Leksell Gamma Knife® Perfexion™, Icon™, and Elekta Esprit

Licensing Guidance

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U.S. Nuclear Regulatory Commission Contact

Katie Tapp

Katherine.Tapp@nrc.gov

MedicalQuestions.Resource@nrc.gov

Table of Contents

1. 10 CFR 35.1000 Use 1
2. Licensing Guidance....1
3. Requirements not Specific to 10 CFR 35.1000 Use 2
   - 3.1 General 2
   - 3.2 10 CFR Part 37 2
4. Specific Licensing for Perfection™, Icon™, and Elekta Esprit 3
5. Training and Experience 3
   - 5.1 Authorized Individuals 3
     - 5.1.1 Authorized Users....4
     - 5.1.2 Authorized Medical Physicists 5
     - 5.1.3 Radiation Safety Officers....6
6. Licensing Commitments: 7
   - 6.1 Written Directive....7
   - 6.2 Specific Information on Radiation Safety Precautions and Instructions 8
   - 6.3 Physical Presence Required by 35.615(f)(3) 13
   - 6.4 Procedures Required by 35.610 and 35.645 14
   - 6.5 Published Protocols Accepted by Nationally Recognized Bodies 14
   - 6.6 Full Inspection and Service of the Perfexion™, Icon™, and Elekta Esprit Units 14
7. Notes to Licensees....15
   - 7.1 Alterations to Perfexion™, Icon™, or Elekta Esprit Units 15
   - 7.2 Changes in Physical Conditions of Use....15
   - 7.3 Notification for AUs and AMPs 15
   - 7.3 Grandfathering 16
   - 7.4 Revisions to Existing Perfexion™, Icon™, or Elekta Esprit Radiation Safety Programs to Conform to Future Changes in Licensing Guidance and Additional Safety Recommendations from the Manufacturer 16
8. Note to Regulators 17
   - 8.1 Program Code....17
   - 8.2 Inspection Frequency....17
9. Paperwork Reduction Act Statement....17
10. Public Protection Notification 17

1. 10 CFR 35.1000 Use

Although the Leksell Gamma Knife® Perfexion™, Leksell Gamma Knife® Icon,™ and Elekta Elekta Esprit (hereafter the Perfexion™, Icon™, and Elekta Esprit respectively) are gamma stereotactic radiosurgery units, they include a number of engineering changes that make their components and operation significantly different from the gamma stereotactic radiosurgery units currently regulated in 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 engineering changes include the elimination of helmets, relative helmet factors, helmet microswitches, hydraulic backups, trunnions, and a trunnion centricity point; the sources are located in movable sectors; the source exposure indicator is on the treatment room wall and not on the unit itself; and a movable bed. The Perfexion™ makes use of the stereotactic head frame and frame adapter. The Icon™ and Elekta Esprit units have additional features compared to the Perfexion™ unit in that these units include the addition of an x-ray tube system mounted onto the unit to take cone beam computed tomography (CBCT) images to obtain stereotactic reference information and position references. In the Icon™ and Elekta Esprit units, the patient's head can be immobilized with either the stereotactic head frame with frame adapter or with the aid of a frameless thermoplastic mask and mask adapter system. The Icon™ and Elekta Esprit will use the High Definition Motion Management (HDMM) system to monitor movements of the patient during setup and treatment while the patient is immobilized by the mask. Perfexion™ units can be upgraded to the Icon™ unit by attaching the CBCT system, adding the mask adapter system, performing software changes to incorporate the functionality of the CBCT, and replacing the exterior covers and labels. The Elekta Esprit unit is similar to the Icon™ unit in that it has these same features important to radiation safety. Both Perfexion™ and Icon™ units can be upgraded to an Elekta Esprit unit. As a result of these differences from the gamma stereotactic radiosurgery units currently regulated in 10 CFR Part 35, Subpart H, the Perfexion™, Icon™, and Elekta Esprit units are regulated under 10 CFR Part 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation From Byproduct Material."

2. Licensing Guidance

This guidance provides applicants with an acceptable means of satisfying the requirements for a license for the use of the Perfexion™, Icon™, and Elekta Esprit and 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 35.12 as described below. The applicant must either submit additional information and commitments requested below or, unless the information is specifically required by regulation, submit alternative commitments for review by the U.S. Nuclear Regulatory Commission (NRC) staff to determine whether the regulatory requirements are met. The commitments incorporated into the applicant's license by license condition 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."

