

UNITED STATES

NUCLEAR REGULATORY COMMISSION

In the Matter of

Christian E. Chinwuba, M.D.
Washington, D.C.

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Docket No. 30-30810
License No. 08-28277-01
EA 89-27

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Christian E. Chinwuba, M.D., Southwest Imaging Lab, Washington, D.C. ("licensee") is the holder of License No. 08-28277-01 ("license") issued by the Nuclear Regulatory Commission ("Commission" or "NRC") which authorizes the medical use of byproduct material by the licensee in accordance with the conditions specified therein. The license was issued on December 8, 1988 and is due to expire on December 31, 1993.

II

An NRC safety inspection of the licensee's activities under the license was conducted on January 26, 1989. During the inspection, the NRC staff determined 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 was served upon the licensee by letter dated April 5, 1989. The Notice states the nature of the violations, the provisions of the Nuclear Regulatory Commission's requirements that the licensee had violated, and the civil penalty amount for the violations. A response, dated May 12, 1989, to the Notice of Violation and Proposed Imposition of Civil Penalty, was received from the licensee.

III

Upon consideration of the answer received, the statements of fact, explanations, and argument for remission or mitigation of the proposed civil penalty contained

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therein, the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support has determined, as set forth in the Appendix to this Order, that the penalty proposed for the violations designated in the Notice of Violation and Proposed Imposition of Civil Penalty 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 Two Hundred Fifty Dollars (\$250) within thirty 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, within thirty days of the date of this order, request a hearing. A request for a hearing shall 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. A copy of the hearing request shall also be sent to the Assistant General Counsel for Hearings and Enforcement, Office of the

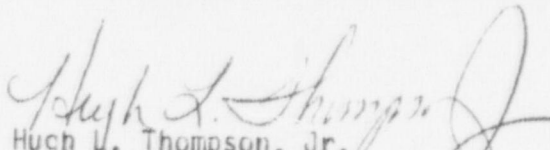
General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555,
and to the Regional Administrator, Region I, 475 Allendale Road, King of
Prussia, Pennsylvania 19406.

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 thirty 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 the Notice of Violation and Proposed Imposition of Civil Penalty referenced in Section II above; and
- (b) whether, on the basis of the violations set forth in the Appendix, 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 7th day of July 1989

APPENDIX

EVALUATION AND CONCLUSION

On April 5, 1989 a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations of a license issued to Christian E. Chinwuba, M.D., Southwest Imaging Center. The licensee responded to the Notice on May 12, 1989, admitting Violations A, B, C, and E in total, stating "No Denial" in response to Violation D, and denying Violation F in total. The licensee also requested further mitigation of the civil penalty. The NRC's evaluation and conclusion regarding the licensee's response are as follows:

I. Restatement of Violations

- A. 10 CFR 35.21(b)(2) requires that the Radiation Safety Officer shall establish, collect in one binder or file, and implement written policy and procedures for the operation of the radiation safety program.

Contrary to the above, as of January 26, 1989, the Radiation Safety Officer had not collected in one binder or file nor implemented written policy and procedures for the operation of the radiation safety program. A specific example is that the Radiation Safety Officer failed to establish and implement action levels for performing dose calibrator constancy checks as required by the dose calibrator calibration procedures referenced in the licensee's letter dated October 31, 1988, which is listed as a basis of the license by License Condition 13.

- B. 10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of January 26, 1989, the technologist working in the Nuclear Medicine Area, a restricted area, had not been instructed in the provisions of the regulations or the license.

- C. 10 CFR 35.59(d) requires that records of leak test results contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries, a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer. A licensee shall retain such leakage test records for five years.

Contrary to the above, as of January 26, 1989, the record of the results of barium-133 leak tests performed on November 22, 1988 did not contain the signature of the Radiation Safety Officer and there was no record of the cesium-137 leak test results.

- D. 10 CFR 35.50(b)(2) requires that the accuracy of the dose calibrator be determined at installation and annually thereafter. 10 CFR 35.50(b)(3) requires that the linearity of the dose calibrator be determined at installation and quarterly thereafter.

Contrary to the above, as of January 12, 1989, the dose calibrator had been installed, but accuracy and linearity had not been determined. Specifically, initial testing of the dose calibrator on January 4-6, 1989 indicated an equipment malfunction in that accuracy and linearity testing revealed errors in excess of 10 percent, and repeat testing of the dose calibrator was not completed before initiation of a patient study on January 12, 1989.

