Leksell Gamma Knife® Perfexion™ - Licensing Guidance

10 CFR 35.1000 use

Although the Leksell Gamma Knife® Perfexion™ (here after the Perfexion™) is a gamma stereotactic radiosurgery unit, it includes a number of engineering changes that make its 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." As a result, the Perfexion™ is regulated under 10 CFR Part 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation From Byproduct Material."

Licensing Guidance

Below are some recommended areas that applicants are encouraged to address in order to obtain license authorization for the use of the Perfexion.

This guidance represents an acceptable means of complying with regulations that apply to the Perfexion™ and is not intended to be the only means of satisfying requirements for a license. Therefore, to meet the requirements of 10 CFR 30.33 and 10 CFR 35.12, the applicant must provide the information requested below or may, unless the information is specifically required by regulation, submit alternative commitments for review by the NRC staff to determine whether the regulatory requirements are met. In addition, the commitments incorporated into the applicants 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. In most cases, the requirements for gamma stereotactic radiosurgery units also apply to the Perfexion™. However, in other cases departures from the requirements are needed to address the Perfexion™ unit's unique features and operations.

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 must 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.

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

Identify the radionuclides, chemical/physical form, maximum possession limit, and purpose of use. For example, the following provides the format for an acceptable request:

Radionuclides, Form, Possession Limits

Authorization 6: Cobalt -60

Authorization 7: Sealed sources (manufacturer and model number, e.g. Elekta model 43685 or General Electric AB ELEKTA model 43047)

Authorization 8: 36 curies per source not to exceed 6600 curies total (or 10000 curies during source exchange);

Purpose of Use

Authorization 9: For 35.1000 medical use in the Leksell Gamma Knife® Perfexion™ gamma stereotactic radiosurgery unit.

Facility Address and Description:

Provide an address of use and submit a facility diagram and description of the location where the Perfexion™ gamma stereotactic radiosurgery unit will be used, or stored [10 CFR 30.33(a)(2) and 10 CFR 35.12(b)(1)].

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

NRC has determined that individuals meeting the guidance provided below will be considered qualified and authorized for the Perfexion™ gamma stereotactic radiosurgery unit. Applicants may also submit alternative training and experience commitments to be reviewed on a case-by-case basis by 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.

Note: The manufacturer of the Perfexion has indicated that training locations for the Perfexion unit should be operational within the next year. NRC therefore will not require that individuals authorized for use of other gamma stereotactic radiosurgery units obtain a preceptor statement for use of the Perfexion. For all other individuals, the NRC is postponing requiring a written attestation until July 1, 2009. NRC will continue to review the availability of preceptors and may revise this guidance in this respect at such time as it determines that sufficient preceptors have become available. In addition, all individuals seeking authorization for use of the Perfexion must submit documentation of successful completion of required training.

Identify each **authorized user** (AU) of the Perfexion™ gamma stereotactic radiosurgery unit and provide documention of his/her training and experience in the use of the Perfexion™ unit. 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™ gamma stereotactic radiosurgery unit if the individual meets the following:

1. Is listed on a license or permit (NRC, Agreement State, or NRC Master Materials Licensee) as an AU for 35.600 medical use of a gamma stereotactic radiosurgery unit; or is board certified by a recognized board listed on 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 training in 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 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 and/or by receiving training supervised by an AU or authorized medical physicist (AMP), as appropriate, who is authorized for the Perfexion™ use;

AND

3. For an AU authorized for the 10 CFR 35.600 medical use of a gamma stereotactic radiosurgery unit, documentation that the AU has satisfactorily completed the above training;

or

For all other physicians applying before July 1, 2009, documentation that the physician has satisfactorily completed the above training. For all other physicians applying on or after July 1, 2009, a written attestation from a preceptor AU that the individual has satisfactorily completed the above training and has achieved a level of competency sufficient to function independently as an AU for the Perfexion™ unit. The written attestation must be signed by a preceptor AU who is authorized for the Perfexion™ unit.

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

1. Is listed on a license or permit (NRC, Agreement State, or NRC Master Materials licensee) as an AMP for gamma radiosurgery unit use; or is board certified by a board listed on 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 radiosurgery unit use;

AND

2. Received 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 unit, in accordance with 10 CFR 35.51(c), this training must also include instruction in 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. For an AMP that is authorized for the 10 CFR 35.600 medical use of a gamma stereotactic radiosurgery unit, documentation that the AMP has satisfactorily completed the above training;

or

For all other individuals applying before July 1, 2009, documentation that the individual has satisfactorily completed the above training. For all other individuals applying on or after July 1, 2009, a written attestation that the individual has satisfactorily completed the above training, and has achieved a level of competency sufficient to function independently as an AMP for the Perfexion™ unit. The written attestation must be signed by a preceptor AMP authorized for the Perfexion™ unit.

Identify the **Radiation Safety Officer** (RSO) with responsibility for the Perfexion™ gamma stereotactic radiosurgery unit and provide documention of his/her training and experience in radiation safety for the Perfexion™ 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. NRC recognizes that some applicants with new installations could have an individual who will have RSO responsibilities for the Perfexion™ unit but may not have access to an operational Perfexion™ 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 Perfexion™ 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 radiosurgery unit medical use, or is board certified by a board listed on 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 radiosurgery unit use;

AND

2. Received training in the radiation safety, regulatory issues, and emergency procedures for the Perfexion™ 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 on the differences in the radiation safety, regulatory issues, and emergency procedures of the Perfexion™ unit and other gamma stereotactic radiosurgery units for which the 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. The individual should complete or commit to complete supplemental hands-on radiation safety and emergency procedures training on an operational Perfexion™ unit before first use of the unit for patient treatment;

AND

3. For an RSO on a license authorized for the 10 CFR 35.600 medical use of a gamma

stereotactic radiosurgery unit, documentation that the RSO has satisfactorily completed the above training and completed or provided documention of a commitment to complete the supplemental hands-on training;

or

For all other individuals applying before July 1, 2009, 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 on or after July 1, 2009, a written attestation, signed by a preceptor (RSO, AMP, or AU) authorized for the Perfexion™, that the individual has satisfactorily completed the above training and has achieved a level of radiation safety knowledge sufficient to function independently as a RSO for the medical use of the Perfexion™ gamma stereotactic radiosurgery unit.

Written Directives:

The Perfexion™ 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 for each treatment shot should include the sector positions in addition to the target coordinate settings. 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; 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 to have procedures that provide high confidence that each administration is in accordance with the written directive. Under 10 CFR 35.41(2)(b)(4) these procedure are required to address, among other things, verifying that any computer-generated dose calculations are correctly transferred into the consoles 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™ 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 Perfexion™ unit, procedures that provide high confidence that each administration is in accordance with the written directive will address verifying that any computer-generated dose calculations (including target coordinate and sector settings) are correctly transferred into the Perfexion™ console."

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, which ever comes first.

The applicant should confirm the following:

> "Our program to provide high confidence that the administration is in accordance with the written directive will include written procedures for: (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, which ever 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™ unit is a gamma stereotactic radiosurgery unit, the applicant may simplify its submission by confirming the following:

> "For use of the Leksell Gamma Knife ® Perfexion™ unit , 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™ unit are located in the sectors which move. 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 source(s), or compromise the radiation safety of the unit or the source(s).

The applicant should confirm the following:

> "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 source(s) shielding, the sector drive unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s). We will retain information described in Section 35.2652 for the period stated in Section 35.2652."

Because the source exposure indicator for the Perfexion™ unit is on the treatment room wall instead of on the gamma stereotactic radiosurgery unit and the Perfexion™ unit does not include helmets, relative helmet factors, helmet microswitches, 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.

The applicant should confirm the following:

> "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 microswitches, 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."

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™ unit.

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.

The individual removable collimator helmets have been replaced by eight permanently installed independently movable sectors in the Perfexion™ 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/or function of the sectors, the patient bed, the docking device, the frame adapter, 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™ unit, and should be tested as part of the spot-checks 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 these reasons, the applicant should commit to the following actions:

"Before each patient use, 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 Perfexion™ 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 Perfexion™ 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™ 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 Perfexion™ 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 Perfexion™ 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 Perfexion™ 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, a test is developed that uses a diode or other radiation measurement precisely located in an off-centered position, 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 Perfexion™ 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 clearance test check tool is used to test for collisions. If, at a later date, this tool or another can be used to test the off center positions of the table, the tool or test should also be used to verify table position accuracy.)

"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 Perfexion™ 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 vender 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.)

"We confirm that if the frame 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 and "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."

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 Leksell Gamma knife® Perfexion™ unit contains components and features that are not addressed in the full calibration procedures accepted and published by nationally recognized bodies. In this case, the applicant may use procedures developed by the manufacturer.

The applicant should confirm the following:

"We will perform full calibration measurement procedures in accordance with published protocols accepted by nationally recognized bodies, except when nationally recognized bodies have not published required full calibration procedures for components and features of the Perfexion™ unit. In the absence of published protocols for the Perfexion™ 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™ unit radiation safety program only the procedures in 10 CFR 35.610 and 35.645 are appropriate.

It is not necessary for the applicant to provide spot-check procedures for determinating proper function of helmet microswitches, trunnion centricity, or source exposure indicator light on the unit because the Perfexion™ unit does not have components needed for these tests. However, the applicant should provide additional daily spot-check procedures for proper operation of the frame adapter, 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™ unit, and
Spot-check procedures for the Perfexion™ unit.

Full inspection and service of the Perfexion™ unit.

Under 10 CFR 35.655, NRC requires a five-year inspection for gamma stereotactic radiosurgery units or at source replacement, whichever comes first. 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™ unit can only be performed at source exchange.

The applicant should confirm the following:

"We will commit to have each Perfexion™ gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement to assure proper functioning of the source exposure mechanism.

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

Suggested Revisions to Existing Perfexion™ Programs to Conform to this Licensing Guidance

(Note: 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™ gamma stereotactic radiosurgery unit safety program that might otherwise require a license amendment).

The above licensing guidance may be revised as additional experience is gained regarding medical use of the Perfexion™ gamma stereotactic radiosurgery unit. A licensee already

authorized to use the Perfexion™ gamma stereotactic radiosurgery unit and committed by license condition to follow the provisions in the guidance existing at the time of commitment must apply for and receive an amendment to its license in order to make changes to conform to the revised provisions.

An applicant initially applying for authorization for medical use of the Perfexion™ 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:

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

The revision is based on the current guidance for the Perfexion™ gamma stereotactic radiosurgery unit 35.1000 use posted on the NRC website;

The revision has been reviewed and approved by the licensee's Radiation Safety Officer and management;

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

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

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