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

April 10, 2012

NRC INFORMATION NOTICE 2012-08: HIGH DOSE-RATE REMOTE AFTERLOADER (HDR) PHYSICAL PRESENCE REQUIREMENTS

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 remind addressees of the HDR physical presence requirements described in 10 CFR 35.615(f)(2). 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

During inspections of HDR facilities, the NRC staff has identified several issues associated with implementation of the physical presence requirement in 10 CFR 35.615(f)(2). The following is a brief overview of NRC staff findings:

Case #1

During an inspection in 2008, NRC inspectors noted that the licensee's procedures allowed an authorized user (AU) to designate and train a non-AU physician to fulfill the physical presence requirement during the initiation and continuation of HDR treatments.

Case #2

During an inspection in 2008 to follow-up on a reported medical event, NRC inspectors noted that an AU was not within normal hearing distance of the HDR console and was not able to assist the authorized medical physicist (AMP) in responding to a device error message. The AMP's erroneous response to the error message resulted in a medical event. In this event, the AU was not afforded the opportunity to review the error message or the AMP's response to the error message, which resulted in a change from the intended treatment position.

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Case #3

During an inspection in 2009, NRC inspectors observed that the only person physically present at the console during an HDR patient treatment was the AMP, who also served as the Radiation Safety Officer (RSO). The AMP/RSO stated that the AU had been present for initiation of the treatment, but then had to leave for a meeting outside of the department. The AU stated they were typically physically present for the initiation but not during continuation of HDR treatments. The AU usually remained within the Radiation Oncology Department, seeing other patients or working in their office, but did not remain within "hearing distance of normal voice" of the HDR control console.

Case #4

During an inspection in 2010, NRC inspectors observed a patient undergoing an HDR treatment and noted when the treatment was initiated the AMP was not present at the console, but a dosimetrist and the AU were present. The AMP was in another area of the Radiation Oncology Department, not within "hearing distance of normal voice" of the HDR control console, at the initiation of the patient treatment.

Case #5

During an inspection in 2010, NRC inspectors noted that an AU and AMP were present for the initiation and continuation of patient treatment as required by 10 CFR 35.615(f)(2). However, when reviewing the licensee's procedures for HDR treatments, the inspectors noted that the procedures did not appear to meet the physical presence requirements contained in the regulations. Specifically, the inspectors noted that the licensee's procedures allowed for either an AU or AMP to be physically present. The licensee indicated that the procedures had been developed in accordance with the manufacturer's instructions.

Case #6

During an inspection in 2011, NRC inspectors identified that after initiation of an HDR treatment, the AU routinely left the console area to conduct various tasks or to sometimes see patients in other rooms within the Radiation Oncology Department. Typically, the door to the console area was closed to maintain patient privacy. During HDR treatments, the AU periodically checked the treatment progress, and met with the patient at the conclusion of the treatment. The licensee also described that the AU could be summoned by the intercom to return to the treatment area if needed.

DISCUSSION

After analyzing these incidents, the NRC staff has recognized three types of errors associated with licensee interpretation of the physical presence requirement for HDR treatments. The errors are described in detail below and include: (1) the AU or AMP was not physically present in the HDR console area during initiation or continuation of a patient treatment; (2) the AU or AMP relied on alternate personnel to meet the physical presence requirements; and (3) the licensee's procedures allowed either the AU or AMP to leave the console area.

The regulations in 10 CFR 35.615(f)(2) state that the licensee shall, "for [HDR] units, require an [AU] and an [AMP] to be physically present during the initiation of all patient treatments involving the unit; and an [AMP] and either an [AU] or a physician, under the supervision of an [AU], who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit." The meaning of "physically present" as used in the regulations was defined in the April 24, 2002 *Federal Register* Notice, Section V, "Summary of Changes," (67 FR 20355) as "within hearing distance of normal voice." The word "normal" as used within the context of "normal hearing distance" should be given its dictionary meaning of "regular," "average," or "not deviating from an established rule."

Based on the definition for normal voice, the NRC has determined that the need for a raised voice in order for the AU and AMP to communicate with each other does not fit the definition of "normal" as used within the context of "normal hearing distance." Therefore, the location of the HDR console (for instance, around a corner or behind a door), or high background noise due to loud equipment, will affect what the "normal hearing distance" is. Licensees should take into consideration the specific environment in which the HDR unit is operating, remaining mindful that communication between the AU and AMP must be such that the use of a raised voice is not necessary. Furthermore, the NRC has determined for other therapy devices that the use of communication devices, such as "walkie talkies," intercoms, or any device used to transmit or amplify the human voice, does not meet the description of "normal hearing distance" [see Regulatory Issue Summary (RIS) 2005-023], and therefore, their use is not allowed as a means of fulfilling the physical presence requirement in 10 CFR 35.615.

