



UNITED STATES  
 NUCLEAR REGULATORY COMMISSION  
 REGION II  
 101 MARIETTA STREET, N.W.  
 ATLANTA, GEORGIA 30323

CC

AUG 28 1991

Docket Nos.	030-13584	License Nos.	52-01946-07
	030-31462		52-01946-09
	030-01183		52-01986-04
	030-01182		52-01986-01
	030-14313		52-10510-04
	030-19550		52-19434-02

EA 91-089

University of Puerto Rico  
 ATTN: Dr. Jose M. Saldana  
 President  
 General Post Office Box 364984  
 San Juan, Puerto Rico 00936-4984

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$6,250  
 (INSPECTION REPORT NOS. 52-01946-07/91-01, 52-01946-09/91-01,  
 52-01986-04/91-01, 52-01986-01/91-01, 52-10510-04/91-01, AND  
 52-19434-02/91-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Ms. C. Connell, Mr. H. Bermudez, Mr. J. Ennis, and Mr. L. Franklin on June 17-21, 1991, at the University of Puerto Rico facilities located on the Medical Sciences Campus, College of Natural Sciences Campus, Mayaguez Campus, and the Agricultural Experiment Station, in Puerto Rico. The inspection included a review of the organization and administration of each licensed program, radiation safety aspects of each program, radiation safety training of personnel, and radioactive waste storage and disposal. In addition, the inspection placed special emphasis on the review of management control and oversight of licensed activities. The report documenting this inspection was sent to you by letter dated July 23, 1991. As a result of this inspection, multiple failures to comply with NRC requirements were identified. An enforcement conference was held on July 26, 1991, with Dr. Saldana and other members of your staff in the Region II office to discuss the violations, their cause, and your corrective actions to preclude recurrence. A summary of this conference was sent to you by letter dated August 14, 1991.

The violations in Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) were identified by the NRC during the inspection of the broad scope NRC license program at the Medical Sciences Campus and include failures to: secure licensed material against unauthorized removal, conduct leak tests of sealed sources at the required intervals, properly evaluate dosimetry data, survey radiopharmaceutical waste storage areas, properly label radioactive material containers, adhere to Radiation Safety Committee meeting requirements, properly maintain sealed source inventory

488

records, and maintain leak test records for sealed sources. Additional details regarding the violations are described in the previously issued NRC inspection report referred to above.

We are concerned with the results of the inspection of the University's Medical Sciences Campus broad license, particularly the research program. A similar concern was made known to you previously as a result of an NRC inspection conducted in April 1990 which resulted in the imposition of a civil penalty of \$12,500 for violations associated with both your broad license, specifically the nuclear medicine program operated under that license, and the teletherapy license. The 11 violations that were cited against your broad license resulted in a civil penalty of \$6,250. In our letter of July 19, 1990, which transmitted the Notice of Violation and Proposed Imposition of Civil Penalties, you were informed then of the NRC's concern about your inadequate management oversight and control and your apparent inability to assure lasting effectiveness of corrective actions. In addition, you were advised that repetitious violations were of particular concern and could not be tolerated. During this inspection, however, there were violations cited that were similar to previously cited violations.

It is apparent that the root causes of your continuing poor performance are inadequate management oversight, your staff's lack of understanding of the regulatory requirements associated with your broad license, and your failure to assure that corrective actions to resolve violations in one area of your broad license (nuclear medicine) were applied to other areas such as research. Effective management oversight and control is extremely important because of the wide range of authority associated with your broad license. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1991), the violations in Section I are classified in the aggregate as a Severity Level III problem.

To emphasize again the need for stronger management oversight, more effective control of your licensed radiation programs, and effective implementation of corrective actions throughout the entire program so as to ensure that problems and potential violations are self-identified, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$6,250 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is \$2,500. The escalation and mitigation factors in the Enforcement Policy were considered. The base civil penalty has been increased by 50 percent because the violations were identified by the NRC. Neither escalation nor mitigation was warranted for corrective action to prevent recurrence because, even though immediate corrective actions were taken for some of the violations, adequate long term corrective action to address the root cause issues had not been formulated and implemented at the time of the enforcement conference (for example, actions to assure adequate understanding of the regulatory requirements associated with your broad license). Additional escalation of 100 percent was warranted

because of your poor past enforcement history. It is apparent that the corrective actions implemented in response to the enforcement action, EA 90-076, which was issued on July 19, 1990, have not been effective in preventing non-compliance with the regulations as identified in Inspection Report 52-01946-07/91-01. None of the other factors warranted further adjustment of the civil penalty. Therefore, based on the above, the base civil penalty has been increased by 150 percent.

