ARIZONA RADIATION REGULATORY AGENCY

Janice K. Brewer
Governor

Aubrey V. Godwin
Director

4814 South 40th Street **Phoenix, Arizona 85040-2940** **(602) 255-4845**
Fax (602) 437-0705

September 5, 2013

ARRA INFORMATION NOTICE **2013-IN-05**: IMPORTANCE OF VERIFICATION OF TREATMENT PARAMETERS FOR HIGH DOSE-RATE REMOTE AFTERLOADER ADMINISTRATIONS

ADDRESSES

All Arizona Radiation Regulatory Agency (ARRA) high dose-rate remote afterloader (HDR) Licensees.

PURPOSE

The ARRA is issuing this information notice (IN) to stress the importance of verifying the accuracy of treatment parameters prior to HDR administrations in order to provide high confidence that administrations are in accordance with written directives. No specific action or written response is required. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar issues.

DESCRIPTION OF CIRCUMSTANCES

As a result of reported incidents involving HDR administrations, weaknesses were identified in licensees' procedures to provide high confidence that administrations are in accordance with written directives, as required by R12-1-707. Specifically, in certain cases, licensees' procedures did not ensure verification that the parameters of the treatment conformed to those specified in the written directive. The following are several recent examples:

Incorrect Step Size

Between 2009 and 2011, a licensee had 11 HDR patient treatments that resulted in medical events. In all instances, the licensee was using multi-catheter applicators, but because of the number of channels that the HDR unit could treat, the licensee had to divide each treatment plan into multiple plans. As a result, the licensee had to manually input the treatment parameters into the treatment console. During treatment planning, a 5-millimeter (mm) step size was used; however, the treatment console had a default setting of 2.5 mm, and the licensee failed to change the step size to 5 mm in the treatment console. The error resulted in an underdose near the connector end of the applicator and a higher-than-expected dose to the tip end of the applicator. As a result, there was an underdose to the patient. The doses delivered to the intended treatment site ranged from 47.01 percent to 64.58 percent of the dose that was prescribed in the written directive (WD) and specified in the treatment plan. As of the conclusion of the NRC's review of this medical event, no patients had reported any medical effects as a result of the error. The licensee's corrective actions included changes to its procedures to verify that the programmed treatment parameters agree with the written directive and treatment plan and training for personnel on the procedural revisions.

Incorrect Measurement of Distance to Catheter Tips

In 2010 and 2012, during preparations for HDR administrations with multi-catheter applicators, two licensees did not correctly measure the distance to the tips of the catheters and consequently input the erroneous distance measurements into the treatment planning system.

As a result, in both cases, the sources were 100 mm proximal to the intended position during treatment, delivering dose to an unintended site.

In the 2010 case, the intended treatment site received only 10 percent of the prescribed dose, and a small volume of the patient's skin received a dose equal to 200 percent of the prescribed dose, which resulted in radiodermatitis. The cause of not correctly measuring the distance to the top of the catheter was the licensee's use of a damaged source positioning simulator (SPS) tool. The licensee's corrective actions included removing the damaged SPS tool from service and obtaining a new one, developing and posting a reference table of common catheter distances, revising procedures to require a double-check of all patient measurements, and training personnel on the new reference table and procedural revisions.

In the 2012 case, the patient also received an overdose to the skin, which resulted in skin erythema that progressed to ulceration and ultimately necrosis. The incorrect catheter length was entered into the treatment planning system for the first and the third of 10 prescribed fractions. The licensee's corrective actions included revisions to written procedures, personnel training, and organizational changes.

Incorrect Reference Points

In 2010 and 2012, two licensees incorrectly constructed the applicators in the treatment planning system. In both cases, the licensees set the reference point of the applicator as "catheter end" instead of "tip end." As a result, the source's dwell positions were in relation to the opposite end of the applicator than intended. The treatment sites did not receive the prescribed doses, and the patients' tissues near the catheter end of the applicator received unintended doses. In both cases, the patients experienced effects such as erythema and ulceration. The licensee's corrective actions in the 2010 case included personnel training and procedure modification to add a step in the planning process to verify that the catheter orientation is correct in the treatment plan. The licensee's corrective actions in the 2012 case included modification of its procedures to include an independent review of HDR treatment plans, an additional independent check to verify the orientation of the catheter, and personnel training.

