UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 24, 2020

ALL AGREEMENT STATES

NOTIFICATION OF ISSUANCE OF XCISION® GAMMAPOD™ LICENSING GUIDANCE (STC-20-007)

Purpose: To inform the Agreement States that the Xcision® GammaPod Licensing Guidance was published on January 22, 2020.

Background: On December 22, 2017, the GammaPod™ received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for use as a non-invasive stereotactic radiotherapy system utilizing 36 or 25 Cobalt-60 (Co-60) sources to treat breast cancer. The GammaPod™ system is different from traditional gamma stereotactic radiosurgery units as it uses a vacuum-assisted breast cup immobilization and stereotactic localization system, rotating source and collimator carriers, and table motion during treatment.

A joint Organization of Agreement States and U.S. Nuclear Regulatory Commission (NRC) working group was created to: (1) confirm the need to license the Xcision® GammaPod under Title 10 *Code of Federal Regulations* (CFR) 35.1000 rather than 10 CFR 35, Subpart H, and (2) develop an associated 10 CFR 35.1000 licensing guidance document if necessary.

Discussion: Although GammaPod™ is a gamma stereotactic radiosurgery device, the working group concluded that it includes several engineering changes that make its components and operation significantly different from the gamma stereotactic radiosurgery units currently regulated in 10 CFR 35, Subpart H. These engineering changes include the elimination of helmets, relative helmet factors, helmet microswitches, hydraulic backups, trunnions, and a trunnion centricity point, all of which are described in 10 CFR 35, Subpart H. In addition, the GammaPod's several new engineering features described above were not included in 10 CFR 35, Subpart H. As a result, the working group concluded the Gammapod will need to be licensed under 10 CFR Part 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material," and developed associated licensing guidance.

This licensing guidance is available at http://www.nrc.gov/materials/miau/med-use-toolkit.html.

If you have any questions regarding this correspondence, please contact me at 301-415-0324 or the individual named below:

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and Safeguards

Enclosure:
Xcision® GammaPod Licensing
Guidance

SUBJECT: NOTIFICATION OF ISSUANCE OF XCISION® GAMMAPOD™ LICENSING GUIDANCE (STC-20-007)

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Xcision® GammaPod™ Licensing Guidance

January 22, 2020

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1. 10 CFR 35.1000 Use

The Xcision® GammaPod™ (hereafter, GammaPod™) is a gamma stereotactic radiosurgery unit dedicated to non-invasive stereotactic delivery of a therapeutic dose to a partial volume of the breast as a component of Breast Conserving Therapy for breast cancer. Although GammaPod™ is a gamma stereotactic radiosurgery device, it includes a number of engineering changes that make its components and operation significantly different from the gamma stereotactic radiosurgery units currently regulated in Title 10 *Code of Federal Regulations* (10 CFR) Part 35, Subpart H, "Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units." These engineering changes include the elimination of helmets, relative helmet factors, helmet microswitches, hydraulic backups, trunnions, and a trunnion centricity point, all of which are described in 10 CFR 35, Subpart H. In addition, GammaPod™ has several new engineering features that were not included in 10 CFR 35, Subpart H, including its vacuum-assisted breast cup immobilization and stereotactic localization system, rotating source and collimator carriers, and table motion during treatment. As a result, the GammaPod™ is regulated under 10 CFR Part 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."

2. Licensing Guidance

This guidance provides applicants with an acceptable means of satisfying the requirements for a license for the use of the GammaPod™ 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[1] must still meet the general requirements in 10 CFR Part 35, Subparts ***A, B, C, L, and M***, except as specified in this guidance. Additionally, applicants must meet applicable requirements of 10 CFR Parts 19, 20, 30 and 37.

3. General

3.1. Sensitive Security-Related Information:

Certain sensitive security-related information such as information about quantities and locations of radioactive materials at licensed facilities is no longer released to the public.

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

[1] This regulation at 10 CFR 35.1000 is designated as Compatibility Category D. Agreement States are not required to adopt these regulations for purposes of compatibility.

