

UNITED STATES  
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-32240
TWIN FALLS CLINIC & HOSPITAL	)	License No. 11-27085-01
Twin Falls, Idaho	)	EA 93-082

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Twin Falls Clinic & Hospital (Licensee) is the holder of NRC License No. 11-27085-01 issued by the Nuclear Regulatory Commission (NRC or Commission) on September 30, 1992. The license authorizes the Licensee to use various radioisotopes in accordance with the conditions specified therein. The license is due to expire on October 31, 1996.

II

An inspection of the Licensee's activities was conducted during March 17-18, 1993. 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 May 20, 1993. The Notice states the nature of the violation, the provisions 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 May 21, 1993. In its response, the Licensee admitted the violation which resulted in the proposed civil penalty, but requested mitigation for reasons that are summarized in the Appendix to this Order.

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 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, 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, Washington, D.C. 20555, with

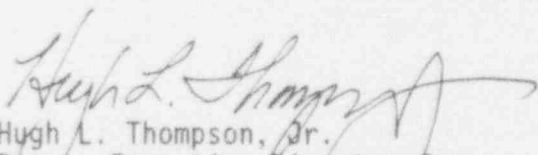
a copy to the Commission's Document Control Desk, Washington, D. C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

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 6<sup>th</sup> day of August 1993

## APPENDIX

### EVALUATION AND CONCLUSION

On May 20, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for a violation identified during an NRC inspection. Twin Falls Clinic & Hospital responded to the Notice on May 21, 1993. The Licensee admitted the violation that resulted in the proposed civil penalty, but requested mitigation. The NRC's evaluation and conclusion regarding the Licensee's request are as follows:

#### Restatement of Violation

10 CFR 35.32(a), which became effective January 27, 1992, states, in part, that each licensee under this part, as applicable, shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet specific objectives for, among other things, any administration of quantities greater than 30 microcuries of I-131.

Contrary to the above, between November 17, 1992, and March 15, 1993, the licensee administered I-131 to 14 patients in quantities greater than 30 microcuries and did not establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material would be administered as directed by the authorized user.

This is a Severity Level III violation (Supplement VI).  
Civil Penalty - \$5,000

#### Summary of Licensee's Request for Mitigation

In its May 21, 1993, letter, the Licensee admitted the above violation but requested mitigation of the penalty, citing the following reasons:

1. During a "licensing inspection" of the facility on January 14, 1992, less than two weeks before the QMP was to be submitted, the inspector endorsed the activities of Twin Falls Clinic & Hospital (TFC&H). No mention of 10 CFR 35.32(a) was made by the inspector, thus giving TFC&H a false impression of compliance with all NRC regulations.
2. TFC&H took immediate action to establish a written QMP upon discovery of the violation, and now requires the Radiation Safety Committee to review documentation from NRC to ensure that the Nuclear Medicine Department remains in compliance with changing requirements.
3. NRC Inspection Report 030-32240/93-01 identifies this violation as a level IV which would carry no associated penalty.

NRC Evaluation of Licensee's Request for Mitigation

The NRC's evaluation of the Licensee's arguments for mitigation is as follows:

1. The NRC has no record of any NRC inspection of TFC&H around the January 14, 1992 timeframe, and NRC cannot confirm TFC&H's assertion that NRC inspected TFC&H on January 14, 1992. The Licensee may be confused because the NRC issued a byproduct material license to TFC&H on January 14, 1992. In any event, TFC&H is responsible for ensuring that it is familiar with and complies with all NRC requirements applicable to their licensed activities, including the requirement to establish and maintain a written QMP.
2. The Enforcement Policy provides for up to 50 percent mitigation for prompt and extensive corrective action. Licensees are expected and required to take corrective actions for violations. The NRC gave TFC&H credit for its corrective actions in the May 20, 1993 Notice. As the letter transmitting the Notice indicated on Page 2 and 3, the penalty was decreased by 50 percent of the base value "... because TFC&H took immediate corrective action and action to prevent a recurrence of the violation."
3. The NRC has reviewed Inspection Report 030-32240/93-01 and is unable to find any reference to this violation of 10 CFR 35.32(a) being classified at Severity Level IV. Four additional violations were found during the inspection and were cited at Severity Level IV in a Notice of Violation issued with the inspection report. However, they were unrelated to the violation of 10 CFR 35.32(a) that was the subject of the enforcement conference and the basis for the civil penalty. The NRC has classified the violation at Severity Level III in accordance with the Enforcement Policy, Supplement VI, C.6. In this case, the example given for a Severity Level III violation is a substantial failure to implement the QMP as required by 10 CFR 35.32. TFC&H had no written QMP or procedures established to meet the objectives and requirements of 10 CFR 35.32.

NRC Conclusion

The NRC has concluded that the licensee has not provided any information that would give the NRC a basis for considering a reduction in the size of the proposed civil penalty. Consequently, the proposed civil penalty in the amount of \$5,000 should be imposed.

Twin Falls Clinic  
and Hospital

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