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REGULATORY ISSUE SUMMARY 2011-01

TO: Radioactive Material Medical Use Licensees—Written Directive Required

FROM: Department of Health Services
Radioactive Materials Program

DATE: February 18, 2011

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

PURPOSE:

On July 21, 2010, the Wisconsin Department of Health Services issued an Information Notice concerning licensees who did not have criteria for determining whether or not prostate brachytherapy implants were performed in accordance with the written directive (DHS 157.61(5)(a)2). In addition, licensees did not have quantitative dose-based criteria for determining whether a medical event had occurred. This Regulatory Issue Summary is being issued to provide an update based on our subsequent inspections of licensees who perform prostate manual brachytherapy.

It is expected that recipients will review this information for applicability to their licensed activities and pursue actions, as appropriate, to avoid similar problems. **If your brachytherapy program has not been inspected since July 2010, submit the attached form with the requested information by March 31, 2011.** Subjects contained in this Regulatory Issue Summary are not new DHS requirements.

DESCRIPTION OF CIRCUMSTANCES

DHS 157.61(5)(a) states that, for any administration requiring a written directive, licensees must develop, implement and maintain written procedures to help ensure that each administration of radioactive material is performed according to the provisions of a written directive. DHS expects licensees to have written dose-based criteria which will allow a medical physicist, authorized user or other individual to verify that permanent prostate seed implants were performed according to the provisions of a written directive.

DHS 157.72(1)(a) requires, in part, that licensees report to the Department events in which the total dose delivered differs from the prescribed dose by 20% or more.

DISCUSSION

The Department is aware that there are conflicting recommendations between regulatory authorities and professional organizations on what should constitute a medical event for permanent prostate implants. The Department is attentive to the varying recommendations, but licensees are reminded that existing regulations [DHS 157.72(1)(a)] are dose-based and require reporting of events when the dose delivered is not within $\pm 20\%$ of the prescribed dose. The prescribed dose is the dose recorded by the authorized user physician on the written directive.

In the last six months the Department has asked the following questions during inspections of licensees who perform prostate brachytherapy. We are sharing these with you as additional guidance and to provide you with some lessons learned.

1. Does the written directive capture the intent of the authorized user? The Department has observed that treatment planning for prostate brachytherapy implants often utilizes a target dose value (i.e., D90) which is higher, and sometimes significantly higher, than the prescribed dose as recorded on the written directive. DHS expects licensees to have written procedures which document the intent of the authorized user. For example, a licensee's procedures may state that treatments will be planned to D90 of 110% of the prescription dose, and the post-treatment evaluation will compare the post-plan D90 value to the authorized user's prescribed dose. This is needed both for evaluating whether the dose was delivered in accordance with the written directive (as required by DHS 157.62(5)(a)) and for determining events which require reporting to the Department in accordance with DHS 157.72(1)(a).
2. Is the licensee utilizing the Dosimetric Quality Alert feature in the VariSeed® Treatment Planning Software? Recent versions of the VariSeed® treatment planning software support the "Dosimetric Quality Alert" feature. This feature must be user-activated. Users are able to input dose parameters, and during treatment planning, a Dosimetric Quality Alert box graphically indicates if a treatment is being planned too cold, within the specified parameters, or too hot. If licensees use VariSeed® Treatment Planning Software, DHS strongly encourages using the Dosimetric Quality Alert feature as one method for ensuring that treatments are planned according to their intended dose parameters.
3. How did the licensee select their medical event criteria? Some licensees have based their criteria on Section 6.2.12.2 of the Radiation Therapy Oncology Group (RTOG) 0232 protocol which states that the "variation acceptable" for the dose delivered to the prostate (as defined by the post-implant CT) is 80% of the prescription dose $< D90 < 130\%$ of the prescription dose. The Department has accepted criteria that permit doses up to 30% over the prescribed dose for licensees who identify medical events based on Section 6.2.12.2 of RTOG 0232. The Department has also accepted a variety of criteria for identifying medical events based on other dose methodologies.
4. Is the licensee defining a range as "clinically acceptable" and then adding a 20% "buffer" to that to identify a medical event? Several licensees submitted medical event criteria to the Department which add an additional 20% beyond the licensee's defined "acceptable