3.2. 10 CFR Part 37

Applicants requesting authorization for the GammaPod™ unit must be in compliance with 10 CFR Part 37 upon the installation sources for this unit. Note that individuals who are servicing or inspecting (i.e., NRC or Agreement State inspectors) the GammaPod™ unit must be escorted at all times unless they fall under the relief granted under 10 CFR 37.29. In addition, if an applicant never implemented 10 CFR Part 37 requirements before, an on-site security review will be conducted prior to license issuance. For more information, see NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses;" NUREG-2155, "Implementation Guidance for 10 CFR Part 37, 'Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material;'" and NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

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

Pursuant to 10 CFR 35.12, the applicant shall identify the radionuclides, chemical/physical form, requested maximum possession limit, and purpose of use. NRC Form 313, "Application for Materials License," may be used to submit this information. For example, the following provides the format for an acceptable request:

Radionuclides, Form, Possession Limits

Radionuclides: (NRC Form 313 Item 5)	A. Cobalt-60
Chemical/Physical Form: (NRC Form 313 Item 5)	B. Sealed sources (Manufacturer and Model Number, e.g. Xcision Model INIS-SF-1.0-03-AE)
Maximum Possession Limit: (NRC Form 313 Item 5)	C. 198 curies per source not to exceed 4,950 curies total (or 10000 curies during source exchange)
Purpose: (NRC Form 313 Item 6)	For 10 CFR 35.1000 medical use in the Xcision® GammaPod™ gamma stereotactic radiosurgery unit.

3.4. 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 GammaPod™ gamma stereotactic radiosurgery unit will be used or stored. For more information, see the section entitled "Facility Diagram" in NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Medical Use Licenses", Revision 3.

4. Training and Experience

4.1 Authorized Individuals [10 CFR 30.33(a)(3), 10 CFR 35.12(b)(1), 10 CFR 35.50, 10 CFR 35.51, and 10 CFR 35.690]

The NRC has determined that individuals meeting the guidance provided below will be considered qualified and authorized for the GammaPod™ gamma stereotactic radiosurgery unit. Applicants may also submit alternative training and experience criteria to be reviewed on a case-by-case basis by the NRC staff. The alternative criteria should include an explanation of

why the applicant believes the alternative criteria demonstrates that the individuals are qualified to be authorized individuals.

All individuals seeking authorization for use of the GammaPod™ unit must submit documentation of successful completion of required training in accordance with 10 CFR 35.12(b)(1). The training and experience must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience in accordance with 10 CFR 35.59. Because there are a limited number of GammaPod™ units approved for medical use in the United States at the time this licensing guidance was published in 2020, there are a limited number of preceptors available to sign attestations. Therefore, the NRC is postponing requiring a written attestation until **[2 years from the issuance of this guidance]** for authorized users (AU) and authorized medical physicists (AMP). At that time, attestations will be required for individuals who do not hold certification by a recognized specialty board.[2] The NRC will continue to review the availability of preceptors and may revise this guidance if it determines that sufficient preceptors have not become available by **[2 years from the issuance of this guidance]**.

4.1.1. Authorized Users

Applicants and licensees should identify each AU of the GammaPod™ gamma stereotactic radiosurgery unit and provide documentation of their training and experience in the use of the GammaPod™ unit. The NRC Form 313A (AUS), "Authorized User Training, Experience and Preceptor Attestation," or other formats may be used to document this training and experience. The physician will be considered qualified for use of the GammaPod™ 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 medical use of a gamma stereotactic radiosurgery unit under 10 CFR 35.600 or 10 CFR 35.1000; or is certified by a recognized board listed on the NRC's Web site[2] under 10 CFR 35.690, "Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units;" or meets the criteria in 10 CFR 35.690(b)(1) and (2);

AND

2) Received documented training in hands-on device operation, safety procedures, and clinical use that includes preparing treatment plans and calculating treatment doses and times, for the GammaPod™ gamma stereotactic radiosurgery unit. If the individual is already an AU for another gamma stereotactic radiosurgery unit, this training must also include the differences in the device operation, safety procedures, and clinical use of the GammaPod™ compared to the other gamma stereotactic radiosurgery unit(s). This training requirement may be satisfied by satisfactory completion of a training program provided by the GammaPod™ vendor or by receiving training supervised by an AU or authorized medical physicist (AMP), as appropriate, who is authorized for the GammaPod™ use. Table 3.e. in NRC Form 313a (AUS) maybe used to provide documentation of this training;