Applicants are also 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, L, and M, except as specified in this guidance. Additionally, applicants must meet applicable requirements of 10 CFR Parts 19, 20 and 30.

[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.

This guidance supersedes the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ 10 CFR 35.1000 licensing guidance issued in 2019, 2016, and 2007. The primary update to this revision is to include the Leksell Gamma Knife® Elekta Esprit throughout the guidance.

Icon™ and Elekta Esprit make use of an integrated CBCT imaging system to ensure the patient is properly positioned for 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. The CBCT is not licensed or registered by the NRC. However, because the CBCT is critical to verifying the accuracy of the patient positioning, the 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 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 facility's address and description and applicable model procedures for audits, occupational dose monitoring programs, and surveys. Applicants should also refer to https://www.nrc.gov/reading-rm/sensitive-info/materials.html for information regarding submissions of information containing sensitive security-related information, such as information about quantities and locations of radioactive materials at licensed facilities. Guidance specific for the use of Perfexion™, Icon™, and Elekta Esprit under 10 CFR 35.1000, "Other medical uses of byproduct material or radiation from byproduct material" are contained herein.

3. Requirements not Specific to 10 CFR 35.1000 Use

3.1 General

Applicants must commit to meet the general requirements in 10 CFR Part 35, Subpart A—"General Information;" Subpart B—"General Administrative Requirements;" Subpart C—"General Technical Requirements;" Subpart L—"Records;" and Subpart M—"Reports," except as specified in this guidance. Additionally, applicants must meet applicable requirements of 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations;" Part 20, "Standards for Protection Against Radiation;" Part 30, "Rules of General Applicability to Domestic Licensing of byproduct material;" and Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." The attached consolidated technical analysis table provides a list of applicable requirements in Part 35.

3.2 10 CFR Part 37

Applicants requesting authorization for the Perfexion™, Icon™, or Elekta Esprit unit must comply with 10 CFR Part 37 before installing sources for this unit.

Note that individuals who have not been granted unescorted access in accordance with 10 CFR Part 37 must be escorted at all times when they are servicing the CBCT component or are inspecting (i.e., NRC or Agreement State inspectors) the Perfexion™, Icon™, Elekta Esprit unit(s) 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."

4. Specific Licensing for Perfection™, Icon™, and Elekta Esprit

4.1 Radionuclides, Form, Possession Limits, and Purpose of Use

Pursuant to 10 CFR 35.12(c), the applicant must identify the radionuclides, chemical/physical form, requested maximum possession limit, and purpose of use. NRC Form 313, "Application for Materials License," may be used to submit this information. The information in the table below provides the suggested format for completing Item 5 (Radioactive Material) and Item 6 (Purpose of Use) on the NRC Form 313, "Application for Materials License."

Radionuclides, Form, Possession Limits

Radionuclides: (NRC Form 313 Item 5)	A. Cobalt-60
Chemical/Physical Form: (NRC Form 313 Item 5)	B. Sealed sources (Manufacturer and Model Number, e.g., Elekta Model 43685 or General Electric AB ELEKTA Model 43047)
Maximum Possession Limit: (NRC Form 313 Item 5)	C. 36 curies per source not to exceed 6600 curies total (or 10000 curies during source exchange)
Purpose: (NRC Form 313 Item 6)	For 10 CFR 35.1000 medical use in the Leksell Gamma Knife® _____(select Perfexion™, Icon™, or Elekta Esprit)* gamma stereotactic radiosurgery unit

*There are five configurations available: (1) Leksell Gamma Knife® Perfexion™ (serial number less than 8001); (2) Leksell Gamma Knife® Perfexion™ with modified inner radiation unit without CBCT system (serial number greater than or equal to 8001); (3) Leksell Gamma Knife® Perfexion™ with CBCT system (which then becomes the Leksell Gamma Knife® Icon™); (4) Leksell Gamma Knife® Icon™; and (5) Leksell Gamma Knife® - Elekta Esprit. For the purposes of licensing, configurations (1) and (2) will follow the licensing conditions for the Perfexion™. Configurations (3), (4), and (5) will follow the licensing conditions for the Icon™ and Elekta Esprit.

5. Training and Experience

5.1 Authorized Individuals [10 CFR 30.33(a)(3), § 35.12(b)(1), § 35.50, § 35.51, and § 35.690]**:**

The NRC has determined that individuals meeting the guidance provided below will be considered qualified and authorized for the Perfexion™, Icon™, or Elekta Esprit gamma stereotactic radiosurgery 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.

