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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 PENALTY - $5,000

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 describe one violation. You informed us of the event upon which the violation is based.

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.

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

After consideration of your responses, we have concluded for the reasons given in the appendix attached to the enclosed Order Imposing Civil Monetary Penalty that mitigation or remission is unwarranted in this case. Accordingly, we hereby serve the enclosed Order on Tripler Army Medical Center imposing a civil monetary penalty in the amount of $5,000. We will review the effectiveness of your corrective actions during a future inspection.

A1)

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. In its December 22, 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, that the Licensee's arguments for mitigation or remission are not persuasive, and that the penalty proposed for the violation 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 a civil penalty in the amount of $5,000 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 Secretary, U.S. Nuclear Regulatory Commission and 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 violations 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 __ day of February, 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 is 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 a December 7, 1990 Reply, in a December 21, 1990 Answer the Licensee requested mitigation or remission of the civil penalty. Tripler argues that several factors support its argument. First, Tripler identified the incident and did not attempt to conceal it, seeking NRC guidance six days later on whether it was reportable. Second, corrective actions were comprehensive and were implemented the day after Tripler's discovery of the incident. Third, in response to the NRC's explanation in its cover letter that the CP 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 medical center decisions are by their very nature serious and often matters of life and death. Everything that effects patient care is important and is emphasized constantly. ... [But] human error can and does occur despite constant emphasis on patient care and safety. Could it have been prevented by more supervision?

> Since nothing of this kind had happened before during thousands of administrations, nor had there been any reported incidents from other hospitals or the NRC, our actions certainly met or exceeded the reasonably prudent persons standard. ... The NRC's emphasis should ... not [be] on making [Tripler] an example by penalty. ... Other medical centers will change their procedures to comply with good patient care when they are given notice of a problem or incident. Their motive is better treatment and care, not the fact that another center was fined." Reply at 6-7.

NRC Evaluation of Licensee's Request for Mitigation

Before issuing the proposed civil penalty, we considered most of the arguments now submitted by the Licensee. For example, we noted in our October 22, 1990 letter to the Licensee that a civil penalty was warranted despite its commendable identification and reporting of the event and its prompt, aggressive corrective actions. Further, while the Licensee's other points have merit, we question whether it was reasonably prudent to permit reliance on informal, oral communications and to have no redundant checks before administering a radiopharmaceutical. Moreover, while a civil penalty may not be a panacea in terms of deterrence, we disagree with the Licensee that a penalty will have no deterrent effect.

NRC Conclusion

The NRC has concluded that this violation occurred as stated, and that neither mitigation nor remission of the civil penalty is warranted. Consequently, the proposed civil penalty in the amount of $5,000 should be imposed.