AND

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

3) As of **[2 years from the issuance of this guidance]**, for proposed AU demonstrating training and experience who is not certified by a recognized board listed on the NRC's Web site[2] under 10 CFR 35.690(a) or not already authorized for use of GammaPod™; obtained a written attestation that the individual has satisfactorily completed the training requirements above and is able to independently fulfill the radiation safety-related duties as an AU for the GammaPod™ unit. The written attestation must be signed by a preceptor AU who is authorized for the GammaPod™ unit.

4.1.2 Authorized Medical Physicists

Applicants and licensees should identify each AMP for the GammaPod™ gamma stereotactic radiosurgery unit and provide documentation of his/her training and experience in the use of the GammaPod™ unit. The NRC Form 313A (AMP), "Authorized Medical Physicist and Ophthalmic Physicist Training, Experience and Preceptor Attestation," or other formats may be used to document this training and experience. The medical physicist will be considered qualified for use of the GammaPod™ 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; or is certified by a recognized board listed on the NRC's Web site[2] under 10 CFR 35.51, "Training for an authorized medical physicist;" or meets the criteria in 10 CFR 35.51(b)(1) for gamma stereotactic radiosurgery unit use;

AND

2) Received documented training in hands-on device operation, safety procedures, clinical use, and the operation of the treatment planning system used with the GammaPod™ unit. If the individual is already an AMP for another 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 operation of the treatment planning system used with the GammaPod™ unit compared to the other gamma stereotactic radiosurgery unit(s). This training requirement may be satisfied by satisfactory completion of a training program provided by the GammaPod™ vendor or by receiving training supervised by an AMP authorized for GammaPod™ use. Table 3.c. in NRC Form 313a (AMP) maybe used to provide documentation of this training;

AND

3) As of **[2 years from the issuance of this guidance]**, for proposed AMP who is not certified by a recognized board listed on the NRC's Web site[2] under 10 CFR 35.51 or who is not already authorized for use of GammaPod™; obtained a written attestation that the individual has satisfactorily completed the training requirements above and is able to independently fulfill the radiation safety-related duties as an AMP for the GammaPod™ unit. The written attestation must be signed by a preceptor AMP who is authorized for the GammaPod™ unit.

4.1.3 Radiation Safety Officers

Identify the **Radiation Safety Officer** (RSO) with responsibility for the GammaPod™ gamma stereotactic radiosurgery unit and provide documentation of his/her training and experience in radiation safety for the GammaPod™ unit. If desired, identify an individual who will be assigned duties and tasks as an Associate RSO (ARSO) for the GammaPod™ unit in accordance with 10 CFR 35.24(b). For both the RSO and ARSO, NRC Form 313A (RSO), "Radiation Safety Officer or ARSO Training, Experience and Preceptor Attestation," 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 or ARSO duties for the unit but may not have access to an operational GammaPod™ unit at the time of the radiation safety, regulatory issues, and emergency procedures training. For this reason, the applicant may commit that the individual(s) will complete supplemental hands-on radiation safety and emergency procedure training before first patient treatment using the GammaPod™ unit. The individual(s) will be considered qualified to be the RSO or ARSO, if applicable, for the GammaPod™ gamma stereotactic radiosurgery unit if the individual(s) meet the following:

1) Is listed as an RSO or ARSO on a license or permit (NRC, Agreement State, Broad Scope License, or NRC Master Materials License) authorizing gamma stereotactic radiosurgery unit medical use; or is certified by a recognized board listed on the NRC's Web site[2] under 10 CFR 35.50, "Training for Radiation Safety Officer and Associate Radiation Safety Officer;" or meets the criteria in 35.50(b)(1) or (c) for gamma stereotactic radiosurgery unit use;

