UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-03465
University of Wisconsin - Madison	)	License No. 48-09843-18
Madison, Wisconsin	)	EA 90-098

ORDER IMPOSING CIVIL MONETARY PENALTIES

I

The University of Wisconsin - Madison (Licensee) is the holder of Byproduct Materials License No. 48-09843-18 (license) initially issued by the Nuclear Regulatory Commission (NRC or Commission) on August 8, 1956. The license was most recently renewed on February 7, 1989 and is due to expire on March 31, 1994. The license authorizes the Licensee to use a variety of byproduct materials for medical and research applications at various locations within the University complex in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted on March 26 through May 2, 1990. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was served upon the Licensee by letter dated July 25, 1990. The Notice stated the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalties proposed for the Violations. The Licensee responded to the Notice on September 24, 1990. In its response, the Licensee admitted Violation I.A of the Notice, but argued

that escalation of the base civil penalty was unwarranted; denied Violation I.B of the Notice in its entirety; and admitted Violation II of the Notice.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violations occurred as stated and that the penalties proposed for the violations designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay civil penalties in the amount of $7,500 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) whether the Licensee was in violation of the Commission's requirements as set forth in Violation I.B. of the Notice referenced in Section II above, and

(b) whether, on the basis of such violation and the additional violations set forth in the Notice of Violation that the Licensee admitted, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director
for Nuclear Materials, Safety, Safeguards,
and Operations Support

Dated at Rockville, Maryland
this 28th day of December 1990

APPENDIX

EVALUATIONS AND CONCLUSIONS

On July 25, 1990, a Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was issued for violations identified during an NRC inspection on March 26 through May 2, 1990. The University of Wisconsin-Madison (Licensee) responded to the Notice on September 24, 1990. In its response, the Licensee admitted Violations I.A., II.A. and II.B. and denied Violation I.B. In addition, the Licensee requested reduction of the 50 percent escalation of the base civil penalty for Violation I.A. The NRC's evaluation and conclusions regarding the Licensee's requests are as follows:

I. Restatement of Violation I.A.

License Condition No. 23 requires, in part, that the Licensee conduct its program in accordance with statements, representations, and procedures contained in the application dated January 10, 1989.

The application dated January 10, 1989, Attachment VI, Procedures, Section 1, Operating Procedures, requires that operating procedures be established, in writing, and implemented.

An operating procedure reviewed and approved by the Radiation Safety Committee in April 1989, High Dose-Rate Remote Afterloader, Section A.2, requires that a trained operator be present during any use of the unit.

Contrary to the above, on two occasions during the period April 1989 through March 26, 1990, the High Dose-Rate Remote Afterloader was used to treat patients and a trained operator was not present.

Summary of Licensee's Response to Violation I.A.

The Licensee admits this violation occurred as stated. The proposed civil penalty was escalated 50 percent for NRC identification of the violation; however, the Licensee protests this escalation, and requests that, instead, the base civil penalty be mitigated 50 percent because it identified the violation after the first incident occurred.

The first incident occurred when a physicist left a nurse alone at the HDR unit treatment console while a patient was undergoing treatment. The Licensee admits the nurse was an untrained operator. It contends this incident was identified by the University shortly after it occurred and before the NRC inspection. It states the physicist involved was informed this was unacceptable and was not to happen in the future.

The Licensee believes it should not be cited for the second incident involving an untrained operator because it could not have reasonably discovered this violation before it occurred. The second incident occurred when the physicist responsible for the treatment was called away and left an untrained dosimetrist alone at the HDR treatment control console. The Licensee contends the physicist allowed the dosimetrist to be alone at the control console because he assumed she had received the required vendor-provided training since he had seen her name on the attendance roster for

the training. In fact, the dosimetrist had not received this training because she was called away for other duties about ten minutes after the training began. Another attendee signed the dosimetrist's name to the attendance sheet on the assumption that the dosimetrist would return momentarily.