Individuals seeking authorization for the Perfexion™, Icon™, or Elekta Esprit are required to obtain a written attestation that the individual has satisfactorily completed the training below and is able to independently fulfill the radiation safety-related duties as an authorized user (AU), authorized medical physicist (AMP), or Radiation Safety Officer (RSO) for the unit. The written attestation must be signed by a preceptor AU, AMP, or RSO authorized for Perfexion™, Icon™, or Elekta Esprit. The written attestation is not required for individuals who hold certification by a

recognized specialty board or are already authorized for other gamma stereotactic radiosurgery units.

5.1.1 Authorized Users

Applicants and licensees should identify each AU of the Perfexion™, Icon™, or Elekta Esprit gamma stereotactic radiosurgery unit and provide documentation of his/her training and experience in the use of the Perfexion™, Icon™, or Elekta Esprit 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 Perfexion™, Icon™, or Elekta Esprit gamma stereotactic radiosurgery 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 gamma stereotactic radiosurgery unit or as an AU for 10 CFR 35.1000 medical use of one of the Leksell Gamma Knife® models, is board certified by a recognized board listed on the NRC's Web site[2] under 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 gamma stereotactic radiosurgery unit use;

AND

2) Received documented training in hands-on device operation, safety procedures, and clinical use, which includes the preparing treatment plans and calculating treatment doses and times, for the gamma stereotactic radiosurgery unit which authorization is being sought. If the individual is already an AU for a gamma stereotactic radiosurgery 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 requested unit and the other gamma stereotactic radiosurgery units that the individual is authorized to use. In order to function independently as an AU for the Icon™ and Elekta Esprit, the individual shall also have training with treatment using both a stereotactic frame and the patient immobilization system, which is a frameless therapy system. The training requirement in this criterion may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an AU or AMP, as appropriate, who is authorized for the unit which authorization is being sought;

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 AU for the unit which authorization is being sought. The written attestation must be signed by a preceptor AU who is authorized for the unit which authorization is being sought. The written attestation is not required for individuals who hold certification by a recognized specialty board or are already authorized for use of another Leksell Gamma Knife® model or other gamma stereotactic radiosurgery units licensed under 10 CFR 35.600.

[2] https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

5.1.2 Authorized Medical Physicists

Identify each AMP for the Perfexion™, Icon™, or Elekta Esprit gamma stereotactic radiosurgery unit and provide documentation of his/her training and experience in the use of the Perfexion™ or Icon™ 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 Perfexion™, Icon™, or Elekta Esprit gamma stereotactic radiosurgery 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 10 CFR 35.600 medical use of a gamma stereotactic radiosurgery unit or as an AMP for 10 CFR 35.1000 medical use of one of the Leksell Gamma Knife® models; or is board certified by a board listed on the NRC's Web site[2] under 10 CFR 35.51, "Training for an authorized medical physicist;" or meets the criteria in 35.51(b)(1) and (2) for gamma stereotactic radiosurgery 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 unit which authorization is sought. If the individual is already an AMP for a gamma stereotactic radiosurgery 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 requested unit and other gamma stereotactic radiosurgery units for which the individual is already authorized. In order to function independently as an AMP for the Icon™ and Elekta Esprit, the individual shall have had training using both a stereotactic frame and the patient immobilization system, which is a frameless therapy system. The training requirement in this criterion may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an AMP authorized for the unit which authorization is being sought;

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 unit which authorization is being sought. The written attestation must be signed by a preceptor AMP authorized for the unit which authorization is being sought. The written attestation is not required for individuals who hold certification by a recognized specialty board or are already authorized for use of another Leksell Gamma Knife® model or other gamma stereotactic radiosurgery units licensed under 10 CFR 35.600.