AND

2) Received documented training in the radiation safety, regulatory issues, and emergency procedures for the GammaPod™ gamma stereotactic radiosurgery unit in accordance with 10 CFR 35.50(d). If the individual is already an RSO or ARSO for another gamma stereotactic radiosurgery unit, in accordance with 10 CFR 35.50(d), this training must also include the differences in the radiation safety, regulatory issues, and emergency procedures for the GammaPod™ unit compared to the other gamma stereotactic radiosurgery unit(s). This training requirement may be satisfied by satisfactory completion of a training program provided by the GammaPod™ vendor or by receiving training supervised by an RSO, ARSO, AMP, or AU, as appropriate, who is authorized on an NRC or Agreement State license for the GammaPod™ unit. Table 5.c. in NRC Form 313a (RSO) may be used to provide documentation of this training. In addition, the individual should complete or, for a newly requested unit, commit to complete supplemental hands-on radiation safety and emergency procedures training on an operational GammaPod™ unit before first use of the unit for patient treatment;

AND

3) For proposed RSO or ARSO who is not certified by a recognized board listed on the NRC's Web site under 10 CFR 35.50(a) or 10 CFR 35.51(a) or who is not already listed on a license or permit as the RSO or ARSO for the GammaPod™ or another gamma stereotactic radiosurgery unit; obtained a written attestation in accordance with 10 CFR 35.50 (b)(2) that the individual has satisfactorily completed the training requirements in 10 CFR 35.50 (b)(1) and (d) and is able to independently fulfill the radiation

safety-related duties as an RSO or as an ARSO, if applicable, for the GammaPod™ gamma stereotactic radiosurgery unit. The written attestation must be signed by a preceptor RSO or ARSO who has experience with the radiation safety aspects of similar types of use of byproduct material, generally the GammaPod™ unit, or another Gamma Stereotactic Radiosurgery (GSR) unit. The written attestation is not required for individuals who hold a certification by a recognized specialty board under 10 CFR 35.50(a) or 10 CFR 35.51(a); or who are currently listed on a license or permit for another gamma stereotactic radiosurgery unit where their training in accordance with 10 CFR 35.50, including preceptor attestation, was already evaluated.

5. Licensing Commitments:

5.1. Written Directives [10 CFR 35.40]

The GammaPod™ is a GSR unit and, under 10 CFR 35.40, requires a written directive. While target coordinate settings are required to be in the written directive for GSR under 10 CFR 35.40, it is inapplicable for GammaPod™ as the treatment is not controlled by distinct target coordinate settings. In addition, some GammaPod™ treatment protocols use fractions. Therefore, to assure the dose is delivered in accordance with the AU's direction, the written directive should provide the following commitment in place of 10 CFR 35.40(b)(3):

> *"For the GammaPod™ gamma stereotactic radiosurgery unit use, the written directive will contain the patient or human research subject's name; the total dose; the treatment site, including the planning target volume; dose per fraction; number of fractions; and the inner and outer breast cup sizes."*

Licensees must meet the requirements in 10 CFR 35.40(a), (c), and (d).

Licensees are required under 10 CFR 35.41(a)(2) to have procedures that provide high confidence that each administration is in accordance with the written directive. Under 10 CFR 35.41(b)(4), these procedures are required to address, among other things, verification that any computer-generated dose calculations are correctly transferred into the console 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.

The GammaPod™ treatment is delivered via a series of movements through a series of control points designed to match the treatment plan. In addition, proper localization and immobilization is necessary for a successful treatment. For this reason, the applicant should provide the following commitment in addition to 10 CFR 35.41:

> *"For the GammaPod™ unit, we will develop, implement, and maintain procedures that provide high confidence that each administration is in accordance with the written directive, which will include (1) verification that the control points are consistent with the treatment control system's displayed target volume, (2) verification of proper pump pressure and inner and outer cup breast cup sizes, (3) verification that the proper treatment plan has been selected, (4) pausing treatment and checking the patient set-up if a patient is observed to move such that delivery of the treatment would be effected, and (5) visually checking the patient set up at the initiation, re-initiation, and end of treatment."*

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

The applicant must submit the information required by 10 CFR 35.12(d), which can be met by the applicant confirming the following:

"*For use of the Xcision® GammaPod™, we will meet the following requirements for a gamma stereotactic radiosurgery unit in 10 CFR Part 35, Subpart H:*

Section 35.600;

Section 35.605 (and retain records of the information described in Section 35.2605 for 3 years);

Section 35.610 (and retain procedures described in Sections 35.610(a)(4) and (d)(2) until the licensee no longer possesses the unit);

Section 35.615(a) through (d), (g), 35.615(f)(4);

Section 35.615(f)(3) (with modifications discussed below);

Section 35.630 (and retain a copy of the information described in Section 35.2630 for the 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 35.652;

Section 35.655;

Section 35.657 (with modifications discussed below)."

