RTi. Applicants may submit alternative list of regulations and specific conditions to be reviewed on a case-by-case basis by NRC staff.

Section	Description	Regulation Applicable to Akesis	Deviation Explanation and Specifics for Licensing Guidance
Subpart A – General Information			
35.1	Purpose and scope	☒Yes ☐No ☐N/A	
35.2	Definitions	☒Yes ☐No ☐N/A	
35.5	Maintenance of records	☒Yes ☐No ☐N/A	
35.6	Provisions for the protection of human research subjects	☒Yes ☐No ☐N/A	
35.7	FDA, other Federal, and State requirements	☒Yes ☐No ☐N/A	
35.8	Information collection requirements: OMB approval	☒Yes ☐No ☐N/A	
35.10	Implementation	☒Yes ☐No ☐N/A	
35.11	License required	☒Yes ☐No ☐N/A	
35.12	Application for license, amendment, or renewal	☒Yes ☐No ☐N/A	
35.13	License amendments	☒Yes ☐No ☐N/A	
35.14	Notifications	☒Yes ☐No ☐N/A	
35.15	Exemptions regarding Type A specific licenses of broad scope	☒Yes ☐No ☐N/A	
35.18	License issuance	☒Yes ☐No ☐N/A	
35.19	Specific exemptions	☒Yes ☐No ☐N/A	
Subpart B – General Administrative Requirements			

Section	Description	Regulation Applicable to Akesis	Deviation Explanation and Specifics for Licensing Guidance
35.24	Authority and responsibilities for the radiation protection program	☒Yes ☐No ☐N/A	
35.26	Radiation protection program changes	☐Yes ☒No ☐N/A	Standard 10 CFR 35.1000 language will be added.
35.27	Supervision	☒Yes ☐No ☐N/A	
35.40	Written directives (WDs)	☐Yes ☒No ☐N/A	A written directive (WD) is required to be followed but the specifications of the WD are different as provided in the guidance. The WD will contain the patient or human research subject's name; the total dose; the treatment site; dose per fraction; number of fractions; and the X, Y, Z target coordinate values; gamma angle; beam rotation start and stop angle and collimator size for each treatment shot within an anatomically distinct treatment site.
35.41	Procedures for administrations requiring a WD	☒Yes ☒No ☐N/A	Requirements in 10 CFR 35.41 can be followed but additional commitments should be included as listed in the guidance. For the Akesis Galaxy® RTi GSR unit, procedures that provide high confidence that each administration is in accordance with the WD will address verification that any computer-generated dose calculations are correctly transferred into the Akesis Galaxy® RTi control system.

Section	Description	Regulation Applicable to Akesis	Deviation Explanation and Specifics for Licensing Guidance
35.49	Suppliers for sealed sources or devices for medical use	☒Yes ☐No ☐N/A	SS&D to be issued by CDPH.
35.50	Training for Radiation Safety Officer (RSO) and Associate RSO	☒Yes ☐No ☐N/A	Will mirror regulations but updated for 10 CFR 35.1000.
35.51	Training for an authorized medical physicist (AMP)	☒Yes ☐No ☐N/A	Will mirror regulations but updated for 10 CFR 35.1000.
35.55	Training for an authorized nuclear pharmacist (ANP)	☐Yes ☐No ☒N/A	
35.57	Training for experienced RSO, teletherapy or medical physicist, AMP, authorized user (AU), nuclear pharmacist, and ANP	☒Yes ☐No ☐N/A	Member(s) must have device specific training per 10 CFR 35.690(c).
35.59	Recentness of training	☒Yes ☐No ☐N/A	
Subpart C – General Technical Requirements			
35.60	Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material	☒Yes ☐No ☐N/A	
35.61	Calibration of survey instruments	☒Yes ☐No ☐N/A	
35.63	Determination of dosages of unsealed byproduct material for medical use	☐Yes ☐No ☒N/A	.
35.65	Authorization for calibration, transmission, and reference sources	☒Yes ☐No ☐N/A	
35.67	Requirements for possession of sealed sources and brachytherapy sources	☒Yes ☐No ☐N/A	
35.69	Labeling of vials and syringes	☒Yes ☐No ☐N/A	
35.70	Surveys of ambient radiation exposure rate	☒Yes ☐No ☐N/A	
35.75	Release of individuals containing unsealed byproduct material or implants containing byproduct material	☒Yes ☐No ☐N/A	
35.80	Provision of mobile medical service	☐Yes ☐No ☒N/A	
35.92	Decay-in-storage	☐Yes ☐No ☒N/A	The licensee will not be allowed to have decay in storage for unused Akesis Co-60 material.