5.1.3 Radiation Safety Officers [10 CFR 30.33(a)(3) and 10 CFR 35.12(b)(1)]**:**

Identify the RSO for the Perfexion™, Icon™, or Elekta Esprit gamma stereotactic radiosurgery 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 Icon™ or Elekta Esprit unit but may not have access to an operational Icon™ or Elekta Esprit 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 Icon™ or Elekta Esprit unit. The individual shall be considered qualified to be the RSO for the Perfexion™, Icon™, or Elekta Esprit gamma stereotactic radiosurgery unit if the individual meets the following:

1) Is listed as an RSO on a NRC or Agreement State license (or NRC Master Materials License permit) authorizing a gamma stereotactic radiosurgery unit for 10 CFR 35.600 use or 10 CFR 35.1000 medical use of one of the Leksell Gamma Knife® models , or is board certified by a board listed on the NRC's Web site[2] under 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 gamma stereotactic radiosurgery unit use;

AND

2) Received documented training in the radiation safety, regulatory issues, and emergency procedures for the unit which authorization is sought. If the individual already has RSO responsibilities for a gamma stereotactic radiosurgery 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 requested unit and other gamma stereotactic radiosurgery units for which the individual has RSO responsibility. This training requirement may be satisfied by completing training that is provided by the vendor or supervised by an individual (RSO or AMP or AU) that is authorized for the unit which authorization is being sought. The individual should complete or commit to complete supplemental hands-on radiation safety and emergency procedures training on an operational unit before first use of the unit for patient treatment;

AND

4) 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 unit which authorization is being sought. The written attestation must be signed by a preceptor RSO, AMP, or AU authorized for the unit which authorization is being sought. 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 Leksell Gamma Knife® model or other gamma stereotactic radiosurgery units licensed under 10 CFR 35.600.

6. Licensing Commitments:

6.1 Written Directive [10 CFR 35.40]

The Perfexion™, Icon™, and Elekta Esprit gamma stereotactic radiosurgery units deliver therapeutic dose of radiation from byproduct material and under 10 CFR 35.40 requires a written directive signed and dated by an AU. Unlike earlier gamma stereotactic radiosurgery units, calculation of the dose to the treatment site for the Perfexion™, Icon™, and Elekta Esprit units is dependent on the shaping of the radiation field at the focal point by selection of different collimators for each of the eight sectors. Therefore, to assure the dose is delivered in accordance with the AU's direction, the written directive should include the sector positions in addition to the target coordinate settings for each treatment shot. The applicant should provide the following commitment:

> "For the Perfexion™ gamma stereotactic radiosurgery unit use, the written directive will contain the patient or human research subject's name; the total dose; the treatment site; the gamma angle; and the values for the target coordinate settings and sector settings for each treatment shot within an anatomically distinct treatment site."
>
> "For the _____ (select Icon™ or Elekta Esprit) gamma stereotactic radiosurgery unit use, the written directive will contain the patient or human research subject's name; the total dose; the treatment site; the gamma angle; dose per fraction; number of fractions; and the values for the target coordinate settings and sector settings 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 gamma stereotactic radiosurgery medical units authorized by 10 CFR 35.600. This verification is also applicable to gamma stereotactic radiosurgery units regulated under 10 CFR 35.1000. For the Perfexion™, Icon™, and Elekta Esprit gamma stereotactic radiosurgery units, the computer-generated dose calculations for each shot, (i.e., each set of target coordinates) should also include the sector settings for that shot. For this reason, the applicant should provide the following commitment:

> "For the_____ (select Perfexion™, Icon™, or Elekta Esprit) 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 (including target coordinate and sector settings) are correctly transferred into the _____ (select Perfexion™, Icon™, or Elekta Esprit) control system."

Several medical events with earlier models of gamma stereotactic radiosurgery 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 setup if a patient is observed to move during the course of a treatment shot and (2) visually checking the patient setup each time the gamma angle is changed or at the end of the treatment run, whichever comes first.

In addition to the minimum topics that must be addressed in accordance with 10 CFR 35.41, the applicant should commit the following for the Perfexion™:

> "Our program to provide high confidence that the administration is in accordance with the written directive will include written procedures for: (1) verification of the integrity of the fixation before starting the treatment; (2) pausing treatment and checking the patient setup if a patient is observed to move during the course of a treatment shot; 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."

The applicant should confirm the following for the Icon™ and Elekta Esprit.

> "Our program to provide high confidence that the administration is in accordance with the written directive will include written procedures for: (1) verification of the integrity of the fixation before starting the treatment; (2) pausing treatment and checking the patient setup if a patient is observed to move during the course of a treatment and every time the HDMM 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."