- E. 10 CFR 35.51(c) requires that each survey instrument be checked for proper operation with the dedicated check source each day of use.

Contrary to the above, as of January 12, 1989, a survey meter was used to perform required surveys without having been checked with a dedicated check source prior to use, since the licensee did not possess, nor did the instrument contain, a dedicated check source.

- F. 10 CFR 35.220 requires, in part, that licensees authorized to use byproduct material for imaging and localization studies possess a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Contrary to the above, on January 12, 1989, the licensee, who was authorized for imaging and localization studies, did not possess a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

These violations have been categorized in the aggregate as a Severity Level III problem (Supplements IV and VI).

II. Summary of License Response and NRC Evaluation

A. Summary of Licensee Response Stating "No Denial" of Violation D

The licensee states that the tests on the dose calibrator had been carried out, but were being independently checked and verified and that the patient study was performed on the basis that "a cursory review of the test results . . . appeared fairly within allowable limits." The licensee also states that he was not sure that the equipment was functioning normally.

NRC Evaluation

The requirement to perform a test is not fulfilled until the test data is fully analyzed and a final result is obtained. This did not occur until January 13, 1989, when the final results of the dose calibrator accuracy and linearity tests indicated equipment malfunction, causing the licensee to discontinue patient studies. The violation occurred on January 12, 1989 as stated in the Notice because, on that date, the dose calibrator had been installed and was used by the licensee to calibrate a patient dose before the testing for accuracy and linearity was completed.

B. Summary of License Response Concerning Denial of Violation F

The licensee asserts that at the time of the inspection, (January 26, 1989) the NRC was aware that he possessed a Victoreen portable survey instrument which was being recalibrated in California.

NRC Evaluation

10 CFR 35.220 requires the licensee to have in its possession a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem per hour to 1000 millirem per hour. At the time of the violation, the licensee owned such an instrument; however, the instrument was not in the licensee's possession. Rather, as the licensee states, this instrument was away in California for the purpose of being recalibrated. The violation occurred on January 12, 1989 as stated in the Notice because, on that date, the licensee administered a dose to a patient and at the time, he had in his possession only a loaner survey instrument which was not capable of measuring dose rates over the range of 1 millirem per hour to 1000 millirem per hour.

C. Summary of Licensee Response Requesting Further Mitigation of the Civil Penalty

The licensee, in his response, requests mitigation of the civil penalty because: (1) the violations were not willful, but stemmed from difficulty encountered by both he and his consultant in interpreting the new NRC regulations; (2) his corrective actions were extensive and sincere; (3) he has no prior enforcement history; and (4) he has incurred financial losses in implementing the corrective actions.

NRC Evaluation

While the existence of a willful violation may result in an increase in the severity level and consequent escalation of a civil penalty, the fact that a violation was not willful does not form a basis for mitigation of a civil penalty. Furthermore, rather than providing a basis for mitigation, the fact that neither the licensee nor his consultants understood the regulatory requirements and responsibilities associated with the license is additional evidence of an increased need for stronger management oversight and control of the program to ensure that licensed activities are carried out in conformance with license conditions and regulatory requirements.

The NRC recognizes and agrees with the licensee's response that his corrective actions were both prompt and extensive. On that basis, the NRC has already mitigated the base civil penalty by 50% in accordance with the enforcement policy. Full mitigation based on this factor alone is both inappropriate and not in accordance with the established enforcement criteria set forth in 10 CFR Part 2, Appendix C.

The NRC disagrees that the absence of any enforcement history regarding the licensee's facility provides a basis for further mitigation of the civil penalty. The enforcement policy provides for escalation of a civil penalty for a licensee with a poor enforcement history and conversely, for mitigation of a penalty for a licensee with a good enforcement history. However, since this was the first inspection of the licensee's facility, there is no enforcement history and there is no basis for either escalation or mitigation of the civil penalty.

Finally, the incursion of financial losses as a result of corrective actions to achieve regulatory compliance provides no basis for mitigation of a civil penalty. The cost of achieving and maintaining regulatory compliance is an operating cost borne by the licensee.

Accordingly, the licensee has not provided a basis for mitigation of the civil penalty.

III. NRC Conclusion

The licensee did not provide a sufficient basis for withdrawal of Violation D or F, or for any additional mitigation of the amount of the civil penalty. Therefore, the NRC concludes that a civil penalty of \$250 should be imposed.

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