The NRC found that in some cases, licensees misinterpreted the physical presence requirements in 10 CFR 35.615 as being met if the AU and AMP were present only during *initiation* of the treatment. In other cases, licensees believed that either the AU or AMP could be present for *initiation* of the treatment only. And finally, many licensees believed that as long as the individual not present was able to be rapidly summoned via a raised voice or intercom, that physical presence was met. In the cases described, the NRC found that licensees either were not aware of the details of the regulations or were not taking into account their specific operating conditions when determining what constituted physical presence within "hearing distance of normal voice." Licensee procedures should include consideration of their specific operating conditions to ensure that both an AU and AMP are physically present within "normal hearing distance" of the HDR treatment console during initiation of the patient treatment and that an AMP and either the AU or a non-AU physician who meets the requirements in 10 CFR 35.615(f)(2)(ii) are physically present within "normal hearing distance" of the HDR treatment console during continuation of the patient treatment. In addition, licensees who have adopted manufacturers' guidance should review their procedures to ensure that the regulatory requirements are correctly stated.

The NRC also notes that the regulations do not define "initiation of treatment" or specifically describe whether this statement refers to only the first fraction of a treatment course (e.g., during fraction one of five) or to only the first fraction to be delivered on that day, and not to initiation of each treatment fraction. However, to verify that the correct dose is being delivered, it is important to emphasize that the AU and AMP must be physically present during the initiation of each treatment fraction. Therefore, "initiation of treatment" should be considered as the initiation of each treatment fraction and not solely the initiation of the course of treatment.

The NRC also believes that the inherent risk of the HDR procedures justifies the need for a properly trained AU (or AU-supervised physician for continuation) and AMP to be available at all times to verify dose, monitor device operations, and respond to an emergency situation. Therefore, the regulations do not allow for the presence of any other personnel (e.g., dosimetrist) to meet the physical presence requirements of an AMP under any circumstances (initiation or continuation); an AMP must always be physically present during initiation and continuation of HDR treatments. Also, in addition to the AMP, although 10 CFR 35.615(f)(2)(ii) allows a non-AU physician under the supervision of an AU to fulfill the physical presence requirements during the continuation of an HDR treatment, 10 CFR 35.615(f)(2)(i) allows only an AU to fulfill the physical presence requirements during the initiation of an HDR treatment. This ensures appropriate personnel are available to verify that the correct dose is being delivered to the patient (i.e., AU and AMP) and to respond to an emergency (i.e., AMP and physician trained to respond to emergencies).

For additional information, licensees can find frequently asked questions regarding the physical presence requirement during HDR treatments on the NRC's Medical Uses Licensee Toolkit Web site, at: http://www.nrc.gov/materials/miau/med-use-toolkit/faqs-part35.html.

RELATED GENERIC COMMUNICATION

RIS 2005-23, "Clarification of the Physical Presence Requirement During Gamma Stereotactic Radiosurgery Treatments."

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.

/Pam Henderson for/RA/

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Enclosure:
List of Recently Issued FSME Generic
Communications

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OFC	RI/DNMS	RI/DNMS	FSME/RMSB	FSME/RMSB
NAME	PLanzisera	*MFerdas	MFuller	AMcIntosh
DATE	10/18/11	10/18/11	10/20/11	10/18/11
OFC	FSME/RMSB	OGC	FSME/MSSA	FSME/MSSA
NAME	CEinberg	BJones	PHenderson	BMcDermott
DATE	10/23/11	11/3/11	4/10/12	4/1012

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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
03/20/2012	RIS-2012-04	Notice of Revision to the Criteria for Identifying Materials Licensees for Discussion at the Agency Action Review Meeting	All U.S. Nuclear Regulatory Commission materials licensees (including fuel cycle facilities and master material licensees), Agreement State Radiation Control Program Directors, and State Liaison Officers.
01/17/2012	RIS-2012-01	Availability of Safety Culture Policy Statement	All U.S. Nuclear Regulatory Commission licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants subject to NRC authority. All Agreement State Radiation Control Program Directors, State Liaison Officers, and other interested stakeholders.
12/14/2011	RIS-2006-20, Rev. 1	Guidance for Receiving Enforcement Discretion When Concentrating Uranium at Community Water Systems	All community water systems in the U.S. Nuclear Regulatory Commission non-Agreement States that, while treating drinking water, may accumulate and concentrate naturally-occurring uranium in media, effluents, and other residuals, above 0.05 percent by weight. All Agreement State and Non-Agreement State Radiation Control Program Directors and State Liaison Officers
09/29/2011	RIS-2011-11	Regarding Long-Term Surveillance Charge for Conventional or Heap Leach Uranium Recovery Facilities Licensed Under 10 CFR Part 40	All holders of operating licenses for conventional or heap leach uranium recovery facilities; holders of licenses for conventional or heap leach uranium recovery facilities in decommissioning; companies that have submitted applications to construct new conventional or heap leach uranium recovery facilities or letters of intent to submit such applications; UMTRCA Title II sites; Agreement State Radiation Control Program Directors, and State Liaison Officers
08/31/2011	RIS-2011-10	Informing Licensees About the NRC's Public Web Site for Significant Enforcement Actions When Evaluating Individuals for Employment	All U.S. Nuclear Regulatory Commission licensees, certificate holders, permit holders, applicants, Agreement State Radiation Control Program Directors, State Liaison Officers, and other interested stakeholders.

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

Date	GC No.	Subject	Addressees
08/16/2011	RIS-2011-09	Available Resources Associated with Extended Storage of Low-Level Radioactive Waste	All U.S. Nuclear Regulatory Commission licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants subject to NRC authority. All Agreement State Radiation Control Program Directors, State Liaison Officers, and other interested stakeholders.

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