

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of

José L. Fernández, M.D.
San Juan, Puerto Rico)
)
)
)Docket No. 030-31873
License No. 52-25114-01
EA 96-154

ORDER MODIFYING LICENSE (EFFECTIVE IMMEDIATELY)

I

José L. Fernández, M.D. (Licensee) is the holder of Byproduct Nuclear Material License No. 52-25114-01 (License) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 35. The License authorized the possession and use of a total of two strontium-90 sources not to exceed 150 millicuries for the treatment of superficial eye conditions on humans at medical facilities located at 160 Ponce de León Avenue, Puerta de Tierra, San Juan, Puerto Rico and at La Palma Building, Suite 1-A, Peral-De Diego Street, Mayagüez, Puerto Rico. The License, originally issued to the Licensee on March 22, 1991, was amended on January 14, 1994, and expired on February 28, 1996. Pursuant to 10 CFR 30.36(c), the Licensee is authorized to possess but not use licensed material.

II

A routine, unannounced inspection of the Licensee's activities at the Mayagüez, Puerto Rico, facility was performed on October 18, 1995. During the inspection, an issue regarding the validity of the calibration of one of the Licensee's strontium-90 eye applicators and the possibility of multiple misadministrations was identified. The Licensee was unable to provide adequate documentation of source strength (i.e., a calibration from the National Institute of Standards and Technology or the source manufacturer).

A Confirmatory Action Letter (CAL) was issued on October 19, 1995, which confirmed the Licensee's agreement to discontinue any use of the strontium-90 eye applicator and place it in storage until: (1) a Quality Management Program (QMP) was submitted to the NRC, and (2) NRC approved resumption of operations. Subsequently, a calibration of the source located at the Mayagüez office was performed by the source manufacturer, which indicated that the source delivered approximately 53 centigrays per second, rather than the 24 centigrays per second that was assumed by the Licensee and used in treatments. The Licensee and the source manufacturer notified the NRC of the source dose rate on February 8, 1996.

Based on the fact that there was an error in the radiation dose rate and that this error caused patients to receive doses in amounts greater than that intended by the physician, the NRC issued a second CAL to the Licensee on February 9, 1996, to confirm that the Licensee would: (1) review, within 30 days, all patient radiation dose administrations performed at the Mayagüez office to identify any medical misadministrations; (2) comply with the notification and reporting requirements of 10 CFR 35.33 (within the time frame specified in the regulations) for each misadministration identified; and (3) maintain the strontium-90 sources in safe storage and refrain from using them until authorized by the NRC.

The Licensee notified the NRC, via the NRC Operations Center, on March 1, 1996, that 71 patients had received misadministrations. In a letter received on March 15, 1996, the Licensee notified the NRC, in accordance with 10 CFR 35.33, that all patients determined to have received a

misadministration had been notified in writing by March 8, 1996. However, the written notification to the NRC failed to indicate whether the patients were notified within 24 hours of discovery, as required by 10 CFR 35.33(a)(3) and, if not, why not, and whether records of the misadministrations were retained by the Licensee as required by NRC requirements.

To verify the status of the Licensee's actions to identify misadministrations and to complete patient notifications, the NRC conducted a second inspection at the Licensee's Mayagüez facility on April 8-10, 1996. During the inspection, the NRC determined, based on its review of Licensee records, that the Licensee had failed to: (1) identify 16 additional misadministrations that occurred since October 1994, (2) notify, within 24-hours of discovery as required by 10 CFR 35.33(a)(3), three individuals of their misadministrations, (3) provide written reports of misadministrations to three individuals within the 15 days required by 10 CFR 35.33(a)(4), and (4) retain complete misadministration records as required by 10 CFR 35.33(b) in that only 67 records were documented instead of the 71 originally identified by the Licensee (the four records were misplaced by the Licensee after the misadministrations were identified).

In addition, during the October 1995 inspection, the Licensee informed the NRC that he had purchased the Mayagüez facility including one of the strontium-90 eye applicators in October 1994. Therefore, during the April 1996 inspection, the scope of the review was specifically confined to the period between October 1994 and October 1995. However, the NRC determined that the initial date of operation (i.e., start of the possession and use of byproduct material

at the Mayagüez facility) was not October 1994, as originally related by the Licensee. The Licensee actually took possession of the byproduct material in January 1994, prior to the change in ownership in October 1994 and following receipt of the NRC's authorization to work under the Mayagüez license (amended on January 14, 1994). The NRC also determined that, during the period between January and October 1994, the Licensee's byproduct material had been used by an unauthorized user on at least two occasions, contrary to the requirements of 10 CFR 35.11. Moreover, the Licensee further identified 17 additional misadministrations that occurred during this period.