The applicant must provide a copy of spot-checks and emergency procedures for the GammaPod™ unit in accordance with 10 CFR 35.12. For more information on these regulations, see sections on "Operating and Emergency Procedures" and "Emergency Procedures for Therapy Devices Containing Sealed Sources," in NUREG-1556, Volume 9, Revision 3.

5.3. Full Calibration Measurements and Periodic Spot-Checks and Full Calibration Measurements

Due to the design of the GammaPod™, there are some required spot-checks and calibrations in 10 CFR 35.635 and 35.645 that cannot be performed, and associated required records described in 10 CFR 35.2632 and 35.2645 that cannot be completed. For example, the GammaPod™ does not have a helmet for localization. Therefore, spot-checks on helmet

microswitches and trunnions and calibration on relative helmet factors, trunnions, and helmet microswitches cannot be performed. Further, the GammaPod™ has unique features, which were not considered during the development of 10 CFR 35, Subpart H, that require additional spot-checks and calibrations to ensure proper operations and functioning of the system to minimize risks of a potential medical event. These features include a breast immobilization and localization system; treatment table, sources, and collimators, which move during treatment; and the function of the uninterrupted power supply during a power failure event. Refer to the Sealed Source and Device registration certificate for more information about these design features.

5.3.1. Full Calibration Measurements [10 CFR 35.635]

As described above, some of the full calibration measurements described in 10 CFR 35.635 are not applicable. The applicable full calibration requirements for the GammaPod™ unit are 10 CFR 35.635:

- (b)(1), (3), (4), (5), and (9)
- (c), (e), (f), (g)

Therefore, the applicant should commit to the following:

- *"We will follow the applicable full calibration requirements of 10 CFR 35.635 and retain the information described in 10 CFR 35.2632 for each full calibration except for those requirements that are not applicable. We will keep each record of the full calibration for 3 years. We shall perform full calibration measurements as specified in 10 CFR 35.635(a). In addition, we shall perform full calibration measurements following any repair of the GammaPod™ unit that may affect dose output or the GammaPod's internal coordinate system, including major repair of the components associated with the collimator assembly or equipment, such as motors, associated with localization during patient treatment.*"

Due to GammaPod's unique design features, the applicant should commit to the following for the GammaPod™ in addition to those in 10 CFR 35.635:

- *"We will perform full calibration measurement procedures for the components and features of the GammaPod™ unit 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 GammaPod™ unit. In the absence of published protocols for the GammaPod™ unit accepted by nationally recognized bodies, we will use the most current procedures developed by the manufacturer.*

- *As part of full calibration measurements completed at intervals as specified in 10 CFR 35.635(a), we will perform a comprehensive routine quality check that includes:*
    - *all manufacturer suggested safety checks;*
    - *dosimetry accuracy and geometry accuracy tests;*
    - *end-to-end plan verification;*
    - *verification of proper functioning of all safety sensors, including proximity sensor ensuring proper docking;*

- *area surveys in both non-treating and treating conditions;*
- *the integrity of the uninterruptible power supply (UPS) system, including verification of collimator closure in event of power failure;*
- *localization system and docking devices; and*
- *the PodScope and other QA test tools.*

- *We confirm that if:*
  - *the localization system (i.e. breast cups, flange, and suction pump) fails to perform as designed, we will remove the defective part from service until repaired or replaced.*
  - *the docking devices (i.e. clamp, table loader, etc.), source and collimator movement, or table movement or 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.*
  - *QA survey instruments, the PodScope, or other QA test tool fails to function as specified by the manufacturer, we will have the tool repaired or replaced before needed to meet QA frequency requirements or the next patient treatment requiring the proper function of that tool.*