The Licensee notes that its corrective action for this violation includes revising the training of HDR operators and submission of an amendment request setting forth new requirements. This request was approved by the NRC. The new training requirements for operators include 4 hours of training, passing a written exam and performing treatments under the direct supervision of a trained operator.

The Licensee did not contest the other escalation and mitigation factors originally proposed.

NRC's Evaluation of Licensee's Response to Violation I.A.

The Licensee's letter dated September 24, 1990, states it had identified the first example of the violation involving the nurse prior to the NRC inspection. However, it did not provide any documentation to support this contention. During the inspection on March 26, 27, and 28, 1990, the NRC inspectors questioned the Radiation Safety Officer as to whether any incidents, other than the two reported misadministrations which initiated the special inspection documented in NRC's letter dated May 21, 1990, had occurred with the use of the HDR unit. The Radiation Safety Officer denied any other incidents had occurred.

During the inspection, on March 28, 1990, a dosimetrist mentioned the first incident involving the nurse and the inspectors made an inquiry into the event. During a telephone interview with the inspector on April 2, 1990, the nurse was asked whether she had mentioned this incident to the Chief Physicist, Dr. Paliwal, or to anyone else. She stated she could not recall informing her supervisors of this incident, but apparently did mention it to her peers because a dosimetrist told the inspectors about it.

Based on the information collected by the inspectors during and after the inspection, it appears that Licensee management as well as other physicists who were involved in the program were not aware of this event or that corrective actions were to be taken. Had the Licensee identified the incident involving the nurse described in the first example of the violation and reported it to the inspectors in response to their questions during the inspection or reported it internally to Radiation Safety program management, mitigation may have been considered. However, no such report or documentation of the incident supporting the Licensee's contention that it identified this violation was given the inspectors during the inspection or presented or discussed during the enforcement conference. Therefore, the NRC concludes that there was insufficient information provided to show that the Licensee identified this event as a violation, and, as such, there was no basis for mitigation of the base civil penalty.

The second example of Violation I.A involved a dosimetrist. A Nucletron training session attendance list indicated that eight people, including this dosimetrist, attended the training session on April 13, 1989. Also in attendance was the physicist who left this dosimetrist alone at the treatment control console on one of the occasions indicated in Violation I.A. During the inspection, it was learned that this dosimetrist was only present at the course for approximately 10 minutes and another attendee had signed the dosimetrist's name on the attendance sheet on the assumption that she would return shortly and complete the training. However, the dosimetrist did not return and her name was not struck from the attendance roster.

The NRC concludes that the physicist's contention that he reasonably assumed the dosimetrist had completed the training, based on his recollection that the dosimetrist's name was on an attendance roster for training that occurred 11 months prior to the incident, is without merit. It is clear that the dosimetrist was not trained and was left alone at the control panel by the physicist. This was a violation as set forth in Violation I.A. The accuracy of the training list is the responsibility of the Licensee and any mistake regarding that list does not justify or mitigate the instant violation. Moreover, it is reasonable to expect that a person supervising a critical task such as the operation of the High Dose-Rate Remote Afterloader, would confirm that the dosimetrist was qualified prior to leaving the person alone.

The NRC did not escalate or mitigate this case on the basis of corrective actions. However the Licensee discussed its corrective actions as an additional basis for mitigation. Although the Licensee's corrective actions, as submitted in the license amendment request dated April 6, 1990 and incorporated as Amendment No. 72 dated May 3, 1990, are appropriate and extensive, the submission of this amendment was initiated at the request of NRC and therefore not considered prompt. NRC requested that the Licensee prepare an amendment to its license and provided specific information as to what the amendment should contain. Therefore, the NRC still concludes that neither escalation or mitigation is appropriate under the corrective action factor.

II. Restatement of Violation I.B.

License Condition No. 23 requires, in part, that the Licensee conduct its program in accordance with statements, representations, and procedures contained in the application dated January 10, 1989.

1. The application dated January 10, 1989, Attachment VI, Procedures, Section 4, Treatment Time Calculations, requires that treatment time calculations be independently verified.

