ARIZONA RADIATION REGULATORY AGENCY

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ARRA INFORMATION NOTICE **2013-IN-08**: THE NEED TO PERFORM PROCEDURES THAT WILL PROVIDE A HIGH CONFIDENCE THAT THE ADMINISTRATION OF PERMANENT IMPLANT BRACHYTHERAPY SOURCES ARE IN ACCORDANCE WITH A WRITTEN DIRECTIVE

ADDRESSES

After a thorough investigation by the NRC, it was determined that medical licensees who implant permanent brachytherapy sources are not performing necessary procedures to ensure the dose ordered is the dose delivered to a patient.

PURPOSE

The Arizona Radiation Regulatory Agency is issuing this information notice (IN) to inform medical licensees of the Agency's concern for lack of safety procedures to ensure treatment planning and nomogram techniques, used to determine dose to the volume of interest, deliver the dose as intended in the written directive. This IN provides guidance as to what should be performed by licensees to meet the intent of A.A.C. R12-1-708. Whatever safety analysis is performed, it should be vigorous enough to allow the licensee to assess the dose to the prostate (treatment site) and other affected tissues or organs, in assessing whether a medical event has occurred.

DESCRIPTION OF CIRCUMSTANCES

Even though there is professional guidance available for Arizona licensee to follow, it is believed this information may be overlooked for the sake of cost and time associated with implementation of additional safeguards. In general, the areas of concern include all of the following in some capacity: treatment planning, treatment administration, and treatment verification. The following Discussion is offered from the NRC and does agree in many respects with the guidelines of the AAPM.

DISCUSSION

Each medical licensee should examine the following areas to ensure patient safety is held to the highest standard:

- Implement acceptance testing on the treatment planning software, in accordance with R12-1-743;
- Ensuring the treatment plan is verified and approved by the authorized user, in accordance with R12-1-708;

- Ensuring that written directives are updated as necessary, in accordance with R12-1-707;
- For pre-loaded sources, ensuring the sources loaded are in fact the sources ordered for the treatment, in accordance with R12-1-708;
- For each patient who is treated, implement patient identification verification is occurring, in accordance with R12-1-708;
- Ensure that the implantation procedures include:
    a. Source counting and tracking, in accordance with R12-1-724;
    b. Source imaging to verify placement, in accordance with R12-1-708;
    c. Source retrieval from the bladder as applicable, in accordance with r12-1-724; and
    d. Surveys after implant, in accordance with R12-1-724.
- Ensuring the treatment was given in accordance with a written directive and treatment plan, if applicable, by performing post implant imaging such as CT or MRI, and dose calculations to compare the delivered dose to the calculated dose, in accordance with R12-1-707; and
- Ensuring the staff is aware of the Medical Event action levels so that they are reported as required, in accordance R12-1-745.
- As can be seen from this discussion, there is a great deal of emphasis placed on the dose verification activities during and after the implant procedure. With this said, the written directive must be completed before the procedure is completed, which is generally considered to occur when the patient leaves the recovery room, as required in R12-1-707.

It is important to remember that records of these activities must be maintained in accordance with Agency rule.

CONCLUSION

The Agency inspectors will be examining the areas covered in the above Discussion during future inspections. In this regard, the inspectors may want to interview any member of the implant team to better understand the breadth of the quality assurance program implemented by the licensee. Licensee representatives are expected to respond appropriately to all inspection questions**.**

Should a licensee find the Agency's position unacceptable, a written request for a variance should be sent to the Agency stating the above discussion is not acceptable, why it is not acceptable, with a description of the maintenance program that will be employed.

If there are any questions or concerns regarding this informational notice, please contact Brian Goretzki, Program Manager of the Radioactive Materials Program, at 602-255-4845 ext 234.

Sincerely,

Aubrey V. Godwin, M.S., C.H.P.
Director

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