



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

MAY 13 1991

Docket No. 030-03537
License No. 53-00458-04
EA 90-132

Department of the Army
Commander, Tripler Army Medical Center
Tripler AMC, Hawaii 96859

Attention: Major General Girard Seitter III
Commanding Officer

Dear Sir:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - \$2,500

This refers to your letters dated December 7 and 21, 1990 in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated October 22, 1990. Our letter and Notice described one violation that led to the ingestion of radioactive milk by the nursing infant of a lactating patient who had received radioactive iodine as part of her diagnostic examination at your facility.

To emphasize the importance of strict compliance with NRC requirements to protect public health and safety, and to emphasize that you and other medical licensees must assure that management controls are adequate so that the necessary resources, oversight, and attention to detail prevent similar violations from occurring in the future, a civil penalty of \$5,000 was proposed. Because of the radiation injury to the infant involved in the incident, NRC classified this event as one of very significant regulatory concern (Severity Level I). In assessing the civil penalty, NRC acknowledged your identification and reporting of the event and your prompt, aggressive corrective actions. As NRC stated at that time, but for those actions, additional enforcement action would have been considered.

In your responses, you admitted the violation, but requested mitigation or remission of the civil penalty.

After consideration of your responses and further consultation with the Commission, we have concluded for the reasons given in the appendix attached to the enclosed Order Imposing Civil Monetary Penalty that mitigation of the proposed civil penalty by 50% is appropriate. Accordingly, we hereby serve the enclosed Order on Tripler Army Medical Center imposing a civil monetary penalty in the amount of \$2,500. We will review the effectiveness of your corrective actions during a future inspection.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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Department of the Army
Tripler AMC

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In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,



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

Enclosures:
As stated

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of)	
Department of the Army)	Docket No. 030-03537
Tripler Army Medical Center)	License No. 53-00458-04
Tripler AMC, Hawaii)	EA 90-132

ORDER IMPOSING CIVIL MONETARY PENALTY

I

The Department of the Army, Tripler Army Medical Center (Licensee) is the holder of Materials License No. 53-00458-04, issued by the Nuclear Regulatory Commission (NRC or Commission) on September 29, 1986. The license authorizes the medical and research use of radioactive materials in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted from June 29 to July 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 Penalty (Notice) was served upon the Licensee by letter dated October 22, 1990. The Notice states the nature of the violation, the provision of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violation. The Licensee responded to the Notice dated October 22, 1990 by letters dated December 7 and 21, 1990. In its December 21, 1990 response, the Licensee admitted the violation, but argued that the \$5,000 civil penalty proposed by the NRC should be mitigated or remitted.

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 violation occurred as stated, but that mitigation of the proposed civil penalty by 50% is appropriate, and that a penalty in the amount of \$2,500 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 a civil penalty in the amount of \$2,500 within 30 days of the date of this Order, by check, draft, or money order, 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 V, 1450 Maria Lane, Suite 210, Walnut Creek, CA 94596.

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 issue to be considered at such hearing shall be:

Whether on the basis of the violation admitted by the Licensee, 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 13th day of May 1991

APPENDIX

EVALUATIONS AND CONCLUSIONS

On October 22, 1990, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for a violation identified during an NRC inspection. The Department of the Army, Tripler Army Medical Center (Licensee or Tripler) responded to the Notice on December 7 and 21, 1990. Tripler admitted the violation but argued for mitigation or remission of the \$5,000 civil penalty proposed by the NRC. The NRC's evaluation and conclusion regarding the Licensee's request are as follows:

Restatement of Violation

- A. 10 CFR 35.25(a)(2) provides, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the instructions of the supervising authorized user.

The instructions of the supervising authorized user, entitled "Management of Pregnant Patients", dated May 25, 1989, require, in part, that all female patients between the ages of 12 and 60 fill out a pregnancy statement. The statement asks if the patient is pregnant or nursing (breast feeding). The instructions further require, with exceptions not applicable here, that no patient who indicates that she is pregnant or lactating be given a radioactive substance.