6.2 Specific Information on Radiation Safety Precautions and Instructions
[10 CFR 35.12(d)(1)(i)]

The applicant must submit the information required by 10 CFR 35.12(d). Because the Perfexion™, Icon™, and Elekta Esprit units are gamma stereotactic radiosurgery units, the applicant may simplify its submission by confirming the following:

> "For use of the Leksell Gamma® Knife _____ (select Perfexion™, Icon™, or Elekta Esprit) we will meet the following requirements for a gamma stereotactic radiosurgery 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) until the licensee no longer possesses the unit),
>
> Section 35.615(a) through (d), (g), 35.615(f)(4),
>
> Section 35.615(f)(3) (with modifications discussed 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 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), and

Section 35.657."

Unlike earlier models, the sources in the Perfexion™, Icon™, or Elekta Esprit units are located in the movable sectors. 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 spot test and full calibration test should include assessing whether the patient docking systems function correctly to place the mechanical center (x = 100 millimeters (mm), y = 100 mm, and z = 100 mm) 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 point and the accuracy of the dose calculations for the Perfexion™, Icon™, or Elekta Esprit unit.

The requirements in 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 Perfexion™, Icon™, or Elekta Esprit units. For example, for the Perfexion™ unit, the patient's head in the stereotactic head frame is attached in an "immovable" position to the bed (by the docking device and frame adapter) and the bed itself is moved over small distances to center the treatment site at the radiation focal point. For the Icon™ and Elekta Esprit units, the patient's head is either immobilized with the aid of a stereotactic head frame or with the aid of a frameless thermoplastic 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 bed, and the bed itself is moved over small distances to center the treatment site at the radiation focal point.

The individual removable collimator helmets in earlier gamma stereotactic radiosurgery units have been replaced by eight permanently installed independently movable sectors in the Perfexion™, Icon™, or Elekta Esprit units. The eight sectors contain the radiation sources and are mounted on the collimator body. The collimator body contains three different sets of fixed collimator apertures (4 mm, 8 mm, and 16 mm) as well as two shielded positions (off and home). The angle of each collimator aperture is set so that the focal point remains constant. The location of each sector determines the collimation for that set of sources. The collimator cap isolates the patient from the collimators and blocks the view of the collimator body. While increasing treatment flexibility, this configuration prevents the AU or AMP from visually confirming the collimation before initiating a set of treatment shots. Therefore, location and function of the sectors, the patient bed, the docking device, the frame adapter, the mask adapter (Icon™ and Elekta Esprit), and source exposure indicator light inside the treatment room are critical to the safe use of and proper functioning of the Perfexion™, Icon™, or Elekta Esprit units, 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 determining the location of the radiation focal point, table location, and

frame adapter function. For the Icon™ and Elekta Esprit units, the verification of the accuracy of the patient positioning with the CBCT is critical and therefore the QA-measurements described in the vendor-supplied operating manual *Instructions for Use* shall be performed exactly as stated.

The Icon™ and Elekta Esprit units will use the HDMM system, in the frameless mask mode, to monitor patient movements during setup and treatment while immobilized by the mask. The HDMM system can also be used when the patient is immobilized with the Vantage stereotactic head frame. However, the HDMM system cannot be used with the Perfexion™ or when the patient is immobilized with the Coordinate G stereotactic head frame. The HDMM uses infrared markers to position and will pause the patient treatment when the system is in active mode in the event that the patient moves outside of the alarm set distance (default of 1.5 mm) from the original positioning when the HDMM is in active mode. The HDMM can also be in passive mode, which will not pause the treatment if a patient moves outside the alarm set distance. The system defaults to active mode during frameless mask treatments but defaults to passive when the Vantage head frame is used.

The applicant should confirm the following for the Perfexion™, Icon™, and Elekta Esprit:

> "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 sources shielding, the sector drive 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. We will retain information described in Section 35.2652 for the duration of the use of the unit."
>
> "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 spot-check except for those requirements which are not applicable. We will keep each record of the full calibration and spot-checks for 3 years."
>
> "Before the first use of the _____ (select Perfexion™, Icon™, or Elekta Esprit) unit each day, we will confirm that the docking device is securely mounted to the 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 _____ (select Perfexion™, Icon™, or Elekta Esprit) 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 _____ (select Perfexion™, Icon™, or Elekta Esprit) unit each day, we will confirm proper functioning of the source exposure indicator light in the treatment room. 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 _____ (select Perfexion™, Icon™, or Elekta Esprit) 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 frame, we will confirm that the frame adapter is functioning correctly and can be attached correctly to the patient’s 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 _____ (select Perfexion™, Icon™, or Elekta Esprit) 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, with respect to the table 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 _____ (select Perfexion™, Icon™, or Elekta Esprit) unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.”

