

Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance

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U.S. Nuclear Regulatory Commission Contact

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10 CFR 35.1000 Use

Although the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ (hereafter the Perfexion™ and Icon™, 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 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; the sources are located in moveable sectors; the source exposure indicator is on the treatment room wall and not the on the unit itself; and a moveable bed. The Perfexion™ makes use of the stereotactic head frame and frame adapter (Leksell G-frame). The Icon™ unit is an upgrade to the Perfexion™ unit in that it includes 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. The Icon™ unit can immobilize the patient’s head with either the Leksell G-frame or with the aid of a frameless thermoplastic mask and mask adapter system. The Icon™ will use the Intra-Fraction Motion Management (IFMM) system to monitor movements of the patient during setup and treatment while 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. As a result, the Perfexion™ and Icon™ units are regulated under 10 CFR Part 35, Subpart K, “Other Medical Uses of Byproduct Material or Radiation From Byproduct Material.”

Licensing Guidance

This guidance provides applicants with an acceptable means of satisfying the requirements for a license for the use of the Perfexion™ and Icon™, 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 submit additional information and commitments requested below or may, 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. Applicants are reminded that licenses issued pursuant to 10 CFR 35.1000 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.

This guidance supersedes the Leksell Gamma Knife Perfexion™ 10 CFR 35.1000 licensing guidance issued in 2007. Applicants for the Icon™ may follow the guidance outlined below. A summary of the Icon™ guidance can be found in the last section titled, “List of Guidance for Icon™ Units.”

The Icon™ makes use of an integrated CBCT imaging system in order to ensure the patient is properly positioned for treatment. The specific license issued by 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, 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."

General

Sensitive Security-Related Information:

Certain sensitive security-related information such as information about 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 Issues Summary 2005-31, available at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf>.

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

Part 37

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

Note that individuals who service the cone beam computed tomography (CBCT) component or are inspecting (i.e., NRC or Agreement State inspectors) the Perfexion™ or Icon™ unit(s) must be escorted at all times unless they fall under the relief granted under 10 CFR 37.29.

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

The applicant shall identify the radionuclides, chemical/physical form, requested maximum possession limit, and purpose of use. NRC Form 313 may be used to submit this information. For example, the following provides the format for an acceptable request:

Radionuclides (Authorization 6)	Cobalt-60
Chemical/Physical Form (Authorization 7)	Sealed sources (Manufacturer and Model Number, e.g. Elekta Model 43685 or General Electric AB ELEKTA Model 43047)
Maximum Possession Limit (Authorization 8)	36 curies per source not to exceed 6600 curies total (or 10000 curies during source exchange)
Authorized Use (Authorization 9)	For 35.1000 medical use in the Leksell Gamma Knife® _____ (select Perfexion™ or Icon™)* gamma stereotactic radiosurgery unit.

*There are four 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 (will be rebranded as the Leksell Gamma Knife® Icon™); and (4) Leksell Gamma Knife® Icon™. For the purposes of licensing, configurations (1) and (2) will follow the licensing conditions for the Perfexion™. Configurations (3) and (4) will follow the licensing conditions for the Icon™.

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 Perfexion™ or Icon™ gamma stereotactic radiosurgery unit will be used or stored.

Authorized Individuals [10 CFR 30.33(a)(3) and 10 CFR 35.12(b)(1)]:

The NRC has determined that individuals meeting the guidance provided below will be considered qualified and authorized for the Perfexion™ or Icon™ 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.

In accordance with the previously issued licensing guidance for the Perfexion™, individuals seeking authorization for the Perfexion™ after July 1, 2009, 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 Perfexion™ unit. The written attestation must be signed by a preceptor AU, AMP or RSO authorized for the Perfexion™ unit. The written attestation is not required for individuals who hold certification by a recognized specialty board.

The manufacturer of the Icon™ has indicated that training locations for the Icon™ unit should be operational within the next year. Because there were no Icon™ units approved for medical use in the United States at the time this licensing guidance was published, there are no preceptors available to sign attestations. Therefore, the NRC is postponing requiring a written attestation until May 25, 2019. 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 Perfexion™ units or other gamma stereotactic radiosurgery units. The NRC will continue to review the availability of preceptors and may revise this guidance if it determines that sufficient preceptors have become available. In addition, all individuals seeking authorization for use of the Icon™ must submit documentation of successful completion of required training.