Contrary to the above, on June 19, 1990, a nuclear medicine technologist, an individual under the supervision of the licensee's authorized user, administered 4.89 millicuries of iodine-131 to a patient without having the patient complete the required "pregnancy statement", specifically, the portion that asks if the patient is nursing (breast feeding); and the patient was lactating at the time.

Summary of Licensee's Request for Mitigation or Remission

While admitting the violation in its December 7, 1990 Reply to the Notice of Violation, in its December 21, 1990 Answer to the Notice of Violation the Licensee requested mitigation or remission of the civil penalty. Tripler relies on several factors to support its request.

First, Tripler identified the incident and did not attempt to conceal it, seeking NRC guidance six days after the incident as to whether it was reportable.

Second, corrective actions were comprehensive and were implemented the day after Tripler's discovery of the incident.

Third, the misadministration was a one-time incident and immediate steps were taken to respond to the incident.

Fourth, in response to the NRC's explanation in its cover letter that the civil penalty was proposed to "emphasize the importance of strict compliance with" NRC safety requirements and of management controls adequate to prevent similar violations, Tripler argues that no such emphasis is needed because human error can and does occur despite constant emphasis on patient care and safety, because Tripler's actions and procedures met or exceeded the reasonable prudent person standard, because the lesson has already been learned and corrective action taken, and because the NRC's emphasis should be on what was done to correct and treat and not on making Tripler an example by penalty. In this connection, the Licensee argues that it should be an example of a medical center that reported and rectified the situation, and that other medical centers will change their procedures with the motive of providing better treatment and patient care, not because another center was fined.

Fifth, the Licensee states that the radiation dosimetry studies that it performed in connection with this incident provide further evidence of its spirit of cooperation and compliance, garnered praise from NRC's medical consultant, and will aid future research and patient care.

Sixth, the Licensee states that the amount of the civil penalty is not insignificant, especially with tightened Federal spending, and that it has already spent thousands of dollars and anticipates spending more than that amount for transportation and treatment connected with the incident.

NRC Evaluation of Licensee's Request for Mitigation

At the time the civil penalty of \$5,000 was proposed, the NRC considered the facts that the Licensee identified and reported this event even though it may not fit the customary definition of "misadministration" in 10 CFR 35.2, that the Licensee took prompt and effective corrective action in strengthening its programmatic controls, that the Licensee subsequently established a program of follow-up medical care for the infant involved in the incident, that the Licensee is incurring significant cost in providing that care, and that the Licensee performed radiation dosimetry studies following the incident. Further, the NRC recognized that this was a one-time incident that involved human error, and that the adjustment factors in NRC's Enforcement Policy normally provide for mitigation of a civil penalty based on identification and reporting as well as prompt and effective corrective action. Nevertheless, the NRC determined that a civil penalty is appropriate in this case because of the very serious nature of the event (i.e., the event involved a significant injury having life-long effects on an individual), and to emphasize to this Licensee and similar licensees the importance of meticulous attention to detail in preventing such occurrences in the future. In reaching this decision, it was recognized that the Enforcement Policy is just that, a policy, and the NRC may deviate from it as is deemed appropriate under the circumstances, with statutory authority to impose civil penalties not to exceed \$100,000 per violation per day.

However, the NRC staff, after consultation with the Commission, has reconsidered its position and has determined that the proposed civil penalty should be mitigated by 50% in recognition of the facts that the Licensee identified the event, reported it to the NRC, and promptly instituted aggressive corrective action. The NRC believes that 50% mitigation strikes the proper balance between the need to emphasize the very serious nature of this event and the need to encourage and support positive licensee actions that may be taken after such an event occurs.

Finally, in response to the Licensee's argument that other medical centers will change their procedures with the motive of providing better patient care and not because another center was fined, the NRC recognizes that licensees have many incentives and rewards for good performance. Nevertheless, this case involves an unintended and very serious radiation exposure. The purpose of the NRC's program of licensing and regulation is to avoid such events. By imposing a civil penalty in this case, the NRC expects that there will be a positive deterrent effect on this and similar licensees by providing an additional incentive for good performance.

NRC Conclusion

The NRC has concluded that this violation occurred as stated, but that mitigation of the proposed civil penalty by 50% is warranted. Consequently, a civil penalty in the amount of \$2,500 should be imposed.