range” of treatment. These licensees were using medical event criteria which were, for example, $D90 < 60\%$ of the prescription dose or $D90 > 150\%$ of the prescription dose. DHS does not consider these expanded criteria reasonable as they significantly exceed the $\pm 20\%$ criteria of the event reporting requirements in DHS 157.72(1)(a).

Medical event identification is not equivalent to clinical unacceptability. Medical events do not necessarily indicate harm to patients; medical events may indicate radiation safety problems or treatment planning issues at a licensee’s facility. It is possible to plan and deliver prostate implants within 20% of a prescribed dose. The Department has gathered data from 11 licensees who have collectively reviewed over 1200 prostate brachytherapy implants performed since 2003. Of these, less than 3% of implants have been identified as medical events. A number of licensees identified no implants where the delivered dose was less than 80% or greater than 120% of the prescribed dose.

5. Were medical events identified for implants performed more than 1 year ago due to a retrospective review using newly established criteria? Several licensees identified medical events as the result of their retrospective review of prostate brachytherapy procedures. The Department understands the issues involved with notifying a patient whose implant meets a licensee’s criteria of a medical event but whose implant occurred several years ago and was considered clinically acceptable. In accordance with DHS 157.72(1)(e), the licensee is able to use discretion and not notify a patient who is the subject of a medical event if the referring physician decides, based on medical judgment, that telling the patient would be harmful and the referring physician informs the licensee of this decision. Consider using this discretion for implants performed more than one year ago. When reporting a medical event to the Department, licensees should specifically indicate whether or not the patient was notified.
6. What is the value of conducting a comprehensive review of prostate brachytherapy implants? Many licensees have reviewed prostate brachytherapy procedures performed under their licenses since 2003. This review has prompted identification of multiple areas where licensees can improve radiation safety and procedural techniques which would otherwise have gone unnoticed. Process improvements we are aware of include:
 - improving ultrasound visualization during implants;
 - building second checks in to the treatment planning process;
 - instituting a “treatment planning team” concept in the operating room; and
 - using intraoperative planning, allowing seeds to be added to cover cold spots.

If you have any questions about the information in this notice, please contact Mark Paulson at (608) 264-6516 or email at mark.paulson@wisconsin.gov; or Megan Shober at (608) 287-4422 or email at megan.shober@wisconsin.gov.

Reference

The Department’s July 21, 2010 Information Notice may be accessed at http://www.dhs.wisconsin.gov/dph_beh/RadioactiveMat/pdf/InformationNoticeJuly212010.pdf

REQUEST FOR INFORMATION

If your license authorizes you to perform permanent prostate brachytherapy and your prostate brachytherapy program has not been inspected by the Department of Health Services, Radioactive Materials Program since July 2010, submit the following information to the Department **by March 31, 2011**. You may submit facsimiles to 608-267-3695. For licensing purposes, your response will **not** be considered a license commitment.

1. Have you established dose-based criteria for identifying medical events for prostate brachytherapy?
2. If yes, identify the dose-based criteria used to identify medical events for prostate brachytherapy.
 - a. Overdose to the prostate:
 - b. Underdose to the prostate:
 - c. Overdose to other organs of interest (i.e., bladder, rectum, urethra):
3. Have you begun a retrospective review of prostate brachytherapy implants performed under your license?
4. Estimated completion date:
5. For prostate brachytherapy, my facility uses (check appropriate boxes):

☐ I-125 ☐ Pd-103 ☐ Cs-131
6. Name of individual completing this survey:
7. Phone number of individual completing this survey:
8. Radioactive Materials License number: