April 11, 1997

EA 97-172

José L. Fernández, M.D.
160 Ponce de León Avenue
Puera de Tierra
San Juan, PR 00901

SUBJECT: NRC INSPECTION REPORT NOS. 52-25114-01/95-01 AND 96-01
NRC ORDER MODIFYING LICENSE NO. 52-25114-01

Dear Dr. Fernández:

The subject Inspection Reports and Order were transmitted to you by letters dated June 6, 1996, September 10, 1996 and October 21, 1996, respectively. We have completed a review of the issues associated with the subject documents to determine whether violations of NRC requirements have occurred.

Based on the results of our review, nine apparent violations were identified at your Mayagüez, Puerto Rico (PR) and San Juan, PR ophthalmology practices and are being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600. However, no Notice of Violation is being issued at this time. The apparent violations are described in Enclosure 1, "Summary of Issues," and were discussed in detail in the subject Inspection Reports and Order. The apparent violations involve multiple failures of you and your staff to comply with NRC requirements governing: (1) security of licensed material, (2) leak testing of sources, (3) inventories of sealed sources, (4) misadministration notifications (5) misadministration reports, (6) unauthorized use of licensed materials, (7) unauthorized transfer of licensed material, (8) the lack of a Quality Management Program, and (9) timely implementation of the October 21, 1996, Order. These apparent violations reflect a lack of commitment to NRC requirements. Your responses since October 1995, have generally been delayed or inadequate and further reflect your lack of commitment to the regulatory process.

The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and members of your staff at the inspection exit meetings, in person during a meeting in San Juan, PR on September 25, 1996, and in numerous telephone conversations with you and your staff over the past 18 months. Consequently, it may not be necessary for us to conduct a predecisional enforcement conference with you prior to making an enforcement decision. Although on August 7, 1996, you were afforded the opportunity to participate in a predecisional enforcement conference and declined, due to the additional apparent violations that have been identified, we are again offering you an opportunity to either: (1) respond to the apparent violations addressed in this letter within 30 days of the date of this letter or (2) request a predecisional enforcement conference with us in Atlanta, Georgia.

IE07

Please contact John Potter, Chief, Material Licensing/Inspection Branch 2, at 404/331-5571 [voice] or 404/331-5559 [telefax], within seven days of the date of this letter regarding your decision.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations Related to Inspection Report No. 52-25114-01/95-01, 52-25114-01/96-01, and Order Modifying License" and should include for each apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved.

In discussing your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in Enclosure 2, Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. Your response should be submitted under oath or affirmation and may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been requested and granted by the NRC, the NRC will either proceed with its enforcement decision or schedule a predecisional enforcement conference.

Please be advised that the number and characterization of apparent violations may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response (if you choose to provide one) will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy or proprietary information so that it can be placed in the PDR without redaction.

Sincerely,

/S/

Bruce S. Mallett, Director
Division of Nuclear Materials Safety

Docket No. 030-31873
License No. 52-25114-01

Enclosures: 1. Summary of Issues
2. NRC Information Notice 96-28

cc w/encls:
Commonwealth of Puerto Rico
Secretary of Health
Board of Medical Examiners

Distribution w/encls: (See page 3)

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SUMMARY OF ISSUES

The apparent violations summarized below were based on an in-depth review of data collected and conclusions derived from the NRC inspections conducted on October 18, 1995, April 8-10, 1995, and August 7 and 9, 1996, at your Mayagüez and San Juan, Puerto Rico ophthalmology practices and your actions in response to the NRC's October 21, 1996, Order Modifying License.

A. 10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that radiation from byproduct material will be administered as directed by the authorized user. Between July 1, 1994 and October 18, 1995, the licensee used strontium-90 eye applicators for the administration of brachytherapy radiation doses at its Mayagüez and San Juan offices, and the licensee had not established a written quality management program. Numerous patients were administered radiation doses which were not as directed by the authorized user. In Mayagüez, the licensee failed to check the reliability of dosimetry data used in the dosimetry calculations. In San Juan, the licensee failed to decay correct the source output used in the dosimetry calculations. The validation of dosimetric data is an inherent requirement of 10 CFR 35.32(a)(3).

B. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access, licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, "**unrestricted area**" means an area, access to which is neither limited nor controlled by the licensee.

