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ALL AGREEMENT STATES, VERMONT, WYOMING

NOTIFICATION OF ISSUANCE OF LEKSELL GAMMA KNIFE® PERFEXION™ AND LEKSELL GAMMA KNIFE® ICON™ LICENSING GUIDANCE (STC-16-042)

Purpose: To inform the Agreement States that the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance was published in May 2016.

Background: The licensing guidance for the Leksell Gamma Knife® Perfexion™ (hereafter referred to as the Perfexion™) was initially published in July 2007. The U.S. Nuclear Regulatory Commission (NRC) issued this licensing guidance under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.1000 due to the engineering changes, which makes the 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."

The Leksell Gamma Knife® Icon™ (hereafter referred to as the Icon™) is an image-guided gamma stereotactic radiosurgery device similar to the Perfexion™, but has additional modifications, including on-board cone beam computed tomography and a different immobilization system. The NRC issued the Sealed Source and Device Registration (SSDR) certificate for this system on December 01, 2015.

A joint Organization of Agreement States and NRC working group was created to: (1) review and evaluate the Icon™ SSDR and relevant documents; (2) determine if the Perfexion™ and Icon™ units were similar enough that they could be addressed in a single 10 CFR 35.1000 licensing guidance document; and (3) develop the 10 CFR 35.1000 licensing guidance document. The working group revised the Perfexion™ licensing guidance in its entirety to incorporate additional licensing conditions and information for the Icon™ unit. The document is intended to be guidance in licensing Perfexion™ and Icon™ units for applicants, licensees and NRC staff and is also available to the Agreement States to use.

Discussion: This current licensing guidance (published in May 2016) supersedes the previous Perfexion™ licensing guidance. As it was amended in its entirety to include the Icon™, it shall be considered revision 0. Notable changes in the guidance include: (1) the compliance with 10 CFR Part 37; (2) the written preceptor attestation requirement for authorized individuals of the Perfexion™ unit, excluding those who hold certification by a recognized specialty board; (3) the delay of the written preceptor attestation requirement for authorized individuals of the Icon™ unit until 2019, excluding those who hold certification by a recognized specialty board; (4) the full inspection and servicing of the Perfexion™ and Icon™ unit during source replacement, but not to exceed seven years; and (5) the grandfathering of individuals authorized for the Perfexion™ unit under the previous licensing guidance.

This licensing guidance may also be found on the NRC Medical Uses Licensee Toolkit at:
<http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

If you have any questions regarding this correspondence, please contact me at (301) 415-3340 or the individual named below:

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Enclosure:

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

Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes Licensing Guidance

Month Day, 2016, Revision 1

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10 CFR 35.1000 use

The use of iodine-125 (I-125) and palladium-103 (Pd-103) seeds for therapy is currently regulated under Title 10 *Code of Federal Regulations* (10 CFR) 35.400: "Use of sources for manual brachytherapy." Use of byproduct material for localization procedures currently regulated under 10 CFR 35.200 is limited to unsealed byproduct material. Use of sealed sources for diagnosis is currently regulated under 10 CFR 35.500, but is limited to sealed sources that have been explicitly approved for diagnostic medical use in the Sealed Source and Device Registry. In the radioactive seed localization (RSL) procedure, low activity radioactive seeds, including but not limited to I-125 and Pd-103, are implanted for localization and are not intended to deliver a therapeutic dose to tissue. RSL may use decayed radioactive seeds previously approved for the treatment of cancerous tumors under 10 CFR 35.400 or low activity radioactive seeds approved by the U.S. Food and Drug Administration (FDA) specifically for RSL use. Therefore, this application is not regulated under 10 CFR 35.200, 35.400 or 35.500. As a result, the use of these seeds for RSL procedures is regulated under 10 CFR Part 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."

Radioactive Seed Localization

The purpose of RSL of non-palpable lesions¹ and lymph nodes is to localize suspicious tissues for excision with the use of radioactive seeds. For example, typically, I-125 and Pd-103 seeds² between 100 – 300 µCi/seed are implanted using a standard 18-gauge needle. These seeds are normally implanted within mammography or ultrasound suites and removed within surgical suites. The radioactive seed(s) can be easily located with appropriate instrumentation (using a technique with which surgeons are familiar because of its similarity to sentinel lymph node biopsy and radio-guided parathyroidectomy) and surgically removed with minimal injury to non-affected tissue. The seed(s) may be removed from the tissue specimen in surgery, or the tissue specimen containing the seed(s) can be sent to pathology for removal of the seed and analysis of the tissue.

Licensing Guidance

This guidance provides applicants with an acceptable means of satisfying the requirements for a license for the use of RSL 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 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 Part 30.

¹ An area of suspicious tissue detected by an imaging modality such as ultrasound, magnetic resonance imaging or mammography that needs further evaluation.

² Multiple seeds may be used to define irregularly shaped lesions.

This guidance is intended to address situations where the physical locations of implant, excision, and recovery of these seed(s) are all authorized by the same radioactive materials license.

If the licensee intends to transfer the radioactive tissue samples, i.e., the tissues will still contain the seed(s) to an outside pathology laboratory, the licensee must ensure before shipment that the samples will be transferred to an NRC or Agreement State licensed laboratory authorized to receive the seeds or radioactive contaminated tissue (10 CFR 30.41). The applicant must also ensure that packages will be properly prepared in accordance with 10 CFR 71.5.

General

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. The NRC Form 313 may be used to submit this information. For example, the following provides the format for an acceptable request:

Radionuclides (Authorization 6)	Iodine-125 or Palladium-103
Chemical/Physical Form (Authorization 7)	Sealed sources (Manufacturer and Model)*
Maximum Possession Limit (Authorization 8)	300 microcuries per seed and 15 millicuries total
Authorized Use (Authorization 9)	For radioactive seed localization for non-palpable lesions and lymph nodes.

* The licensee may use radioactive seeds previously approved for the treatment of cancerous tumors that have decayed down to an activity range of 100-300 µCi. Alternatively, the licensee may use radioactive seeds approved by the FDA specifically for RSL use. There are currently three FDA-approved manufacturers for pre-loaded/pre-packaged needles for RSL use: Best Medical International, IsoAid, LLC and Theragenics Corporation.

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

Provide an address of use and submit a facility diagram and description of the location(s) where the radioactive sources will be received, used, and stored.

Because the tissues containing the RSL seeds are sent to pathology following surgery, pathology is a location that must be identified as a location of use in the application.

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 RSL. 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 an individual is qualified to be an authorized user (AU).

Identify each AU and provide documentation of their training and experience in the use of the low activity radioactive seeds for the RSL procedure. NRC Form 313A, "Medical Use Training and Experience and Preceptor Attestation," or other formats may be used to document this training and experience. The physician should be considered qualified for implementation, localization and removal of the seeds if the licensee demonstrates that the individual meets the following:

- 1) Is currently listed on a license or permit (NRC, Agreement State, Broad Scope License or NRC Master Materials License) as an AU for 10 CFR 35.490 medical use of manual brachytherapy sources; or is certified by a recognized medical specialty board listed on NRC's Web site under 10 CFR 35.490, "Training for use of manual brachytherapy sources;"

AND

Received and documented training in the use of instrumentation (e.g. intraoperative gamma probe) employed to identify the location of an implanted seed or seeds for excision. Such training should be provided by either a manufacturer's representative, a preceptor AU for RSL, or a 10 CFR 35.290 preceptor AU experienced with sentinel node biopsy using photon emitting radiopharmaceuticals (e.g. technetium-99m);

OR

- 2) Is listed on a license of permit (NRC, Agreement State, Broad Scope License or NRC Master Materials License) as an AU for 10 CFR 35.290 medical use of unsealed byproduct material for imaging and localization studies for which a written directive is not required; or is certified by a recognized medical specialty board listed on NRC's Web site under 10 CFR 35.290, "Training for imaging and localization studies."