Section	Description	Regulation Applicable to Akesis	Deviation Explanation and Specifics for Licensing Guidance
Subpart D – Unsealed Byproduct Material – Written Directive Not Required			
35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a WD is not required	☐Yes ☐No ☒N/A	
35.190	Training for uptake dilution, and excretion studies	☐Yes ☐No ☒N/A	
35.200	Use of unsealed byproduct material for imaging and localization studies for which a WD is not required	☐Yes ☐No ☒N/A	
35.204	Permissible Mo-99, Sr-82, Sr-85 concentrations	☐Yes ☐No ☒N/A	
35.290	Training for imaging and localization studies	☐Yes ☐No ☒N/A	
Subpart E – Unsealed Byproduct Material – WD Required			
35.300	Use of unsealed byproduct material for which a WD is required	☐Yes ☐No ☒N/A	
35.310	Safety instruction	☐Yes ☐No ☒N/A	
35.315	Safety precautions	☐Yes ☐No ☒N/A	
35.390	Training for use of unsealed byproduct material for which a WD is required	☐Yes ☐No ☒N/A	
35.392	Training for the oral administration of NaI I-131 requiring a WD in quantities <= 1.22 GBq (33 mCi)	☐Yes ☐No ☒N/A	
35.394	Training for the oral administration of NaI I-131 requiring a WD in quantities > 1.22 GBq (33 mCi)	☐Yes ☐No ☒N/A	
35.396	Training for the parenteral administration of unsealed byproduct material requiring a WD	☐Yes ☐No ☒N/A	
Subpart F – Manual Brachytherapy			
35.400	Use of sources for manual brachytherapy	☐Yes ☐No ☒N/A	
35.404	Surveys after source implant and removal	☐Yes ☐No ☒N/A	
35.406	Brachytherapy sources accountability	☐Yes ☐No ☒N/A	
35.410	Safety instruction	☐Yes ☐No ☒N/A	
35.415	Safety precautions	☐Yes ☐No ☒N/A	

Section	Description	Regulation Applicable to Akesis	Deviation Explanation and Specifics for Licensing Guidance
35.432	Calibration measurements of brachytherapy sources	☐Yes ☐No ☒N/A	
35.433	Sr-90 sources for ophthalmic treatments	☐Yes ☐No ☒N/A	
35.457	Therapy-related computer systems	☐Yes ☐No ☒N/A	
35.490	Training for use of manual brachytherapy sources	☐Yes ☐No ☒N/A	
35.491	Training for ophthalmic use of Sr-90	☐Yes ☐No ☒N/A	
Subpart G – Sealed Sources for Diagnosis			
35.500	Use of sealed sources and medical devices for diagnosis	☐Yes ☐No ☒N/A	
35.590	Training for use of sealed sources and medical devices for diagnosis	☐Yes ☐No ☒N/A	
Subpart H – Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery (GSR) Units			
35.600	Use of a sealed source in a remote afterloader unit, teletherapy unit, or GSR unit	☐Yes ☒No ☐N/A	Same intent of regulation but will be licensed under 10 CFR 35.1000.
35.604	Surveys of patients and human research subjects treated with a remote afterloader unit	☐Yes ☐No ☒N/A	
35.605	Installation, maintenance, adjustment, and repair	☒Yes ☐No ☐N/A	.
35.610	Safety procedures and instructions for remote afterloader units, teletherapy units, and GSR units	☒Yes ☐No ☐N/A	SOPs shall be generated and provided to NRC for review during the application process as required by 10 CFR 35.610 for all GSR units.
35.615	Safety precautions for remote afterloader units, teletherapy units, and GSR units	☒Yes ☒No ☐N/A	Some requirements in 10 CFR 35.615 can be followed as described in the guidance. However, due to engineering changes, some requirements are not applicable and additional safety precautions should be added as described in the guidance.

