U.S. Nuclear Regulatory Commission (NRC)
Advisory Committee on the Medical Use of Isotopes ACMUI)
Subcommittee on Xcision® GammaPod™ Licensing Guidance

Final Report

October 23, 2019

Subcommittee Members

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Background

The Subcommittee and its Chair were appointed by ACMUI Chairman, Christopher Palestro, on May 16, 2019. The subcommittee charge was to review and comment on the NRC staff's draft Xcision® GammaPod™ Licensing Guidance.

Introduction

The Xcision® GammaPod™ (hereafter the GammaPod™) is a non-invasive gamma stereotactic radiosurgery unit which delivers 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, its design and operation significantly differ from traditional gamma stereotactic radiosurgery units, and a joint NRC/Agreement State working group determined that the GammaPod™ will be licensed under 10 CFR 35.1000. GammaPod™ has several new engineering features that are not addressed 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.

The Subcommittee endorses the draft licensing guidance, subject to the specific changes outlined below.

Training and Experience

Because the GammaPod is very different from the Elekta Gamma Knife (GK) devices, the Subcommittee determined that experience with the GK does not assure competence with GammaPod.

1. The draft guidance does not require attestation for AU's, AMP's, and RSO's who are qualified to use GK.

The Subcommittee recommends attestation for non-board certified AU's, AMP's and RSO's, even if they are already authorized users of other gamma stereotactic radiosurgery units.

The Subcommittee recommends the inclusion of a 2 year delay for the written attestation requirement for the RSO's to conform with the proposed 2 year delay for AUs and AMPs.

2. The draft guidance recommends training on the differences between GK and GammaPod for those who are qualified for GK.

The Subcommittee recommends removing the requirement for GK-trained individuals (AUs, AMPs, RSOs) to be trained on the differences in the device operation, safety procedures, and clinical use of the GammaPod compared to the Elekta GK.

The Subcommittee does not feel training on the differences between Elekta GK and GammaPod provides increased safety with respect to how these devices operate.

3. The draft guidance allows residency program directors to provide written attestation similar to 10 CFR 35.600

The Subcommittee recommends removing the ability of a residency program director to provide a written attestation since it is not likely the programs will include GammaPod experience at this time and it is unlikely GammaPod will be a standard treatment modality included in most residency programs. The attestation should be restricted to the AU for GammaPod.

4. The draft guidance allows a physician, under the supervision of an AU, who has been trained in the operation and emergency response for the unit, to be physically present instead of the AU during continuation of patient treatments.

The Subcommittee recommends explicit specification of who provides training in operation and emergency response for the physical presence requirement.

Associate RSO

Draft guidance provides guidance for an Associate RSO.

The subcommittee recommends not including the ARSO in Part 35.1000 licensing guidance documents because their roles are outlined in the new Part 35 rule and addressed in NUREG-1556, Volume 9. The RSO cannot be replaced by an ARSO. The ARSO involvement confounds the RSO responsibility.

Calibration and Spot Checks

The Subcommittee recommends splitting Full calibration and Periodic Spot checks into two separate sections.

The Subcommittee recommends clearly specifying that the geometric accuracy and source exposure indicator light spot checks be performed on a daily basis.

The Subcommittee recommends deleting the phrase "in addition to daily QA" in the monthly spot check statement.

The draft guidance states the frequency for speed of the table motion and collimator and source rotation and location of the radiation isocenter should be done approximately every 6 months while the sealed source and device (SSD) registration sheet states that these tests should be performed annually.

The Subcommittee recommends resolving the discrepancy between the frequency for speed of the table motion and collimator and source rotation and location of the radiation isocenter.

Written Directive and Source Description

The subcommittee recommends adding dose and frequency of fractions to the written directive to more fully comply with the definition of written directive.

In Section 3.3, the Subcommittee recommends replacing "GammaPod Model A" in the chemical/physical form line with the source models as listed in the SSD registration sheet (e.g., Model INIS-SF-1.0-03-AE for the 25-source configuration) to resolve the discrepancy in chemical language.

The ACMUI unanimously approved this report during its fall 2019 meeting on September 10, 2019.

Respectfully submitted on October 23, 2019,
Subcommittee on Xcision® GammaPod™ Licensing Guidance
Advisory Committee on the Medical Uses of Isotopes (ACMUI),
Nuclear Regulatory Commission (NRC)