- *We will keep each record of the results of the tests for 3 years."*

5.3.2. Periodic Spot-Checks [10 CFR 35.645]

As described above, some of the spot-checks described in 10 CFR 35.645 are not applicable. The applicable spot-check requirements for the GammaPod™ unit are:

- 10 CFR 35.645
  - (b)
  - (c)(1)(i), and (1)(iii);
  - (c)(2)(i), (ii), (iii), (iv), and (v);
  - (d)(1), (3), (4), (5), and (6);
  - (e), as applicable
  - (f), as applicable

Therefore, the applicant should commit to the following:

> *"We will follow the applicable spot-check requirements in 10 CFR 35.645 and retain the information described in 10 CFR 35.2645 for each spot-check, except for those requirements that are not applicable. We shall perform spot-check measurements as specified in 10 CFR 35.645(a). We shall arrange for the repair of any system identified in 10 CFR 35.645(c) that is not operating properly as soon as possible. We shall lock the control console in the off position and not use the unit following any malfunction identified in 10 CFR 35.645(d). We will keep each record of the spot-checks for 3 years."*

In addition, due to the unique design features of the GammaPod, applicants should commit to the following:

"Before each patient use, and when the patient is immobilized~~,~~ we will:

- *confirm the breast immobilization and localization system is operating appropriately;*
- *confirm that the negative pressure pump maintains an air-tight vacuum and is functioning correctly;*
- *visually inspect the condition of the outer cup; and*
- *ensure the cup lock switch is operational, as specified by the manufacturer.*

Before first use on a given day, and after each source installation, we will:

- *confirm the geometric accuracy is in accordance with manufacturer tolerance limits;*
- *confirm proper functioning of the source exposure indicator light on the treatment room wall, in the facility prior to the treatment room, and on the console; and*
- *confirm date/time in the treatment console versus the planning computer.*

On a monthly basis, in addition to daily QA, and during the full calibration measurements, we will:

- *verify no discoloration on the outer breast cups;*
- *verify the condition of the stereotactic frame and verify that it is intact;*
- *confirm that the interlocks for the room door, the breast cup lock, breast suction pressure, and the shielding door are functioning properly;*
- *verify that, when the irradiation is interrupted or completed, the sources go to a shielded position and top shielding door closes; and*
- *verify the congruence between the dosimetric isocenter and mechanical isocenter; dosimetric accuracy; and dose linearity of the timer are within the manufacturer specified tolerance limits.*

If the results of the above checks indicate a malfunction, we shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system. We will keep each record of the results of these tests for 3 years. Attached are the detailed spot-check procedures in accordance with 10 CFR 35.12."

5.3.3 Published Protocols Accepted by Nationally Recognized Bodies

Full calibration measurement procedures for gamma stereotactic radiosurgery units required by 10 CFR 35.635(d) and acceptance testing on the treatment planning system of therapy-related computer systems required by 10 CFR 35.657 must be in accordance with published protocols accepted by nationally recognized bodies. However, the GammaPod™ unit contain components and features that are not addressed in the full calibration and acceptance testing 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 GammaPod™ unit. In the absence of published protocols for the GammaPod™ unit accepted by nationally recognized bodies, we will use procedures developed by the manufacturer."*
>
> *"We will perform acceptance testing on treatment planning systems in accordance with published protocols accepted by nationally recognized bodies, except when nationally recognized bodies have not published procedures for acceptance testing on the treatment planning system for the GammaPod™ System. In the absence of published protocols accepted by nationally recognized bodies, we will use procedures developed by the manufacturer, if available, or equivalent procedures, including execution of an acceptance procedure to verify radiation safety and machine functionality and a commissioning procedure, which includes a full dosimetry calibration and end-to-end verification of dosimetric accuracy, after each source installation."*

5.4. Physical Presence Required by 10 CFR 35.615(f)(3)

As defined in 10 CFR 35.615(f)(3), an AU and an AMP are required to be physically present throughout all patient treatments involving gamma stereotactic radiosurgery units. However, unlike older models of gamma stereotactic radiosurgery units, GammaPod™ has additional safety features, including the pump suction interlock, which will terminate the treatment if suction is lost or reduced below threshold levels, providing adequate assurance that the treatment would be terminated following patient movement. In addition, the system utilizes a completely automated treatment system to deliver dose, which eliminates the need to manually reposition patients following initiation of the treatment. As such, the physical presence of the AU throughout all patient treatments required by 10 CFR 35.615(f)(3) is unnecessary for the GammaPod™ units, provided an AMP and a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, are present during continuation of all treatments.