Applicants and licensees should identify each **authorized user** (AU) of the Perfexion™ or Icon™ 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 (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™ or Icon™ gamma stereotactic radiosurgery unit if the individual meets the following:

For the Perfexion™ unit:

- 1) Is listed on a license or permit (NRC, Agreement State, Broad Scope License or NRC Master Materials License) as an AU for 10 CFR 35.600 medical use of a gamma stereotactic radiosurgery unit; or is certified by a recognized board listed on the NRC's Web site 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 for the Perfexion™ gamma stereotactic radiosurgery unit. 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, which includes preparing treatment plans and calculating treatment doses and times, of the Perfexion™ and the other gamma stereotactic radiosurgery units that the individual is authorized to use. This training requirement may be satisfied by satisfactory completion of a training program provided by the Perfexion™ vendor or by receiving training supervised by an AU or authorized medical physicist (AMP), as appropriate, who is authorized for the Perfexion™ 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 AU for the Perfexion™ unit. The written attestation must be signed by a preceptor AU who is authorized for the Perfexion™ unit. The written attestation is not required for individuals who hold certification by a recognized specialty board.

For the Icon™ unit:

- 1) Is listed on a license or permit (NRC, Agreement State, Broad Scope License or NRC Master Materials License) as an AU for 10 CFR 35.600 medical use of a gamma stereotactic radiosurgery unit; an AU for 10 CFR 35.1000 medical use of the Leksell Gamma Knife Perfexion™; or is board certified by a recognized board listed on the NRC's Web site 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 preparing treatment plans and calculating treatment doses and times, for the Icon™ gamma stereotactic radiosurgery unit. 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 Icon™ and the other gamma stereotactic radiosurgery units that the individual is authorized to use. This training requirement may be satisfied by satisfactory completion of a training program provided by the Icon™ vendor or by receiving training supervised by an AU or authorized medical physicist (AMP), as appropriate, who is authorized for the Icon™ use;

AND

- 3) For physicians applying for the Icon™ before May 25, 2019, has documentation that the physician has satisfactorily completed the above training. For all other physicians applying for the Icon™ on or after May 25, 2019, a written attestation from a preceptor Icon™ AU 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 Icon™ unit. 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 Perfexion™ units or other gamma stereotactic radiosurgery units. In order to function independently as an AU the individual shall have demonstrated familiarity with treatment using both a stereotactic frame and the patient immobilization system which is a frameless therapy system. The written attestation must be signed by a preceptor AU who is authorized for the Icon™ unit.

Identify each **AMP** for the Perfexion™ and/or Icon™ 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™ or Icon™ gamma stereotactic radiosurgery unit, if the individual meets the following:

For the Perfexion™ unit:

- 1) Is listed on a license or permit (NRC, Agreement State, Broad Scope License or NRC Master Materials License) as an AMP for gamma stereotactic radiosurgery unit use; or is board certified by a board listed on the NRC's Web site 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 Perfexion™ unit. 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 Perfexion™ and other gamma stereotactic radiosurgery units for which the individual is authorized. This training requirement may be satisfied by satisfactorily completing either a training program provided by the Perfexion™ vendor or by training supervised by an AMP authorized for Perfexion™ 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 Perfexion™ unit. The written attestation must be signed by a preceptor AMP authorized for the Perfexion™ unit. The written attestation is not required for individuals who hold certification by a recognized specialty board.

For the Icon™ unit:

- 1) Is listed on a license or permit (NRC, Agreement State, Broad Scope License or NRC Master Materials License) as an AMP for gamma stereotactic radiosurgery unit use; an AMP for Leksell Gamma Knife Perfexion™ use; or is board certified by a board listed on the NRC's Web site 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 Icon™ unit. 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 Icon™ and other gamma stereotactic radiosurgery units for which the individual is authorized. This training requirement may be satisfied by satisfactorily completing either a training program provided by the Icon™ vendor or by training supervised by an AMP authorized for Icon™ use;

AND

- 3) For all individuals applying for the Icon™ before May 25, 2019, has documentation that the individual has satisfactorily completed the above training. For all other individuals applying for the Icon™ on or after-May 25, 2019, 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 Icon™ unit. 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 Perfexion™ units or other gamma stereotactic radiosurgery units. In order to function independently as an AMP the individual shall have demonstrated familiarity with treatment using both a stereotactic frame and the patient immobilization system which is a frameless therapy system. The written attestation must be signed by a preceptor AMP authorized for the Icon™ unit.

