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John R. Kasich / Governor

Theodore E. Wymyslo, M.D. / Director of Health

To: All Radioactive Materials Medical Licensees
Date: September 6, 2013

Subject: Information Notice IN1303
Importance Of Verification Of Treatment Parameters For High Dose-Rate Remote Afterloader Administrations

The U.S. Nuclear Regulatory Commission recently issued the enclosed information notice (IN 2013-16) to all their licensees. Copies of this information notice and other NRC information notices may be obtained at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices.

The purpose of forwarding this information is to remind licensees of the importance of verifying treatment parameters for high dose rate remote afterloaders by example of case histories of medical events.

The Bureau of Radiation Protection expects that licensees using HDR afterloaders will review the information for applicability to their facilities and consider actions appropriate to avoid similar issues.

The Bureau of Radiation Protection is forwarding this information notice to you for informational purposes. No specific action or written response is required.

If you have any questions concerning this letter, please contact me by phone at 614-644-2727 or by email.

Sincerely,

Karl Von Ahn

Karl Von Ahn
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Medical Licensing and Inspection Supervisor
Ohio Department of Health

Enclosure: US NRC IN 2013-16

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, D.C. 20555

August 12, 2013

NRC INFORMATION NOTICE 2013-16: IMPORTANCE OF VERIFICATION OF TREATMENT PARAMETERS FOR HIGH DOSE-RATE REMOTE AFTERLOADER ADMINISTRATIONS

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) high dose-rate remote afterloader (HDR) licensees and NRC master materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

PURPOSE

The NRC 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. The NRC is providing this IN to the Agreement States for their information and for distribution to their HDR licensees as appropriate.

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 Title 10 of the *Code of Federal Regulations* (10 CFR) 35.41(a). 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

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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 10 CFR 35.3045(a)(2)(iii). 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 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. Title 10 CFR 35.41(a) 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. Title 10 CFR 35.41(b) requires that, at a minimum, the procedures required 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 10 CFR 35.600 or 35.1000.

Although the regulations in 10 CFR 35.41 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 regulations in 10 CFR 35.41 are not prescriptive in order to allow licensees the flexibility to develop procedures that meet their needs. The NRC recognizes that it is not possible to be able to foresee and prevent every possible error; however, the NRC 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 NRC has observed licensees' implementations of verification programs through a number of means, such as pre-treatment 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 NRC's regulations, licensees have found these actions effective in ensuring that HDR administrations are in accordance with the written directives.

RELATED GENERIC COMMUNICATION

None.

CONTACT

This IN requires no specific action or written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below or the appropriate regional office.

/RA/

Brian J. McDermott, Director
Division of Materials Safety
and State Agreements
Office of Federal and State Materials
and Environmental Programs

Technical Contact: Aaron McCraw, RIII
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E-mail: Michael.Fuller@nrc.gov

Enclosure:
List of Recently Issued FSME Generic
Communications

RELATED GENERIC COMMUNICATION

None.

CONTACT

This IN requires no specific action or written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below or the appropriate regional office.

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Enclosure:
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Communications

*see previous concurrence

OFC	RIII/DNMS	RIII/DNMS	RIII/DNMS	FSME/RMSB
NAME	AMcCraw*	TBloomer*	ATBoland	AMcIntosh* T
DATE	02/12/13	02/13/13	02/27/13	03/26/13
OFC	FSME/RMSB	FSME/RMSB	FSME/RMSB	OGC
NAME	SHoliday	SGabriel	CEinberg	BJones
DATE	05/01/13	05/02/2013	08/06/2013	NLO 07/16/13
OFC	FSME/MSSA	FSME/MSSA		
NAME	PHenderson	BMcDermott		
DATE	8/8/2013	8/12/2013		

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List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications

Date	GC No.	Subject	Addressees
07/12/2013	IN-2013-13	Deficiencies with Effluent Radiation Monitoring System Instrumentation	All holders of operating licenses or a construction permit for a nuclear power reactor or a non-power reactor under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," including those that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel; all holders of and applicants for a power reactor early site permit, combined license, standard design certification, standard design approval, or manufacturing license under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants;" all holders of a materials license, certificate, approval, or registration, including those holders of and applicants for a specific source material license, under 10 CFR Part 40, "Domestic Licensing of Source Material;" all holders of and applicants for a uranium recovery operating license or construction permit under 10 CFR Part 40 which includes conventional mills, heap leach facilities, and in situ recovery facilities; all holders of and applicants for a fuel cycle facility license under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material;" all holders of and applicants for an independent spent fuel storage installation license under 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste."

List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications			
Date	GC No.	Subject	Addressees
06/03/2013	RIS-2013-09	Compressed Flammable Gas Cylinders And Associated Hazards	All holders of an operating license or construction permit for a nuclear facility under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," including those that have permanently ceased operations and have spent fuel in storage in the spent fuel pool. All holders of and applicants for a power reactor early site permit, combined license, standard design certification, standard design approval, or manufacturing license under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."
05/02/2013	RIS-2013-08	Pending Expiration of the NRC Type B Transportation Package Certificate for Sentinel™ Model 660 Series Radiographic Projectors on June 30, 2013	All holders of radiography licenses for SENTINEL™ Model 660 Series radiographic projectors; all Radiation Control Program Directors and State Liaison Officers.
03/25/2013	IN-2013-06	Corrosion In Fire Protection Piping due to Air and Water Interaction	All holders of an operating license or construction permit for a non-power reactor (research reactor, test reactor, or critical assembly) under 10 CFR Part 50, including those that have permanently ceased operations and have spent fuel in storage at their facility. All holders of and applicants for a specific source material license under 10 CFR Part 40, "Domestic Licensing of Source Material."

List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications

Date	GC No.	Subject	Addressees
03/19/2013	IN-2013-02	Issues Potentially Affecting Nuclear Facility Fire Safety	All holders of an operating license or construction permit for a nuclear power reactor under Title 10 of the *Code of Federal Regulations* Part 50, "Domestic Licensing of Production and Utilization Facilities," including those that have permanently ceased operations and have spent fuel in storage in the spent fuel pool; all holders of an operating license or construction permit for a non-power reactor (research reactor, test reactor, or critical assembly) under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," including those that have permanently ceased operations and have spent fuel in storage at their facility; all holders of and applicants for a power reactor early site permit, combined license, standard design certification, standard design approval, or manufacturing license under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants; " all holders of or applicants for a fuel cycle facility license under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"; all holders of or applicants for a special nuclear material license authorizing the possession, use, or transport of formula quantities of strategic special nuclear material under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material;" all holders of or applicants for an independent spent fuel storage installation license or a certificate of compliance under 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste; " all holders of or applicants for a gaseous diffusion plant certificate of compliance or an approved compliance plan under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants;" all holders of and applicants for a specific source material license under 10 CFR Part 40, "Domestic Licensing of Source Material"; all State Radiation Control Program Directors and State Liaison Officers.

List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications

Date	GC No.	Subject	Addressees
03/12/2013	RIS-2013-01	Use of Aftermarket Sealed Sources Registered Under 10 CFR 32.210	All holders of and applicants for a possession and use of byproduct material license for the processing or manufacturing of items that contain byproduct material for commercial distribution under Title 10 of the *Code of Federal Regulations* Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material;" all holders of and applicants for a possession and use of byproduct material license for research and development under 10 CFR Part 30;" all Radiation Control Program Directors and State Liaison Officers; all holders of an operating license or construction permit for a nuclear power reactor under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," that also hold a license under Part 30; all holders of and applicants for a power reactor early site permit, combined license, standard design certification, standard design approval, or manufacturing license under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," that also hold a license under Part 30.

Note: This list contains the six most recently issued generic communications, issued by the Office of Federal and State Materials and Environmental Management Programs (FSME). A full listing of all generic communications may be viewed at the NRC public website at the following address: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html