Therefore, the applicant should confirm to either meeting the requirements in 10 CFR 35.615(f)(3) or the following:

> *"1) An authorized user and an authorized medical physicist will be physically present during the initiation of all patient treatments involving the GammaPod™ unit;*
>
> *2) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, will be physically present during continuation of all patient treatments involving the GammaPod™ unit; and*
>
> *3) An authorized user will return to the GammaPod™ unit console if there is an interruption of treatment to evaluate the patient, to review any information related to an abnormal situation, and to ensure that the treatment is being delivered in accordance with the treatment plan and written direction prior to re-initiation of the treatment."*

6. Notes to Licensees

6.1. Alterations to GammaPod™ Units

This licensing guidance is based on the Sealed Source and Device (SS&D) safety evaluation in ***Registration Sheet MD-1362-D-101-S.*** Modification of the sources, the device, 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 GammaPod™ unit per 10 CFR 35.600(a)(1).

6.2. Changes in Physical Conditions of Use

If the physical conditions of use exceed those reported in the SS&D certificate, the limited specific medical use licensee should request an amendment for the new conditions, and a broad scope licensee should perform its own engineering and radiation safety evaluation addressing those differences.

6.3. Notification for AUs and AMPs

The NRC recognizes that, if an AU or AMP satisfies the training and experience listed in the NRC's licensing guidance for the GammaPod™ unit and is currently listed on a Commission or Agreement State medical use license or permit for the GammaPod™ unit, the AU or AMP should be allowed to work under a different license for the medical use of the GammaPod™ unit. A licensee 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 above;

2) the AU or AMP is currently listed for the GammaPod™ 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;

3) the licensee provides NRC a copy of the license or permit on which the AU or AMP was originally listed for the GammaPod™ 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 GammaPod™ unit.

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

6.4. Revisions to Existing GammaPod™ Radiation Safety Programs to Conform to Future Changes in Licensing Guidance and Additional Safety Recommendations from the Manufacturer

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

The above licensing guidance and safety recommendations from the manufacturer may be revised as additional experience is gained regarding medical use of the GammaPod™ gamma stereotactic radiosurgery unit by the regulator and manufacturer. In contrast with 10 CFR 35.26, a licensee already authorized to use the GammaPod™ gamma stereotactic radiosurgery unit and committed, by license conditions, to follow the provisions in the guidance and Operators Manual existing at the time of commitment must apply for and receive an amendment to its license prior to making changes to conform to the revised guidance and additional radiation safety recommendations.

An applicant initially applying for authorization for medical use of the GammaPod™ 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 radiation safety program, provided the following conditions are met:

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

2) The revision is based on the current guidance for the GammaPod™ under 10 CFR 35.1000 use posted on the NRC Web site;

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

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

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

6) The record will include a copy of the appropriate Web site 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 this authorization is approved, these conditions will be incorporated as license conditions in the licensee's license. This may be done by incorporating the commitments in the tie down condition.

7. Note to Regulators

7.1. Inspection Frequency

Licenses authorizing GammaPod™ 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.

7.2. Program Code

The NRC regions should use program code 02240.

8. Paperwork Reduction Act Statement

This Licensing Guidance provides voluntary guidance for implementing the mandatory information collections in 10 CFR Parts 30 and 35 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget (OMB), approval numbers 3150-0017 and 3150-0010. Send comments regarding this information collection to the Information Services Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555 0001, or by e mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150 0017, 3150-0010), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e mail: oira_submission@omb.eop.gov.

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

9. Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement, unless the requesting document displays a currently valid OMB control number.

SUBJECT: XCISION® GAMMAPOD™ LICENSING GUIDANCE

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