Note: At this time, the test can only be performed with the diode centered in the test tool. If, at a later date, the manufacturer develops a test that uses a diode or other radiation measurement precisely located in an off-centered position that is also available to the end user, this test should also be performed to verify table position.

“On a monthly basis, we will confirm that the location of the table 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 _____ (select Perfexion™, Icon™, or Elekta Esprit) 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 each sector moves correctly to each position 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 _____ (select Perfexion™, Icon™, or Elekta Esprit) unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.”

Note: At this time, the vendor can demonstrate at time of installation or major repair for the licensee’s verification that the sector locations and numbers agree with the computer screen display and the vendor can perform a physical measurement of each sector rod location at each position during the routine six month service. The licensee may use data from the vendor’s measurements to assess sector movement and alignment. If, at a later time, a test is developed that permits the licensee to determine each sector’s alignment and proper movement, this test should also be used to verify sector alignment and proper movement.

“During installation and approximately every six months (with exact date subject to vendor service availability), we will confirm that the vendor will verify that the location of the radiation focal point, with respect to the table position, 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 _____ (select Perfexion™, Icon™, or Elekta Esprit) unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years."

"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 docking device, sector location, sector movement, or table 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 if either the clearance test tool or QA test tool fails to function as specified by the manufacturer, we will have the tool repaired or replaced before the next patient treatment requiring the proper function of that tool."

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

The applicant should confirm the following for the Icon™ and Elekta Esprit:

"Before the first use of the Icon™ and Elekta Esprit unit each day, when using the 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 Icon™ and Elekta Esprit 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 Icon™ and Elekta Esprit 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 Icon™ and Elekta Esprit unit, we will confirm that the HDMM system is working properly by confirming that the HDMM system responds to movements of the patient marker relative to the markers integral to the system. This is done by verifying that a movement of the patient marker is accompanied by a shift of the HDMM response curve. 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 Icon™ and Elekta Esprit 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 HDMM system is working properly by performing a test without a patient present with the aim to check the HDMM system's quantitative output. 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 Icon™ and Elekta Esprit 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 Icon™ and Elekta Esprit unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years."

"We confirm that if the CBCT system and/or the HDMM 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."

6.3 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 gamma stereotactic radiosurgery units. However, unlike previous Gamma Knife® models, the Perfexion™, Icon™, and Elekta Esprit units have additional safety functions and utilize 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 patient couch. In the Icon™ and Elekta Esprit unit, use of CBCT and HDMM systems for frameless procedures ensures the patient is properly positioned prior to treatment and any movement during treatment causes the sources to move to the "blocked" position. If movement ceases within 30 seconds, treatment resumes with no operator intervention needed. However, if movement does not cease within 30 seconds, the treatment is terminated and operator intervention is required to initiate further treatment. As such, the physical presence of the AU throughout all patient treatments required by 10 CFR 35.615(f)(3) for other types of gamma stereotactic radiosurgery units is unnecessary for the Perfexion™, Icon™, and Elekta Esprit units, provided an AMP and a physician, under the supervision of an AU, are present throughout the duration of all treatments.

Therefore, Perfexion™, Icon™, and Elekta Esprit unit licensees should confirm they are meeting the requirements in 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 Perfexion™, Icon™, or Elekta Esprit unit;

2) An AMP and either an AU or a physician, under the supervision of an authorized user, 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 Perfexion™, Icon™, or Elekta Esprit unit; and

3) An AU will return to the Perfexion™, Icon™, or Elekta Esprit 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.

6.4 Procedures Required by 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 Perfexion™, Icon™, and Elekta Esprit units' radiation safety program, only the procedures in 10 CFR 35.610 and 35.645 are appropriate.

The Perfexion™, Icon™, and Elekta Esprit units do not have helmet microswitches, trunnion centricity, or a source exposure indicator light on the unit. 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, mask adapter (Icon™ and Elekta Esprit), docking device, and source exposure indicator light in the treatment room, additional monthly spot-check procedures for the location of the radiation focal point with respect to the table 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 Perfexion™, Icon™, or Elekta Esprit unit and spot-check procedures for the Perfexion™, Icon™, or Elekta Esprit unit.