Subsequently, in a June 13, 1996 letter to the Licensee, the NRC documented the results of a June 11, 1996 telephone call in which Dr. Fernández agreed to hire an independent Health Physicist/Radiation Physicist consultant with expertise in therapy dosimetry calculations to perform a review of the Licensee's patient administration records to identify all misadministrations, to assess the completeness and accuracy of misadministration records, to determine if any unauthorized uses of byproduct materials had occurred, and to assist the Licensee in submitting a report to the NRC on the results of these reviews. On July 10, 1996, the Licensee replied to the NRC's June 13, 1996 letter explaining Licensee difficulties in obtaining an independent consultant to complete the agreed-upon actions.

During a third inspection on August 7 and 9, 1996, the NRC determined that certain of the patients, who received misadministrations and should have been notified of the misadministration verbally and in writing, stated that they had not received such notification. In addition, during this inspection the

NRC identified seven additional misadministrations at the San Juan facility resulting from the failure to correct source strength to account for radioactive decay. These misadministrations appear to involve underdosing patients.

By letter dated August 7, 1996, the NRC again requested the Licensee to provide to the NRC the name of a consultant and his credentials, and the Licensee's schedule for the completion of requested activities. The NRC also offered the Licensee the opportunity to participate in a predecisional enforcement conference. On August 20, 1996, the Licensee replied to the NRC's August 7, 1996 letter reiterating the Licensee's inability to obtain a consultant, stating the intention to terminate the License, and declining the invitation to participate in a predecisional enforcement conference.

As a result of the October 18, 1995, the April 8-10, 1996, and August 7 and 9, 1996 inspections, numerous violations were identified. The violations include the failure of the Licensee to: (1) establish and maintain a QMP, which included assurance that the radiation dose delivered was correct (i.e, the calibration of the applicator was correct), as required by 10 CFR 35.32 (the use of an inaccurate dose rate resulted in at least 104 misadministrations during the period January 1994 through October 1995); (2) maintain the security of byproduct material as required by 10 CFR 20.1801; (3) perform quarterly physical inventories of byproduct material as required by 10 CFR 35.59(g); (4) test sealed sources for leakage at intervals not to exceed six months as required by 10 CFR 35.59(b); (5) notify individuals of a misadministration within 24-hours of discovery as required by 10 CFR

35.33(a)(3); (6) provide written reports to individuals within 15 days of discovery of a misadministration as required by 10 CFR 35.33(a)(4); (7) maintain misadministration records as required by 10 CFR 35.33(b); and (8) amend his license prior to permitting an individual to work as an authorized user as required by 10 CFR 35.11.

Representatives from NRC Region II met with the Licensee on September 27, 1996, and again the Licensee informed the staff that it intended to obtain a consultant to review its activities. At that meeting, NRC provided the Licensee with a list of consultants in Puerto Rico that might be considered. On October 3, 1996, the Licensee called the NRC to request that the NRC provide another copy of the consultant's list because it had lost the one provided on September 27, 1996. At that time the Licensee stated that it planned to review the records, with the assistance of a consultant.

III

Based on the above, the Licensee has demonstrated a significant lack of control and attention to licensed activities. Specifically, the Licensee has failed to use accurate radiation dose rates for the strontium-90 eye applicators which resulted in numerous misadministrations and has repeatedly failed to fully evaluate and identify the number of misadministrations. This raises a significant concern as the patients, depending on the doses received, may develop complications, and without appropriate follow-up actions, these complications may go unrecognized and serious consequences may occur.

Furthermore, the Licensee has failed to: (1) establish and maintain a QMP as required by 10 CFR 35.32; (2) maintain the security of byproduct material as required by 10 CFR 20.1801; (3) perform quarterly physical inventories of byproduct material as required by 10 CFR 35.59(g); (4) test sealed sources for leakage at intervals not to exceed six months as required by 10 CFR 35.59(b); (5) notify individuals of a misadministration within 24-hours of discovery as required by 10 CFR 35.33(a)(3); (6) provide written reports to individuals within 15 days of discovery of a misadministration as required by 10 CFR 35.33(a)(4); (7) maintain misadministration records as required by 10 CFR 35.33(b); and (8) amend his license prior to permitting an individual to work as an authorized user as required by 10 CFR 35.11.

