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February 26, 2020

MEMORANDUM TO: Darlene Metter, M.D., Chairman
Advisory Committee on the Medical Uses of Isotopes

FROM: Christian Einberg, Chief
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Division of Materials Safety, Security, State,
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SUBJECT: RESPONSES TO THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPE'S RECOMMENDATIONS ON DRAFT XCISION GAMMAPOD LICENSING GUIDANCE

Below are the staff responses to the recommendations on the draft Xcision® Gammapod™ Licensing Guidance from the Advisory Committee on the Medical Uses of Isotopes (ACMUI). ACMUI provided its recommendations to the NRC on this licensing guidance on January 22, 2020 (ML19304B370).

1. **ACMUI Recommendation:** ACMUI recommends attestation for all non-board-certified authorized users (AUs), authorized medical physicists (AMPs), and radiation safety officers (RSOs). Even those who are authorized for other gamma stereotactic radiotherapy (GSR) units. The Subcommittee recommends the inclusion of a 2-year delay for the written attestation requirement for the RSO's if this is accepted.

   Staff Response: Partially Accepted: The working group updated the guidance to require attestation for all non-board certified AUs and AMPs. However, the working group decided that a RSO does not need a written attestation if they are already authorized for another gamma stereotactic radiosurgery as radiation safety not related to medical treatment is similar for the Gammapod as with other GSR units. The RSO would still need to have documentation training in the radiation safety, regulatory issues, and emergency procedures specific for the GammaPod,™ but this would not need to be attested to by an RSO. This is consistent with training requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) 35.50.

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2. **ACMUI Recommendation:** ACMUI recommends removing training in the differences between the Gammaknife and Gammapod for AU, AMP, and RSOs as the ACMUI did not feel training on the differences between the Gammaknife and GammaPod provides increased safety with respect to how these devices operate.

   Staff Response: Not Accepted. The working group believes training on differences between GSR units is important to ensure the user is aware those differences. For example, users should be aware of any differences between cranking the sources into a shielded position if there is an emergency situation and the sources get stuck. This training does not replace the training on the Gammapod but should be in addition to it. The working group believes this additional focus is necessary as differences between systems have caused medical events in other modalities, such as high dose rate (HDR), when users assumed the device operation is the same when it is not.

3. **ACMUI Recommendation:** The ACMUI 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.

   Staff Response: **Accepted**. The working group confirmed both operating sites do not include Gammapod in their residency programs and it is not expected this path would be used anytime soon.

4. **ACMUI Recommendation:** The ACMUI recommends explicit specification of who can provide the training in operation and emergency response for the physical presence requirement.

   Staff Response: Not Accepted. The language in the licensing guidance is consistent with language used for the physical presence requirement for HDR. In addition, regulations regarding who can provide supervision and emergency response training in 10 CFR 35.27 and 35.610(e) apply to the GammaPod.

5. **ACMUI Recommendation:** The ACMUI recommends not including the Associate Radiation Safety Officer (ARSO) in Part 35.1000 licensing guidance documents because their roles are outlined in the new Part 35 rule and addressed in NUREG Volume 9. The RSO cannot be replaced by an ARSO. The ARSO involvement confounds the RSO responsibilities.

   Staff Response: Not Accepted. The licensing guidance retained ARSO as it is expected licensees may use an ARSO to support their programs when they have 10 CFR 35.1000 authorization and are allowed under 10 CFR 35.

6. **ACMUI Recommendation:** ACMUI recommends splitting Full calibration and Periodic Spot checks into two separate sections.

   Staff Response: Accepted. The licensing guidance was updated.

7. **ACMUI Recommendation:** The ACMUI recommends the clear specification of the geometric accuracy and source exposure indicator light spot checks be performed on a daily

basis. The ACMUI recommends deleting the phrase “in addition to daily QA” in the monthly spot check statement.

Staff Response: Accepted. The licensing guidance was updated.

8. **ACMUI Recommendation:** The ACMUI recommends resolving the discrepancy between the frequency in the guidance versus the sealed source and device registry for speed of the table motion and collimator and source rotation and location of the radiation isocenter.

   Staff Response: Accepted. The licensing guidance was updated.

9. **ACMUI recommendation:** 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 ACMUI recommends resolving the discrepancy between the frequency for speed of the table motion and collimator and source rotation and location of the radiation isocenter.

   Staff Response: Accepted. Upon further review, these spot checks were removed from the licensing guidance document as the SSD sheet already states annual maintenance is required and the table motion and collimator and source rotation are monitored by redundant sensors or other spot checks and required calibration.

10. **ACMUI Recommendation:** The ACMUI recommends adding frequency of fractions to the written directive.

    Staff Response: Not Accepted. Adding frequency of fractions to the written directive would not be consistent with 10 CFR 35 and there is nothing unique about Gammapod which would account for the inconsistency.

11. **ACMUI Recommendation:** The ACMUI recommends replacing the “ GammaPod Model A “ in the table describing the source model with the source model for the 25-source array “ INF-SF-1.0-03-AE”.

    Staff Response: Accept. The licensing guidance was updated.

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