Identify the **Radiation Safety Officer (RSO)** with responsibility for the Perfexion™ and/or Icon™ gamma stereotactic radiosurgery unit and provide documentation of his/her training and experience in radiation safety for the Perfexion™ or Icon™ 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™ unit but may not have access to an operational Icon™ 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™ unit. The individual shall be considered qualified to be the RSO for the Perfexion™ or Icon™ gamma stereotactic radiosurgery unit if the individual meets the following:

For the Perfexion™ unit:

- 1) Is listed as an RSO on a NRC or Agreement State license (or NRC Master Materials License permit) authorizing gamma stereotactic radiosurgery unit medical use, or is board certified by a board listed on the NRC's Web site 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 Perfexion™ Icon™ gamma stereotactic radiosurgery unit. 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 Perfexion™ or Icon™ 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 Perfexion™ vendor, or supervised by an individual (RSO or AMP or AU) that is authorized for the Perfexion™ unit;

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 Perfexion™ gamma stereotactic radiosurgery unit. The written attestation must be signed by a preceptor RSO, AMP, or AU authorized for the Perfexion™ unit. The written attestation is not required for individuals who hold certification by a recognized specialty board.

For the Icon™ unit:

- 1) Is listed as an RSO on a NRC or Agreement State license (or NRC Master Materials License permit) authorizing gamma stereotactic radiosurgery unit medical use, Leksell Gamma Knife Perfexion™ medical use; or is board certified by a board listed on the NRC's Web site 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 Icon™ gamma stereotactic radiosurgery unit. 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 Icon™ 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 Icon™ vendor, or supervised by an individual (RSO or AMP or AU) that is authorized for the Icon™ unit. The individual should complete or commit to complete supplemental hands-on radiation safety and emergency procedures training on an operational Icon™ unit before first use of the unit for patient treatment;

AND

- 3) For all individuals applying for the Icon™ before May 25, 2019, has documentation that the individual has satisfactorily completed the above training and completed or provided documentation of a commitment to complete the supplemental hands on training. For all other individuals applying for the Icon™ on or after May 25, 2019, 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 Icon™ gamma stereotactic radiosurgery unit. 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 Perfexion™ units or other gamma stereotactic

radiosurgery units. The written attestation must be signed by a preceptor RSO, AMP, or AU authorized for the Icon™ unit.

Written Directive:

The Perfexion™ and Icon™ gamma stereotactic radiosurgery unit delivers a therapeutic dose of radiation from byproduct material and under 10 CFR 35.40 requires a written directive. Unlike earlier gamma stereotactic radiosurgery units, calculation of the dose to the treatment site is now dependent on the shaping of the radiation field at the focal point by selection of different collimators for each of the 8 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 Icon™ gamma stereotactic radiosurgery 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 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 procedure 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™ and Icon™ gamma stereotactic radiosurgery unit, 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™ or Icon™) 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™ or Icon™) control system.”

A number of 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 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 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 set-up 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™:

“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 set-up if a patient is observed to move during the course of a treatment and every time the IFMM 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.”

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™ and Icon™ 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™ or Icon™), 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 the retention period stated in Section 35.2605),

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),

Section 35.615,

Section 35.630 (and retain a copy of the information described in Section 35.2630 for the period stated in Section 35.2630),

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 period stated in Section 35.2632),

Section 35.645 (with modifications discussed below and retain a copy of the information described in Section 35.2645 with modifications discussed below for the period stated in Section 35.2645), and

Section 35.657.”

Unlike earlier models, the sources in the Perfexion™ and Icon™ units are located in the moveable 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 purpose of determining the helmet factors, determining trunnion centricity, testing the helmet switches and testing the trunnions of previous gamma stereotactic radiosurgery models was to assess whether the patient docking systems functioned 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. New tests should be performed as part of the revised spot test and full calibration test to assess these basic properties for the Perfexion™ and Icon™ unit.