Section	Description	Regulation Applicable to Akesis	Deviation Explanation and Specifics for Licensing Guidance
			Therefore, Akesis Galaxy® RTi unit licensees should confirm they are meeting the requirements in 10 CFR 35.615(f)(3) or the following: 1) An AU and an AMP will be physically present during the initiation of all patient treatments involving the Akesis Galaxy® RTi unit; 2) An AMP and either an AU or a physician, under the supervision of an AU, who has been trained in the operation and emergency response for the unit, will be physically present during continuation of all patient treatments involving the Akesis Galaxy® RTi unit; and 3) An AU will return to the Akesis unit console if there is an interruption of treatment to evaluate the patient, to review any information related to an abnormal situation, and to ensure that the treatment is being delivered in accordance with the treatment plan and written directive prior to re-initiation of the treatment.

Section	Description	Regulation Applicable to Akesis	Deviation Explanation and Specifics for Licensing Guidance
35.630	Dosimetry equipment	☒Yes ☐No ☐N/A	
35.632	Full calibration measurements on teletherapy units	☐Yes ☐No ☒N/A	
35.633	Full calibration measurements on remote afterloader units	☐Yes ☐No ☒N/A	
35.635	Full calibration measurements on GSR units	☒Yes ☒No ☐N/A	Some requirements in 10 CFR 35.635 can be followed as described in the guidance. However, due to engineering changes, most measurements will not apply. 10 CFR 35.635 requires full calibration measurement procedures to be performed in accordance with published protocols accepted by nationally recognized bodies. The guidance provides a condition to use manufacturer full calibration procedures for components and features of the Akesis Galaxy® RTi unit as nationally recognized bodies have not yet published calibration procedures for the unit. The Licensee will follow the applicable full calibration requirements of 10 CFR 35.635 and the spot-check requirements in 10 CFR 35.645 and retain the information described in 10

Section	Description	Regulation Applicable to Akesis	Deviation Explanation and Specifics for Licensing Guidance
			CFR 35.2632 for each full calibration and 10 CFR 35.2645 for each check except for those involving helmets, helmet factors, helmet micro-switches, trunnions, and hydraulic backup of the treatment table retraction system. Licensee's will keep each record of the full calibration and spot-checks for 3 years.
35.642	Periodic spot-checks for teletherapy units	☐Yes ☐No ☒N/A	
35.643	Periodic spot-checks for remote afterloader units	☐Yes ☐No ☒N/A	
35.645	Periodic spot-checks for GSR units	☒Yes ☒No ☐N/A	Spot-check required in 10 CFR 35.645 are applicable except for those involving helmets, helmet factors, helmet micro-switches, trunnions, and hydraulic backup of the treatment table retraction system. Therefore, some requirements in 10 CFR 35.645 can be followed as described in the guidance. However, due to engineering changes, some requirements will not apply and additional spot check commitments should be added as described in the guidance.
35.647	Additional technical requirements for mobile remote afterloader units	☐Yes ☐No ☒N/A	
35.652	Radiation surveys	☒Yes ☐No ☐N/A	
35.655	Full-inspection servicing for teletherapy and GSR units	☒Yes ☐No ☐N/A	