AND

Received supervised and documented training and work experience under the supervision of a preceptor AU for RSL or a 10 CFR 35.490 AU. Training and supervised work experience should include the following:

- Work experience which includes at least 3 cases, wherein the RSL preceptor AU utilizes the devices used to implant seeds (i.e. needles);
- Work experience that includes identifying (radioactive seed appearance and characteristics), preparing, implanting, and observation of the removal RSL sources safely, to include safety and handling procedures and precautions;
- Work experience that includes routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a damaged, ruptured or leaking source; and
- Training provided by either a manufacturer's representative, an RSL preceptor AU, or a 10 CFR 35.290 preceptor AU experienced with sentinel node biopsy using photo emitting radiopharmaceuticals (e.g. technetium-99m) to include performing the related radiation surveys using the appropriate instrumentation (e.g. intraoperative gamma probe) to identify the location of an implanted seed(s) for excision.

OR

- 3) A radiologist or surgeon that has completed 80 hours of training and experience, including a minimum of 40 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of sealed sources. The training and experience must include, at a minimum:
- (i) Classroom and laboratory training in the following areas—
 - (A) Radiation physics and instrumentation;
 - (B) Radiation protection;
 - (C) Units of radioactivity and exposure;
 - (D) Radiation biology; and
 - (ii) Work experience, under the supervision of an AU for 10 CFR 35.1000 use of radioactive seeds for localization including:
 - (A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation protection surveys;
 - (B) Characteristics, preparation, safe handling, precautions, and labeling of radioactive seeds and needles containing radioactive seeds. Proper methods for storage, inventory and disposal of sealed sources including decay in storage program;
 - (D) Using administrative controls to prevent a medical event;
 - (E) Instruction on procedures to safely mitigate contamination from a leaking sealed source;
 - (F) Performing routine monitoring after all uses of the seeds to account for all seeds specified in the prescription and to ensure rapid identification and remediation of a damaged, ruptured or leaking source; and
 - (G) Proper use and maintenance of appropriate instrumentation (e.g. intraoperative gamma probe) to identify the location of an implanted seed(s) for excision;
 - (H) Training provided by either a manufacturer's representative, an RSL preceptor AU, or a 10 CFR 25.290 preceptor AU experienced with sentinel node biopsy using photon emitting radiopharmaceuticals (e.g. technetium-99m) to include performing the related radiation surveys using the appropriate instrumentation (e.g. intraoperative gamma probe) to identify the location of an implanted seed(s) for excision; and
 - (I) Work experience which includes participation in at least 3 patient cases.

AND

Obtained written attestation, signed by a preceptor AU for RSL 10 CFR 35.1000 use, that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU for RSL use.

Identify the **Radiation Safety Officer (RSO)** for RSL procedures and provide documentation of his/her training and experience. NRC Form 313A (RSO), "Radiation Safety Officer Training" or other formats may be used to document this training and experience. The individual shall be considered qualified to be the RSO for RSL procedures 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 RSO for medical use; or is certified by a recognized specialty board listed on NRC's Web site under 10 CFR 35.50, "Training for Radiation Safety Officer," or meets the criteria in 10 CFR 35.50(b)(1), 35.50(c)(1), or 35.50(c)(2).

AND

- 2) Has received training in the radiation safety, regulatory issues, and emergency procedures for RSL procedures. This training requirement may be satisfied by completing training that is provided by the manufacturer's representative vendor or supervised by an individual (RSO or AU) that is authorized for RSL procedures.

RSL procedures involve an interdisciplinary team. Therefore, such team members must have the appropriate radiation safety training as described below.

Radiologists, working under the supervision of an AU described above, who implant seeds should complete radiation safety training that includes:

- Identifying radioactive seed appearance, characteristics, safety handling procedures and precautions;
- Utilizing the devices used to implant seeds (i.e. needles);
- Preparing a treatment plan; and
- Performing routine monitoring after all uses of the seeds to account for all seeds specified in the prescription and to ensure rapid identification and remediation of a damaged, ruptured or leaking source.

Such training should be provided by the AU described above or the RSO, as applicable.

Surgeons, working under the supervision of an AU described above, who locate and remove the tissue containing the seed(s) should complete radiation safety training that includes:

- Performing the related radiation surveys using appropriate instrumentation (e.g. intraoperative gamma probe) employed to identify the location of implanted seeds for excision;
- Identifying radioactive seed appearance, characteristics, safety handling procedures and precautions;
- Performing routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a damaged, broken or leaking source; and
- Emergency procedures, including how to respond to a leaking source.