   Contrary to the above, during the period April 1989 through March 26, 1990, at least 35 treatment plans did not have the treatment time calculations verified.

2. The application dated January 10, 1989, Attachment VI, Procedures, Section 1, Operating Procedures, requires that operating procedures be established, in writing, and implemented.

An operating procedure reviewed and approved by the Radiation Safety Committee in April 1989, High Dose-Rate Remote Afterloader, Section C.1.b., requires that the treatment plan be reviewed by a second person to check for possible errors.

Contrary to the above, during the period April 1989 through March 26, 1990, at least 35 treatment plans were not reviewed by a second person to check for possible errors.

Summary of Licensee's Response to Violation I.B.

The Licensee denies the violation and alleges that the NRC does not have regulations or guidance documents establishing the requirements for operation of an HDR unit. The Licensee asserts that the treatment time calculations were independently verified and the treatment plan reviewed by a second person to check for possible errors during preparation of the treatment card when a physicist watched a dosimetrist work up the treatment plan.

The Licensee claims the dosimetrists were trained and capable of preparing HDR treatment plans wholly on their own and that the physicist observing their treatment plan preparation was simultaneously performing the required independent verification of the treatment time calculations and was checking for possible errors.

Until the first misadministration occurred on February 7, 1990, the Licensee claimed it exercised reasonable care in executing an independent verification of treatment plan parameters. After this first misadministration, the Licensee instituted a "functionally independent" verification procedure in which a second physicist working alone checked the plan.

NRC's Evaluation of Licensee's Response to Violation I.B.

Contrary to the Licensee's assertion that NRC does not have regulations or guidance documents for an HDR unit, it should be noted that, on February 20, 1986, NRC issued Policy and Guidance Directive FC 86-4, "Information Required For Licensing Remote Afterloading Devices." Enclosure 2 of this Directive is routinely provided to Licensees upon request, in order to assist in the preparation of an amendment request to add authorization for a remote afterloading device to an existing license. In reviewing the University of Wisconsin-Madison License Amendment No. 68, it is apparent that this guidance document was used to prepare the Licensee's application, dated January 10, 1989, to add the remote afterloading device authorization to its license. The format of the January 10, 1989 application shows a close correlation with the guidance document. This guidance document directs Licensees to make certain commitments in an application for a remote afterloading device, including a commitment to independently verify treatment time calculations before treatment is begun (Section VI. "Operating Procedures," Subitem A.5.). In its application, dated January 10, 1989, the Licensee made this commitment, in accordance with the guidance.

Regarding the dosimetrists' ability to prepare HDR treatment plans on their own, the NRC inspectors interviewed four of the Licensee's dosimetrists

during the inspection. Three of the four indicated discomfort, inexperience and inadequate training for their role in HDR treatment planning. The fourth dosimetrist, who indicated her level of HDR knowledge and experience made her comfortable, was the only one sent to Nucletron for a dedicated three day training session, instead of just having had the four hour training session Nucletron conducted onsite at the Licensee's facilities. Therefore, the NRC has concluded that three of four Licensee dosimetrists, by their own admission, were not qualified to prepare HDR treatment plans on their own. In these cases the physicists were providing assistance in preparing the treatment plan rather than an independent verification. In addition, in its letter, dated September 24, 1990, the Licensee states "...following the first misadministration, we realized that a physicist observing the preparation of a plan was not functionally independent and established a procedure in which a second physicist working alone checked the plan."

The NRC has concluded that the Licensee's argument justifying its interpretation of independent verification of treatment parameters is without merit and does not provide a basis for withdrawing the violation.

III. NRC Conclusion

Based on the information presented by the Licensee and evaluated by the NRC, it has been concluded that the $7,500 in civil penalties proposed by the NRC in its July 25, 1990 Notice of Violation and Proposed Imposition of Civil Penalties is justified and should be imposed.

University of Wisconsin-Madison

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