Because the source exposure indicator for the Perfexion™ and Icon™ unit is on the treatment room wall instead of on the gamma stereotactic radiosurgery unit and the Perfexion™ and Icon™ unit does not include helmets, relative helmet factors, helmet micro-switches, hydraulic backups, trunnions, or a trunnion centricity point, the requirements in 10 CFR 35.635 and 35.645 to determine these values or test these components cannot be performed and the results of such determinations and tests cannot be recorded as described in 10 CFR 35.2632 or 35.2645.

In earlier models, the collimator (i.e., the helmet) was attached to the bed and the patient's head was attached to the helmet by the stereotactic head frame. This configuration resulted in a stationary bed and helmet docked in the gamma knife unit at a fixed and reproducible location. The stereotactic frame was moved small distances to center the treatment site at the radiation focal point. 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™ unit, 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 have been replaced by eight permanently installed independently movable sectors in the Perfexion™ and Icon™ unit. 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 source exposure indicator light on the wall of the treatment room are critical to the safe use of and proper functioning of the Perfexion™ and

Icon™ 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™ 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 operating manual *Instructions for Use* shall be performed exactly as stated.

The Icon™ will use the IFMM system to monitor movements of the patient during setup and treatment while immobilized by the mask. The IFMM cannot be used when the patient is immobilized with the Leksell (Perfexion™) Coordinate Frame. The IFMM uses infrared markers (IR) to determine position. The IFMM will pause the patient treatment in the event that the patient moves 0.5 to 3.0 mm from the original positioning. The IFMM may also be turned off manually, which will result in an alarm, but will not reposition the patient for treatment. The IFMM may also be referred to as the High Definition Motion Management (HDMM) system.

The applicant should confirm the following for both the Perfexion™ and Icon™:

“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 period stated in Section 35.2652.”

“We will follow the 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, hydraulic backup of the treatment table retraction system, or source exposure indicator lights on the unit. We will keep each record of the full calibration and spot-checks 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 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 _____ (select Perfexion™ or Icon™) 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™ or Icon™) 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 _____ (Perfexion™/Icon™) 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™ or Icon™) unit each day, we will confirm proper functioning of the source exposure indicator light on the treatment room wall. 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™ or Icon™) 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™ or Icon™) 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™ or Icon™) 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™ or Icon™) 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™ or Icon™) 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™:

“Before the first use of the Icon™ 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™ 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™ 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™ unit, we will confirm that the IFMM system is working properly by confirming that the IFMM 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 IFMM 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™ 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 IFMM system is working properly by performing a test without a patient present with the aim to check the IFMM 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™ 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™ 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.”

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™ and Icon™ 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™ or Icon™) unit. In the absence of published protocols for the _____(select Perfexion™ or Icon™) unit accepted by nationally recognized bodies, we will use procedures developed by the manufacturer.”

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™ and Icon™ units' radiation safety program only the procedures in 10 CFR 35.610 and 35.645 are appropriate.

The Perfexion™ and Icon™ units do not have helmet micro-switches, 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™), docking device, and source exposure indicator light on the wall of 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™ or Icon™ unit and spot-check procedures for the Perfexion™ or Icon™ unit.

Full Inspection and Service of the Perfexion™ and Icon™ Units

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 the Perfexion™ and Icon™ unit can only be performed at source exchange.

The applicant should confirm the following:

“We will commit to have each _____(select Perfexion™ or Icon™) gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement, but not to exceed seven years, to assure proper functioning of the source exposure mechanism and other safety components.

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 retention period stated in Section 35.2655.”

Notes to Licensees

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

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

Grandfathering

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

Changes in Physical Conditions of Use

If the physical conditions of use exceed those reported in the Sealed Source and Device (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.

Alterations to Perfexion™ or Icon™ Units

This licensing guidance is based on the 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 a new or 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™ or Icon™ unit.

Radiation Safety Program Changes

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 Perfexion™ or Icon™ gamma stereotactic radiosurgery unit safety program that might otherwise require a license amendment.

The NRC may revise this guidance as additional experience is gained regarding medical use of the Perfexion™ or Icon™ gamma stereotactic radiosurgery unit. A licensee currently authorized to use the Perfexion™ gamma stereotactic radiosurgery unit that is committed by license condition to following provisions in the previous Leksell Gamma Knife Perfexion™ guidance may request a license amendment to commit to following this revision of the guidance instead. The licensee must apply for and receive this license amendment in order to make program changes to conform to this revision of the guidance.

