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.

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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.

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			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.

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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	