Incorrect Treatment Setup

In 2012, a licensee inadvertently connected a patient's endobronchial catheter to a one-meter long transfer tube instead of connecting the endobronchial catheter directly to the HDR unit per the manufacturer's instructions. As a result, the source did not reach the intended treatment site and remained outside the patient's body. The skin of the patient's left arm/shoulder area received an unintended dose of 1.8 centigray (rad). No long-term effects were expected from the unintended dose to the patient's skin. The licensee's corrective actions included procedure modifications to include a "time out" to confirm that the correct HDR connections are in place, development of a comprehensive instruction manual for appropriate treatment setups for each applicator, and personnel training.

Incorrect Treatment Plan

In 2012, two licensees reported medical events in which two patients were scheduled to receive HDR treatments on the same day and the second patient was treated using the first patient's treatment plan. In the event that occurred at the first licensee's facility the two patients' treatment plans were similar, and the second patient received a full treatment of 340 rem (3.4 Sv) using the first patient's treatment plan. This was a reportable medical event under R12-1-745. The cause was determined to be operator error and a failure to reprogram the HDR unit. No long-term effects were expected from the error. The licensee's corrective actions included modifying its procedures to require a "time out" to verify the patient's identity, the treatment plan file name, and the treatment settings. In the event that occurred at the second licensee's facility, the second patient's treatment was initiated using the first patient's treatment plan. The error was identified mid-treatment and stopped. The correct treatment plan was eventually

administered; however, the second patient received an unintended, additional dose as a result of the error. No long-term effects were expected from the additional dose. The licensee's corrective actions included providing additional training to personnel and requiring staff to follow established procedures for verifying patient identity.

Incorrect Catheter/Applicator Placement

In 2013, for the first of three prescribed fractions, a licensee inserted the applicator into the patient's rectum instead of the intended treatment site (the vagina). As a result, the intended treatment site was underdosed and the patient's rectum received 132 percent of the expected dose. The Agreement State ultimately determined that a reportable medical event did not occur in this case, because the intended area still received 69 percent of the prescribed dose for the first fraction. Based on the licensee's dose evaluation, the Agreement State also concluded that the incident did not meet the reportable medical event criteria due to the doses received by the unintended treatment areas, because the fractionated dose to the unintended tissue did not differ from the expected dose by 50 percent or more. Subsequent fractions were delivered as originally planned, and the total dose to the treatment site was within 20 percent of the prescribed dose. Corrective actions included adding a step to double check the location and positioning of the applicator.

DISCUSSION

After analyzing these incidents, the NRC/Agreement State staff determined that the root cause of these incidents was human error and that these medical events could have been prevented if the licensees had established effective programs for verifying treatment parameters prior to initiating treatment.

R12-1-707 requires that, for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. R12-1-707 requires that, at a minimum, the procedures mandated by paragraph (a) of this section must address the following items that are applicable to the licensee's use of byproduct material – (1) verifying the identity of the patient or human research subject; (2) verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive; (3) checking both manual and computer-generated dose calculations; and (4) verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by Group 600 in Exhibit A.

Although the rules in R12-1-707 do not specify the treatment parameters that must be verified prior to administration, licensees should ensure that treatment parameters are in accordance with the written directive and treatment plan in order to provide high confidence that HDR administrations are in accordance with their respective written directive. As discussed in in the April 24, 2002 Federal Register Notice, Section V, "Summary of Changes," (67 FR 20345), the rules in R12-1-707 are not prescriptive in order to allow licensees the flexibility to develop procedures that meet their needs. The ARRA recognizes that it is not possible to be able to foresee and prevent every possible error; however, the ARRA believes that an effective verification program will minimize the potential for errors to go undetected prior to initiation of an HDR treatment.

As illustrated by the examples above, errors can be made with regard to a number of HDR treatment parameters, such as step size, catheter length, treatment set-up, computer file name, and treatment site(s). These are just a few of the parameters that licensees may want to consider in ensuring that their written procedures will provide high confidence that HDR administrations will be in accordance with the written directives. The ARRA has observed licensees' implementations of verification programs through a number of means, such as pretreatment checklists (e.g., checking that the programmed treatment parameters are in accordance with the treatment plan, checking the location and positioning of the catheters and/or applicator, and confirming that the correct HDR connections are in place), "time out" procedures to verify the patient's name, treatment plan, and treatment settings, and independent checks by another qualified or trained individual. Although none of these actions are specifically required by the ARRA's rules, licensees have found these actions effective in ensuring that HDR administrations are in accordance with the written directives.

CONCLUSION

This IN requires no specific action or written response. If you have any questions about the information in this notice, please contact Brian Goretzki at 602-255-4845 ext. 234.

Sincerely,

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

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