An applicant initially applying for authorization for medical use of the Perfexion™ or Icon™ gamma stereotactic radiosurgery unit, or a licensee applying for an amendment to conform with this revision of the guidance may request to incorporate into its license a change process similar to 10 CFR 35.26. Such a change process can allow some future changes to radiation safety programs provided that the change process requires the following conditions to be met for revisions to the radiation safety program:

1. The revision is in compliance with the regulations; and
2. the revision is based upon NRC's current guidance for the Perfexion™ and/or Icon™ gamma stereotactic radiosurgery unit 35.1000 use posted on the NRC Medical Uses Licensee Toolkit; and
3. the revision has been reviewed and approved by the licensee's Radiation Safety Officer and management; and
4. the affected individuals are instructed on the revised program before the change is implemented; and

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 management that reviewed and approved the change.

If approved, these conditions for use of updated guidance will be incorporated as license conditions in the licensee's license.

Inspection Frequency

Licenses authorizing Perfexion™ or Icon™ 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.

Program Code

The NRC regions should use program code 02240.

List of Guidance for Icon™ Units

The Icon™ makes use of an integrated CBCT imaging system in order 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 licensee must comply with all applicable rules and regulations, and be subject to routine inspections that the State agency may require.

The manufacturer of the Icon™ has indicated that training locations for the Icon™ unit should be operational within the next year. Because there were no units of the Icon™ unit approved for medical use in the United States at the time this licensing guidance was published, there are no preceptors available to sign attestations. Therefore, the NRC is postponing requiring a written attestation until May 25, 2019. 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 Perfexion™ units or other gamma stereotactic radiosurgery units. The NRC will continue to review the availability of preceptors and may revise this guidance if it determines that sufficient preceptors have become available. In addition, all individuals seeking authorization for use of the Icon™ must submit documentation of successful completion of required training.

Authorized Individuals

Identify each **AU** of the Icon™ gamma stereotactic radiosurgery unit and provide documentation of his/her training and experience in the use of the Icon™ 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 Icon™ gamma stereotactic radiosurgery unit if the individual meets the following:

- 1) Is listed on a license or permit (NRC, Agreement State, Broad Scope License or NRC Master Materials License) as an AU for 10 CFR 35.600 medical use of a gamma stereotactic radiosurgery unit; an AU for 10 CFR 35.1000 medical use of the Leksell Gamma Knife Perfexion™; or is board certified by a recognized board listed on the

NRC's Web site 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(a)(1) and (2) or 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 preparing treatment plans and calculating treatment doses and times, for the Icon™ gamma stereotactic radiosurgery unit. 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 Icon™ and the other gamma stereotactic radiosurgery units that the individual is authorized to use. This training requirement may be satisfied by satisfactory completion of a training program provided by the Icon™ vendor or by receiving training supervised by an AU or authorized medical physicist (AMP), as appropriate, who is authorized for the Icon™ use;

AND

- 3) For physicians applying for the Icon™ before May 25, 2019, has documentation that the physician has satisfactorily completed the above training. For all other physicians applying for the Icon™ on or after May 25, 2019, a written attestation from a preceptor Icon™ AU 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 Icon™ unit. 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 Perfexion™ units or other gamma stereotactic radiosurgery units. In order to function independently as an AU the individual shall have demonstrated familiarity with treatment using both a stereotactic frame and the patient immobilization system which is a frameless therapy system. The written attestation must be signed by a preceptor AU who is authorized for the Icon™ unit.

Identify each **AMP** for the Icon™ gamma stereotactic radiosurgery unit and provide documentation of his/her training and experience in the use of the Perfexion™ and/or Icon™ unit. 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™ and/or Icon™ gamma stereotactic radiosurgery unit, if the individual meets the following:

- 1) Is listed on a license or permit (NRC, Agreement State, Broad Scope License or NRC Master Materials License) as an AMP for gamma stereotactic radiosurgery unit use; an AMP for Leksell Gamma Knife Perfexion™ use; or is board certified by a board listed on the NRC's Web site under 10 CFR 35.51, "Training for an authorized medical physicist;" or meets the criteria 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 Icon™ unit. 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 Icon™ and other gamma stereotactic radiosurgery units for which the individual is authorized. This training requirement may be satisfied by satisfactorily completing either a training program provided by the Icon™ vendor or by training supervised by an AMP authorized for Icon™ use;