Section	Description	Regulation Applicable to Akesis	Deviation Explanation and Specifics for Licensing Guidance
35.657	Therapy-related computer systems	☒Yes ☐No ☐N/A	
35.690	Training for use of remote afterloader units, teletherapy units, and GSR units	☐Yes ☒No ☐N/A	The recommended training and experience criteria is listed in the guidance. This criterion is similar to that listed in 10 CFR 35.690 for other GSR units, but updated to be specific to the Akesis as AU of the Akesis should have training in this unit prior to use.
Subpart L – Records			
35.2024	Records of authority and responsibilities for radiation protection programs	☒Yes ☐No ☐N/A	
35.2026	Records of radiation protection program changes	☒Yes ☐No ☐N/A	
35.2040	Records of WDs	☒Yes ☐No ☐N/A	
35.2041	Records for procedure for administrations requiring a WD	☒Yes ☐No ☐N/A	
35.2060	Records of calibrations of instruments used to measure the activity of unsealed byproduct materials	☒Yes ☐No ☐N/A	
35.2061	Records of radiation survey instrument calibrations	☒Yes ☐No ☐N/A	
35.2063	Records of dosages of unsealed byproduct material for medical use	☐Yes ☐No ☒N/A	
35.2067	Records of leaks tests and inventory of sealed sources and brachytherapy sources	☒Yes ☐No ☐N/A	
35.2070	Records of surveys for ambient radiation exposure rate	☒Yes ☐No ☐N/A	
35.2075	Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material	☒Yes ☐No ☐N/A	
35.2080	Records of mobile medical services	☒Yes ☐No ☒N/A	

Section	Description	Regulation Applicable to Akesis	Deviation Explanation and Specifics for Licensing Guidance
35.2092	Records of decay-in-storage	☒Yes ☐No ☐N/A	
35.2204	Records of Mo-99, Sr-82, and Sr-85 concentrations	☐Yes ☐No ☒N/A	
35.2310	Records of safety instruction	☐Yes ☐No ☒N/A	
35.2404	Records of surveys after source implant and removal	☒Yes ☐No ☐N/A	
35.2406	Records of brachytherapy source accountability	☒Yes ☐No ☐N/A	
35.2432	Records of calibration measurements of brachytherapy sources	☐Yes ☐No ☒N/A	
35.2433	Records of decay of Sr-90 sources for ophthalmic treatments	☐Yes ☐No ☒N/A	
35.2605	Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and GSR units	☒Yes ☐No ☐N/A	
35.2610	Records of safety procedures	☐Yes ☐No ☒N/A	
35.2630	Records of dosimetry equipment used with remote afterloader units, teletherapy units, and GSR units	☐Yes ☐No ☒N/A	
35.2632	Records of teletherapy, remote afterloader, and GSR full calibrations	☒Yes ☒No ☐N/A	Updated to reflect the 10 CFR Part 35.635 calibration tests completed and those that cannot be completed due to engineering design.
35.2642	Records of periodic spot-checks for teletherapy units	☐Yes ☐No ☒N/A	
35.2643	Records of periodic spot-checks for remote afterloader units	☐Yes ☐No ☒N/A	
35.2645	Records of periodic spot-checks for GSR units	☐Yes ☒No ☐N/A	Updated similar to 10 CFR 35.645.
35.2647	Records of additional technical requirements for mobile remote afterloader units	☐Yes ☐No ☒N/A	
35.2652	Records of surveys of therapeutic treatment units	☐Yes ☐No ☒N/A	

Section	Description	Regulation Applicable to Akesis	Deviation Explanation and Specifics for Licensing Guidance
35.2655	Records of full-inspection servicing for teletherapy and GSR units	☒Yes ☐No ☐N/A	
Subpart M – Reports			
35.3045	Report and notification of a medical event	☒Yes ☐No ☐N/A	
35.3047	Report and notification of a dose to an embryo/fetus or a nursing child	☒Yes ☐No ☐N/A	
35.3067	Report of a leaking source	☒Yes ☐No ☐N/A	
35.3204	Report and notification for an eluate exceeding permissible Mo-99, Sr-82, and Sr-85 concentrations	☐Yes ☐No ☒N/A	
Subpart N – Enforcement			
35.4001	Violations	☒Yes ☐No ☐N/A	
35.4002	Criminal penalties	☒Yes ☐No ☐N/A	