Such training should be provided by the AU described above or the RSO, as applicable.

Pathology Personnel handling specimens containing radioactive material should be instructed in the radiation safety aspects of safely handling the seeds and should complete radiation safety training that includes:

- Identifying radioactive seed appearance, characteristics, safe handling procedures and precautions;
- Minimizing time handling the specimen containing the seed(s);
- Using an appropriate survey instrument (e.g. gamma probe) to perform surveys of hands and work areas following handling of the specimen;
- Performing routine monitoring after all uses of the seeds to account for all seeds specified in the prescription and to ensure rapid identification and remediation of a broken or leaking source.
- Emergency procedures to be followed in the event contamination is identified or a seed is suspected of being damaged, ruptured or leaking;
- Accountability, security of the seeds post-implantation; and
- Proper disposal of the seeds and/or specimens containing the seed(s).

Such training should be provided by the AU described above or the RSO, as applicable.

Written Directive:

The sources used for this procedure are low activity radioactive sources that are used for localization purposes, but have the potential to deliver a dose greater than 50 rem at the distance of 5 mm from the axis of a 300 μ Ci seed and on the normal dissector of the source if left in for 47 days in breast tissue. Typical RSL procedures schedule the explantation within 5 days following the implantation date. Therefore, it is recommended that the explantation occur as soon as practical to minimize the exposure to the patient and to allow flexibility for patient management (i.e. scheduling surgery).

RSL is a localization procedure that involves the temporary implantation of a low activity radioactive source(s). The source and surrounding tissue will be excised for pathological processing. In accordance with 10 CFR 35.40, a written directive is needed for an administration of sodium iodide I-131 greater than 30 μ Ci, any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material. None of these apply to RSL; therefore, a written directive is not required.

Medical Event Reporting [10 CFR 35.3045]

The licensee shall commit to report any event, except for an event that results from (a) intervention of a patient or human research subject, (b) the patient or human research subject failing to return to for his/her explantation by the scheduled surgery appointment, or (c) the physician makes the determination not to explant the seed for various patient conditions (e.g. doing so would jeopardize the patient’s well-being) as is documented, in which:

The administration of byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from any of the following:

- a) an administration of the RSL procedure using the wrong radionuclide;
- b) an administration of the RSL procedure to the wrong patient or human research subject;
- c) an administration of the RSL procedure using the wrong number of radioactive seeds;

- d) an administration of the RSL procedure in which the implantation occurs outside of the lesion or lymph node site; or
- e) if the licensee fails to perform the explantation surgery.

Additionally, the licensee shall comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

Specific Information on Radiation Safety Precautions and Instructions for Radioactive Seed Localization [10 CFR 35.12(d)(1)(i)]

The applicant must submit the information required by 10 CFR 35.12(d). Because the low activity seeds are temporary implanted, the applicant may simplify its submission by confirming the following:

“For RSL procedures, we will meet the following requirements in 10 CFR Part 35:

- | | |
|----------------------------------|---------------|
| §35.67; | §35.404; |
| §35.406; | §35.432; |
| and the records requirements in: | |
| §35.2024; | §35.2026; |
| §35.2060 | §35.2067; |
| §35.2075; | §35.2310; |
| §35.2404; | §35.2406; and |
| §35.2432. | |

Because the RSL procedure involves an interdisciplinary team, the applicant must provide the following written procedures to describe the radiation safety program for all departments involved in the RSL procedure, including the surgical unit and the pathology laboratory:

- Written procedures for routine monitoring before, during, and after all uses of the seeds to ensure rapid identification of seed location; and in the remediation of contamination resulting from a broken or leaking source; and
- Written emergency procedures for responding to an abnormal situation to include:
 - instructions for responding to a source rupture (e.g. cut by a scalpel) during surgical removal to include procedures for retrieval of leaking/cut sources, contamination control, decontamination of the patient and area from a ruptured source and saturation of the patient's thyroid with stable iodine in the case of an I-125 source rupture;
 - instructions to pathology personnel for responding to a leaking/cut source and decontamination of personnel and area;