AND

- 3) For all individuals applying for the Icon™ before May 25, 2019, has documentation that the individual has satisfactorily completed the above training. For all other individuals applying for the Icon™ on or after-May 25, 2019, 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 Icon™ unit. 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 Perfexion™ units or other gamma stereotactic radiosurgery units. In order to function independently as an AMP the individual shall have demonstrated familiarity with treatment using both a stereotactic frame and the patient immobilization system which is a frameless therapy system. The written attestation must be signed by a preceptor AMP authorized for the Icon™ unit.

Identify the **RSO** with responsibility for the Icon™ gamma stereotactic radiosurgery unit and provide documentation of his/her training and experience in radiation safety for the Icon™ 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™ unit but may not have access to an operational Icon™ 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. The individual shall be considered qualified to be the RSO for the Icon™ 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 gamma stereotactic radiosurgery unit medical use; Leksell Gamma Knife Perfexion™ medical use; or is board certified by a board listed on the NRC's Web site under 10 CFR 35.50, "Training for Radiation Safety Officer," or meets the criteria 35.50(b)(1), or 35.50(c)(1) or 35.50(c)(2) for gamma stereotactic radiosurgery unit use;

AND

- 2) Received documented training in the radiation safety, regulatory issues, and emergency procedures for the Icon™ gamma stereotactic radiosurgery unit. 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 Icon™ 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 Icon™ vendor, or supervised by an individual (RSO or AMP or AU) that is authorized for the Icon™ unit. The individual should complete or commit to complete

supplemental hands-on radiation safety and emergency procedures training on an operational Icon™ unit before first use of the unit for patient treatment;

AND

- 3) For all individuals applying for the Icon™ before May 25, 2019, has documentation that the individual has satisfactorily completed the above training and completed or provided documentation of a commitment to complete the supplemental hands on training. For all other individuals applying for the Icon™ on or after May 25, 2019, 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 Icon™ gamma stereotactic radiosurgery unit. 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 Perfexion™ units or other gamma stereotactic radiosurgery units. The written attestation must be signed by a preceptor RSO, AMP, or AU authorized for the Icon™ unit.

License Commitments

The applicant may simplify its submission by confirming the following:

“For use of the Leksell Gamma® Knife Icon™, 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 the retention period stated in Section 35.2605),

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),

Section 35.615,

Section 35.630 (and retain a copy of the information described in Section 35.2630 for the period stated in Section 35.2630),

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 period stated in Section 35.2632),

Section 35.645 (with modifications discussed below and retain a copy of the information described in Section 35.2645 with modifications discussed below for the period stated in Section 35.2645), and

Section 35.657.”

The applicant should confirm the following for the Icon™:

“For the Icon™ gamma stereotactic radiosurgery 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 values for the target coordinate settings and sector settings for each treatment shot within an anatomically distinct treatment site.”

“For the Icon™ 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 Icon™ control system.”

“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 set-up if a patient is observed to move during the course of a treatment and every time the IFMM 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.”

“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 period stated in Section 35.2652.”

“We will follow the 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, hydraulic backup of the treatment table retraction system, or source exposure indicator lights on the unit. We will keep each record of the full calibration and spot-checks 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 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 Icon™ 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 Icon™ 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 Icon™ 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 Icon™ unit each day, we will confirm proper functioning of the source exposure indicator light on the treatment room wall. 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™ 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 Icon™ 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 Icon™ 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 Icon™ 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 Icon™ 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.”

“Before the first use of the Icon™ 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™ 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™ 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™ unit, we will confirm that the IFMM system is working properly by confirming that the IFMM 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 IFMM 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™ 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 IFMM system is working properly by performing a test without a patient present with the aim to check the IFMM 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™ 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™ 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.”

“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 Icon™ unit. In the absence of published protocols for the Icon™ unit accepted by nationally recognized bodies, we will use procedures developed by the manufacturer.”

“We will commit to have each Icon™ gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement, but not to exceed seven years, to assure proper functioning of the source exposure mechanism and other safety components.

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 retention period stated in Section 35.2655.”