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INFORMATION NOTICE

TO: Radioactive Material Medical Use Licensees

FROM: Department of Health Services
Radioactive Materials Program

DATE: July 21, 2010

SUBJECT: Information Notice concerning post implant verification of permanent brachytherapy procedures

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PURPOSE:

The Wisconsin Department of Health Services, Radioactive Materials Program is issuing this information notice to inform medical use licensees of recent issues discovered by inspectors at medical licensees in Wisconsin. It is expected that recipients will review this information for applicability to their licensed activities and consider actions, as appropriate, to avoid similar problems. Suggestions contained in this Information Notice are not new DHS requirements; therefore, no specific action or written response is required. The Department does expect the applicable licensees to review their manual brachytherapy programs using a dose-based assessment of prostate implants as necessary to ensure that they have not had any medical events at their facilities.

DESCRIPTION OF CIRCUMSTANCES

The Department of Health Services became aware that two licensees did not have a written procedure to ensure that each brachytherapy administration is performed according to the provisions of a written directive per DHS 157.61(5)(a)2. Additionally, the licensees did not have quantitative dose-based criteria for determining the dose that was administered to the prostate and surrounding organs. Neither licensee performed a review of their prostate implants against the medical event reporting criteria listed in DHS 157.72. This resulted in patient treatments which met the criteria for medical events but were unidentified by the licensee. These patient treatments were identified by DHS inspectors as possible medical events during a routine inspection. In discussions with the Nuclear Regulatory Commission it was discovered that there have been other reported situations where licensees were not reviewing prostate implants using a dose-based criteria.

The first licensee selected a specific dose-based criterion for quantitatively analyzing prostate implants. The licensee identified medical events that included underdoses and overdoses to the prostate. They have also reviewed the dose to adjacent organs and identified additional medical events.

The second licensee had a procedure in place but used a volume based review of the prostate that received the dose delivered. The licensee has committed to perform a review of their prostate implants using dose-based criteria to determine the results of the brachytherapy implants. The licensee will determine the dose received to surrounding organs from these brachytherapy implants as well.

DISCUSSION

The licensees performed reviews of the patient treatment for clinical purposes only and not against the medical event reporting criteria listed in DHS 157.72. Licensees are reminded that they should perform dose-based reviews of all permanent brachytherapy implants.

Licensees should ensure that all Authorized Users (AU) and Authorized Medical Physicists (AMP) are trained on the medical event criteria and review the medical event reporting criteria. Additionally, AUs and AMPs should know the circumstances under which the RSO should be notified.

Licensees should be aware of the current recommendations that have been published concerning which dose-based review of brachytherapy implants should be used to determine the dose that the prostate and the adjacent organs have received following a permanent implant. The report of AAPM Task Group 137, dated December 2009, continues to follow the recommendation made by AAPM Task Group 64, dated July 1999, to use D_{90} and V_{100} for the dosimetric evaluation of comparing the prescribed dose to the dose delivered to the prostate. The Department encourages licensees to consider following AAPM recommendations for post-implant verification of the dose delivered to the prostate.

These two licensees understood how they had failed to ensure that the written directive was administered as prescribed, and agreed to do the following:

- Establish and submit a dose-based criteria to determine if medical events have occurred concerning prostate seed implants;
- Outline the scope of their planned investigation;
- Identify medical events and notify the patients and their physicians;
- Notify the Department of these medical events; and
- Submit a written report to the Department according to DHS 157.72(1)(d)

If licensees determine that they have not been performing post-implant verifications for prostate implants using dose-based criteria, the Department suggests that the licensees with manual brachytherapy programs perform dose-based reviews of all of their prostate implants dating back to August 2003 if they have not previously done so.

If you have any question about the information in this notice, please contact Mark Paulson at (608) 264-6516 or email at Mark.Paulson@wisconsin.gov or Kyle Walton at (608) 267-4791 or email at kyle.walton@wisconsin.gov.

References used:

http://www.aapm.org/pubs/reports/RPT_137.pdf

http://www.aapm.org/pubs/reports/RPT_68.pdf