The Licensee has failed to honor its commitment to obtain a qualified consultant to review its patient records to assure as required by the Commission's regulations that all misadministrations are identified and proper patient notifications have been made. As a result, given the Licensee's past performance, the NRC does not have adequate assurance that all misadministrations have been identified, properly evaluated, and the involved patients properly notified.

It is imperative that licensees conduct activities in accordance with NRC requirements and with the requisite sensitivity and attention to detail, especially with respect to the amount of radiation delivered to individuals. In addition, the Commission must be able to rely on its licensees to provide complete and accurate information.

Consequently, I have concluded that the Licensee has failed to comply with a number of significant NRC requirements and that the actions Ordered in Section IV of this Order are required to protect the public health and safety. Given the number of misadministrations identified to date, the number of violations committed to date by the Licensee, the potential consequences to patients if not identified, notified, and monitored, the difficulty in locating patients over time, and the lack of meeting license requirements and commitments, I have concluded, pursuant to 10 CFR 2.202, that the public health and safety requires that this Order be immediately effective.

IV

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Parts 30 and 35, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE NO. 52-25144-01 IS MODIFIED AS FOLLOWS:

- A. Within 30 days of the date of this Order, the Licensee shall submit to the Regional Administrator, NRC, Region II, for approval, the credentials of an independent Health Physicist/Radiation Physicist Consultant with expertise in therapy dosimetry calculations.
- B. The Licensee shall ensure that, within 45 days of acceptance of the consultant by the NRC, the Consultant:

1. Performs, independent of the Licensee, a review of all patient radiation doses administered by the Licensee at the Mayagüez facility to identify all medical misadministrations that occurred between January 1994 and October 1995 and assure that the dose records are complete and accurate.
2. Reviews the Licensee's misadministration records to verify completeness and accuracy in reference to the requirements of 10 CFR 35.33. To the extent possible, incomplete records shall be appropriately corrected. Where records of individuals may not be accurately reconstructed, the consultant shall assume that the individual has received a misadministration based on 53 centigrays per second, rather than the 24 centigrays per second that was assumed by the Licensee and used in treatments.
3. Reviews the Licensee's radiation dose administration records to determine if any additional unauthorized uses of byproduct material occurred between January 1994 and October 1995.
4. Reviews the Licensee's misadministration notification records to identify any misadministrations where notification was not provided to: (a) the NRC as required by 10 CFR Part 35.33(a)(2); and (b) all affected patients and referring physicians as required by 10 CFR 35.33(a)(3) and (4).

5. Assists the Licensee in the review and submission to the NRC of an updated/revised report pursuant to 10 CFR 35.33(a)(2).
- C. Within 60 days of acceptance of the consultant by the NRC, the Licensee shall:
1. Submit an updated, final report to the NRC, Regional Administrator, Region II, of all misadministrations, pursuant to 10 CFR 35.33(a)(2), including a listing of any additional unauthorized uses of byproduct material that occurred between January 1994 and October 1995.
 2. Notify the referring physician and individuals who received misadministrations, including those individuals whose records may not be accurately reconstructed, of the misadministrations, pursuant to 10 CFR 35.33(a)(3).
- D. The Licensee shall not receive or use any licensed material and shall maintain the strontium-90 sources in locked, safe storage until the material is transferred to an authorized recipient.
- E. The Licensee shall, within 90 days of this Order, transfer all strontium-90 sources in its possession to an authorized recipient and provide to the Regional Administrator, Region II, a completed Form-314.

The Regional Administrator, Region II, may, in writing, relax or rescind any of the above conditions upon demonstration by the Licensee of good cause.

V

In accordance with 10 CFR 2.202, the Licensee must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order, within 20 days of the date of this Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and include a statement of good cause for the extension. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted 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, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Regional Administrator, NRC Region II, 101 Marietta St., NW, Suite 2900, Atlanta, GA 30323-0199, and to the Licensee if the answer or hearing request is by a person other than the Licensee. If a person other than the Licensee requests a hearing, that person

shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by the Licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), the Licensee, or any other person adversely affected by this Order, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received.

AN ANSWER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS
OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

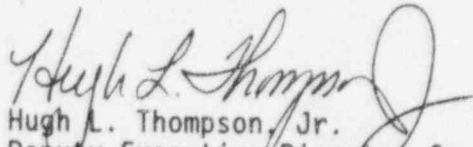
A handwritten signature in cursive script, appearing to read "Hugh L. Thompson, Jr.", is written over the typed name.

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

Dated at Rockville, Maryland
this 21st day of October 1996

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OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

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