Between January 1994 and October 1994, the licensee failed to secure from unauthorized removal or access a strontium 90 eye applicator containing approximately 83 millicuries, located in a materials storage room, an unrestricted area, nor did the licensee control or maintain constant surveillance of this licensed material. Specifically, the licensee amended its license to include a new place of use (Mayagüez office), took possession of the source, and left it unattended at the Mayagüez facility until October 1994. In addition, following initiation of licensed activities at the Mayagüez facility between October 1994 and October 18, 1995, the licensee also failed to secure from unauthorized removal or access a strontium-90 eye applicator containing approximately 83 millicuries, located in a materials storage room, an unrestricted area, nor did the licensee control or maintain constant surveillance of this licensed material.

C. License Condition No. 12 of NRC License No. 52-25114-01 requires that licensed material be used only by José L. Fernández, M.D. As of August 4, 1995, the licensee allowed an individual, other than José L. Fernández, M.D., to use licensed material on at least two occasions on human beings, without Dr. Fernández's supervision or consent.

D. 10 CFR 35.33(a)(3) requires, in part, that, for a misadministration, the licensee notify the patient, within 24 hours after discovery of the misadministration. 10 CFR 35.2 defines, in part, "misadministration," to mean an administered brachytherapy radiation dose that differs from the prescribed dose by more than 20 percent of the prescribed dose. On March 1, 1996, the licensee became aware that 71 misadministrations occurred, and the licensee notified the NRC on March 1, 1996, but did not notify three of the 71 patients about the misadministrations until April 8, 1996, which was longer than 24-hours after discovery of the misadministrations.

E. 10 CFR 35.33(a)(4) states, in part, that, for a misadministration, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either: (1) a copy of the report that was submitted to the NRC; or (2) a brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the NRC can be obtained from the licensee. On March 1, 1996, the licensee became aware that 71 misadministrations occurred, and the licensee notified the NRC on March 1, 1996, but did not provide a written report to three of the 71 patients about the misadministration until April 8, 1996, which was later than 15 days after the discovery of the misadministrations.

F. 10 CFR 35.59(b)(2) requires, in part, that a licensee in possession of a sealed source test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State. As of October 18, 1995, the licensee had not tested a sealed source containing approximately 83 millicuries of strontium-90 for leakage since January 1994, an interval in excess of six months, and no other interval was approved by the Commission or an Agreement State.

G. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source or brachytherapy source conduct a quarterly physical inventory of all such sources in its possession. The licensee did not conduct a physical inventory of its brachytherapy sources from January 1994 to October 1994, a period in excess of a calendar quarter.

H. 10 CFR 30.41(a) and (b)(5) require, in part, that no licensee transfer byproduct material except to a person authorized to receive such byproduct material under the terms of a specific or general license issued by the Commission or Agreement State.

10 CFR 30.41(c) requires that, prior to transferring byproduct material, the licensee verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred. 10 CFR 30.41(d) specifies acceptable methods for this verification.

On February 20 and February 26, 1997, the licensee transferred two sources containing 83 millicuries and 20 millicuries of strontium-90, respectively, to Rafael Cavero, M.D., a person who was not authorized to receive such byproduct material under the terms of a specific license issued by the City of New York, Bureau of Radiological Health. None of the acceptable methods of verification in 10 CFR 30.41(d) were used.

I. 10 CFR 30.34 provides, in part, that licenses issued or granted under Parts 31 through 36 and 39 of Title 10 are subject to all valid rules, regulations, and Orders of the Commission. Item IV.E of "Order Modifying NRC Materials License No. 52-25114-01," issued on October 21, 1996, which required that the licensee, within 90 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 licensee shipped the Mayagüez source on February 20, 1997, and the San Juan source on February 26, 1997, to a physician in the city of New York; however, the transfers were not executed within the 90 days specified in the Order.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

May 1, 1996

NRC INFORMATION NOTICE 96-28: SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Background

On June 30, 1995, NRC revised its Enforcement Policy (NUREG-1600)[1] 60 FR 34381, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, NRC encourages and expects identification and prompt, comprehensive correction of violations.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section VII.B.1 of the Enforcement Policy. Minor violations are not subject to formal enforcement action. Nevertheless, the root cause(s) of minor violations must be identified and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as required by 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence. In some cases, such violations are documented on Form 591 (for materials licensees)

[1]Copies of NUREG-1600 can be obtained by calling the contacts listed at the end of the Information Notice.

which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a predecisional enforcement conference may be held to discuss those actions. The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a predecisional enforcement conference with the licensee and the level of sanction proposed or imposed.

Discussion

Comprehensive corrective action is required for all violations. In most cases, NRC does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation.

It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest, but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation.

Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the particular case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation. Typically, such reviews include:

    - Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers.

- Tours and observations of the area where the violation occurred, particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that may have contributed to the violation as well as those items that may result in future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred.

- Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its overall objectives and requirements are clearly stated and implemented. Procedures should be reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the current requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to provide an auditable record and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns **and** prevent recurrence of the violation.

   It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, **immediate** corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

In evaluating the root causes of a violation and developing effective corrective action, consider the following:

1. Has management been informed of the violation(s)?

2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?

3. Have precursor events been considered and factored into the corrective actions?

4. In the event of loss of radioactive material, should security of radioactive material be enhanced?

5. Has your staff been adequately trained on the applicable requirements?

6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?

7. Has your staff been notified of the violation and of the applicable corrective action?

8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?

9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?

10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?

11. Is a system in place for keeping abreast of new or modified NRC requirements?

12. Does your staff appreciate the need to consider safety in approaching daily assignments?

13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?

14. Have work hours affected the employees' ability to safely perform the job?

15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?

16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?

17. Has management established a work environment that encourages employees to raise safety and compliance concerns?

18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?

19. Has management communicated its expectations for safety and compliance?

20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

signed by

Elizabeth Q. Ten Eyck, Director
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

signed by

Donald A. Cool, Director
Division of Industrial
and Medical Safety
Office of Nuclear Material Safety
and Safeguards

Technical contacts: Nader L. Mamish, OE
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Daniel J. Holody, RI
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Internet:djh@nrc.gov

Bruno Uryc, Jr., RII
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Bruce L. Burgess, RIII
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Internet:blb@nrc.gov

Gary F. Sanborn, RIV
(817) 860-8222
Internet:gfs@nrc.gov

Attachments:
1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
96-21	Safety Concerns Related to the Design of the Door Interlock Circuit on Nucletron High-Dose Rate and Pulsed Dose Rate Remote Afterloading Brachy-therapy Devices	04/10/96	All NRC Medical Licensees authorized to use brachy-therapy sources in high- and pulsed-dose-rate remote
96-20	Demonstration of Associ-ated Equipment Compliance with 10 CFR 34.20	04/04/96	All industrial radiography licensees and radiography equipment manufacturers
96-18	Compliance With 10 CFR Part 20 for Airborne Thorium	03/25/96	All material licensees authorized to possess and use thorium in unsealed form
96-04	Incident Reporting Requirements for Radiography Licensees	01/10/96	All Radiography Licensees and Manufacturers of Radiography Equipment
95-58	10 CFR 34.20; Final Effective Date	12/18/95	Industrial Radiography Licensees.
95-55	Handling Uncontained Yellowcake Outside of a Facility Processing Circuit	12/6/95	All Uranium Recovery Licensees.
95-51	Recent Incidents Involving Potential Loss of Control of Licensed Material	10/27/95	All material and fuel cycle licensees.
95-50	Safety Defect in Gammamed 12i Bronchial Catheter Clamping Adapters	10/30/95	All High Dose Rate Afterloader (HDR) Licensees.
95-44	Ensuring Combatible Use of Drive Cables Incorporating Industrial Nuclear Company Ball-type Male Connectors	09/26/95	All Radiography Licensees.

LIST OF RECENTLY ISSUED
NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
96-27	Potential Clogging of High Pressure Safety Injection Throttle Valves During Recirculation	05/01/96	All holders of OLs or CPs for pressurized water reactors
96-26	Recent Problems with Overhead Cranes	04/30/96	All holders of OLs or CPs for nuclear power reactors
96-25	Transversing In-Core Probe Overwithdrawn at LaSalle County Station, Unit 1	04/30/96	All holders of OLs or CPs for nuclear power reactors
96-24	Preconditioning of Molded-Case Circuit Breakers Before Surveillance Testing	04/25/96	All holders of OLs or CPs for nuclear power reactors
96-23	Fires in Emergency Diesel Generator Exciters During Operation Following Undetected Fuse Blowing	04/22/96	All holders of OLs or CPs for nuclear power reactors
96-22	Improper Equipment Settings Due to the Use of Nontemperature-Compensated Test Equipment	04/11/96	All holders of OLs or CPs for nuclear power reactors
96-21	Safety Concerns Related to the Design of the Door Interlock Circuit on Nucletron High-Dose Rate and Pulsed Dose Rate Remote Afterloading Brachytherapy Devices	04/10/96	All U.S. NRC Medical to the Licensees authorized to use brachytherapy sources in high- and pulsed-dose-rate remote afterloaders
96-20	Demonstration of Associated Equipment Compliance with 10 CFR 34.20	04/04/96	All industrial radiography licensees and radiography equipment manufacturers

OL = Operating License
CP = Construction Permit