6.5 Published Protocols Accepted by Nationally Recognized Bodies

Full calibration measurement procedures for gamma stereotactic radiosurgery units are required by 10 CFR 35.635(d) to be in accordance with published protocols accepted by nationally recognized bodies. However, the Perfexion™, Icon™, and Elekta Esprit units contain 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 _____ (select Perfexion™, Icon™, or Elekta Esprit) unit. In the absence of published protocols for the _____ (select Perfexion™, Icon™, or Elekta Esprit) unit accepted by nationally recognized bodies, we will use procedures developed by the manufacturer."

6.6 Full Inspection and Service of the Perfexion™, Icon™, and Elekta Esprit Units [10 CFR 35.655]

The NRC requires the full inspection and servicing of gamma stereotactic radiosurgery 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 a Perfexion™, Icon™, and Elekta Esprit unit can only be performed at source exchange.

The applicant should confirm the following:

> "We will commit to have each _____ (select Perfexion™, Icon™, or Elekta Esprit) gamma stereotactic radiosurgery unit fully inspected and serviced during each 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 to do so by the Commission or an Agreement State.
>
> We will retain records of the information described in Section 35.2655 for the duration of use of the unit."

7. Notes to Licensees

7.1 Alterations to Perfexion™, Icon™, or Elekta Esprit Units

This licensing guidance is based on the Sealed Source and Device (SS&D) safety evaluation in Registration Sheet NR-0269-D-104-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 Perfexion™, Icon™, or Elekta Esprit unit.

7.2 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.

7.3 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 Perfexion™, Icon™, or Elekta Esprit unit and is currently listed on a Commission or Agreement State medical use license or permit for the Perfexion™, Icon™, or Elekta Esprit unit, the AU or AMP should be allowed to work under a different license for the medical use of the Perfexion™, Icon™, or Elekta Esprit unit. A limited specific medical use applicant initially applying for authorization for the medical use of the Perfexion™, Icon™, or Elekta Esprit 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 Perfexion™, Icon™, or Elekta Esprit unit; and

2) the AU or AMP is currently listed for the Perfexion™, Icon™, or Elekta Esprit 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; and

3) the licensee provides NRC a copy of the license or permit on which the AU or AMP was originally listed for the Perfexion™, Icon™, or Elekta Esprit 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 Perfexion™, Icon™, or Elekta Esprit unit.

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

7.3 Grandfathering

If a licensee adopts this revision of the Perfexion™, Icon™, and Elekta Esprit training and experience criteria, AUs, AMPs, or RSOs who are currently authorized for the medical use of the Perfexion™, Icon™, and/or Elekta Esprit under previous criteria, do not have to meet the revised criteria for the Perfexion™, Icon™, or Elekta Esprit.

7.4 Revisions to Existing Perfexion™, Icon™, or Elekta Esprit Radiation Safety Programs to Conform to Future Changes in Licensing Guidance and Additional Safety Recommendations from the Manufacturer

Requesting authorization in accordance with the following guidance will permit a licensee to make certain changes under 10 CFR 35.26, "Radiation protection program changes," to the Perfexion™, Icon™, or Elekta Esprit gamma stereotactic radiosurgery unit safety program that might otherwise require a license amendment.

The above licensing guidance and safety recommendations from the manufacturer may be revised as additional experience is gained regarding medical use of the Perfexion™, Icon™, or Elekta Esprit gamma stereotactic radiosurgery unit by the regulator and manufacturer. Therefore, in contrast to 10 CFR 35.26, a licensee already authorized to use the Perfexion™, Icon™, or Elekta Esprit gamma stereotactic radiosurgery unit and committed by license condition to follow the provisions in the guidance and 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 Perfexion™, Icon™, or Elekta Esprit gamma stereotactic radiosurgery unit (or a licensee applying later for an amendment to conform to revisions in this 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 on the current guidance for the Perfexion™, Icon™, and/or Elekta Esprit gamma stereotactic radiosurgery unit medical use under 10 CFR 35.1000 use posted on the NRC website or the current operators manual and additional safety recommendations from the manufacturer;

3. The revision has been reviewed and approved by the licensee's Radiation Safety Officer 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 website 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.

8. Note to Regulators

8.1 Program Code

The NRC regions should use program code 02240.

8.2 Inspection Frequency

Licenses authorizing Perfexion™, Icon™, or Elekta Esprit units should be inspected every two years. Licenses authorizing emerging technology in 10 CFR 35.1000 are assigned a Priority 2 inspection code based on program code 02240. The list of the program codes along with the assigned priority codes can be found at https://www.nrc.gov/materials/miau/mat-toolkits.html.

9. 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.

10. 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.