- the process for restricting access to and posting of the implantation/explantation/pathology area in the event of an unaccounted for or ruptured source to minimize the risk of inadvertent exposure from seeds;
- patient follow-up should they not return for explantation, including a commitment to make multiple attempts at contacting the patient and to perform a dose assessment; and
- names and telephone numbers of the AUs and the RSO to be contacted; and

The applicant must confirm the following:

“For RSL procedures, we will commit to the following actions for all departments involved in the RSL procedure, including the surgical unit and the pathology laboratory:

- that emergency response equipment will be available near each surgery suite and pathology laboratory during specimen handling;
- that the activity of sealed sources will be verified prior to each patient implant using a dosimetry system that meets the requirements of 10 CFR 35.630(a) or by using the sealed source activity measurements, after correcting for decay, provided by the manufacturer for pre-loaded/pre-packaged needles approved by the FDA for RSL use. Records of the measured sealed sources will be retained that includes: (i) the radioisotope; (ii) the patient's name or identification number; (iii) the measured activity; and (iv) the name of the individual who measured the activity, if the measurement was not completed by the sealed source manufacturer;
- that procedures will be conducted under the supervision of the AU, who should consult with the surgeon prior to implanting the sources;
- that surveys will be performed and records will be maintained as described in §35.404;
- that procedures will be developed, implemented, and maintained for source accountability from source acquisition, implantation, explantation and final disposal;
- that written waste disposal procedures will be developed, implemented, and maintained for licensed material that meet the requirements of the applicable section of Subpart K to 10 CFR 20 and 35.92;
- that patients will be instructed in writing before implantation and agree in writing to return for removal of the radioactive seeds; and
- that all personnel involved with the RSL procedure, including the RSO, will be trained on routine monitoring and emergency procedures.”

Notes to Licensees

Notification for AUs

The NRC recognizes that if an AU satisfies the training and experience listed in the NRC's licensing guidance for the RSL program and is currently listed on a Commission or Agreement State medical use license or permit for the RSL program, the AU should be allowed to work under a different license for the medical use of the RSL program. A limited specific medical use applicant initially applying for authorization for the medical use of the RSL program 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 satisfies the training and experience criteria listed in NRC's licensing guidance for the RSL program; and
2. the AU is currently listed for RSL program 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 to the NRC a copy of the license or permit on which the AU is listed for the RSL program; and
4. the licensee provides documentation to the NRC for each AU of the above listed conditions no later than 30 days after the date that the licensee allows the AU to work as an AU for the RSL program.

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 RSL training and experience criteria, physicians who are currently authorized for RSL procedures under previous criteria do not have to meet the revised criteria for RSL procedures.

Change in Physical Conditions of Use

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

Radiation Safety Program Changes

Note: 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 RSL safety program that might otherwise require a license amendment).

This guidance may be revised as additional experience is gained regarding medical use of RSL. A licensee currently authorized to use low activity radioactive seeds for RSL that is committed by license condition to following provisions in the previous RSL 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 RSL, 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 RSL 10 CFR 35.1000 use posted on the NRC Medical Uses Licensee Toolkit; and;
3. the revision has been reviewed and approved by the licensee's RSO 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's management representative who 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.

Survey and Source Localization Instrumentation

Licensees must have adequate equipment and provide information on equipment calibration. Licensees should possess and use a portable, properly calibrated radiation survey instrument capable of detecting low activity radioactive seeds. Applicants must submit a description of the survey instrumentation and calibration for the instruments they will use.

Inspection Frequency

Licenses authorizing RSL use should be inspected every five years. Per Enclosure 1 to Inspection Manual Chapter (IMC) 2800, licenses authorizing emerging technology in 10 CFR 35.1000 for diagnostic use are assigned a Priority 5 inspection code.

Program Code

In accordance with IMC 2800, program code 02121 is for a "medical institution – written directive not required." RSL is a diagnostic use of 10 CFR 35.1000 that does not require a written directive. Therefore, NRC regions should use program code 02121.