As discussed during the enforcement conference, the NRC expects the University of Puerto Rico to bring its programs into full compliance. During the enforcement conference it was evident that the University is committed to long term program improvement and that you now recognize the importance of focusing management attention and resources on these problems. It is particularly noteworthy that Dr. Saldana has decided to appoint a high level official from his immediate staff to provide the day-to-day management oversight and control of licensed programs throughout the University system and that this individual will report directly to Dr. Saldana. Also, Dr. Saldana's personal assurance that there is full institutional commitment to the resolution of the problems should have both an immediate and far reaching positive effect on your efforts to achieve and maintain compliance.

The violations in Section II of the enclosed Notice were identified by the NRC during the inspection performed at the College of Natural Sciences, Rio Piedras, and include failure to: check packages for contamination before opening, perform and record surveys, and verify that forms for receiving and handling radioactive material were completed properly.

The violations in Section III of the enclosed Notice were identified by the NRC during the inspection performed at the University's Agricultural Experiment Station, Rio Piedras, and include failure to: perform inventories to account for all sources, properly secure licensed material, and properly post a licensed material storage area.

The violations in Section IV of the enclosed Notice were identified by the NRC during the inspection performed at the University's Mayaguez campus, and include failure to: perform annual audits of the radiation safety program, perform inventories of licensed material, perform monthly surveys, conduct a Radiation Survey Committee meeting during fiscal year 1989, and post required documents and notices at the Marine Sciences Laboratory.

Although the violations in Sections II through IV were categorized at either Severity Level IV or V and were not assessed a civil penalty, they represent a lapse in attention to detail which, if continued in the long term, could lead to more serious violations and escalated enforcement action. It is apparent that the root cause of several of these violations is inadequate training, a recurrent problem that was noted throughout the inspection. We do recognize that there has been some improvement as indicated by the inspection results in the medical teletherapy license program. During the inspection in April 1990, violations associated with that program also resulted in a civil penalty. No violations associated with that program were identified during the June 1991 inspection.

AUG 28 1991

During the inspection at the College of Natural Sciences in Rio Piedras, the inspectors noted that records of routine contamination wipe surveys were being recorded in counts per minute (cpm) instead of disintegrations per minute (dpm), and that licensee personnel did not know the efficiency of the counting equipment used to count the wipe test samples. This resulted in licensee personnel not knowing whether they were exceeding their wipe test action level, which is 100 dpm per 100 square centimeters. To preclude further occurrence of this type of potentially significant problem, you should include in your response to this letter actions taken or planned to assure that the efficiency of the counting equipment is known for all contamination wipe surveys performed in connection with licensed activities under all of the University's NRC licenses, and that the results of the wipe test surveys are recorded in dpm per 100 square centimeters, which is the unit of measurement for wipe test action levels. This issue was discussed during the exit interview and identified as an apparent violation; however no violation is being issued.

Lastly, but of no less significance, the NRC is particularly concerned about the public health and safety implications associated with your lack of aggressive action to resolve your radioactive waste storage and disposal problem. Therefore, in addition to the information that you submitted in your letter of August 6, 1991, we are requesting the specific written information identified below.

We emphasize that a license to use NRC regulated material is a privilege granted by the NRC, and any further recurrence of violations or problems in managing your licensed activities may result in escalated enforcement action, such as higher civil penalties or modification, suspension, or revocation of your licenses.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In addition to this response, we request that you develop and submit to NRC within 60 days of the date of this letter:

- 1.a. A Radiation Safety Improvement Plan, suitable for incorporation into the terms and conditions of your licenses, that addresses those actions necessary to ensure timely and lasting improvement in the radiation safety program, improvements needed in procedures and practices to achieve and maintain compliance with NRC requirements and license conditions, and periodic internal or external audits that you plan to implement to assess your program effectiveness.
- 1.b. A schedule for completion of all actions described in the plan, including interim milestones for the more complex actions.
- 2.a. A description of actions that you have taken or plan to take to ensure that radioactive waste at the University of Puerto Rico is properly identified, packaged, labeled, and stored; and that it is secured against unauthorized removal and disposed of in accordance with regulatory requirements.
- 2.b. A schedule for accomplishing the actions that you describe.

AUG 28 1991

NRC needs this information in order to have assurance that, in the future: 1) your licensed activities will be conducted in accordance with regulatory requirements and 2) the existing radioactive waste disposal problem at the University of Puerto Rico will be resolved in a timely manner and in accordance with regulatory requirements. If you do not intend to develop and submit to NRC the information requested in Paragraphs 1 and 2 above, you are required, pursuant to Section 182 of the Atomic Energy Act of 1954 as amended, to provide in writing, under oath or affirmation, your reasons as to why you should not be required to develop and submit the requested information.

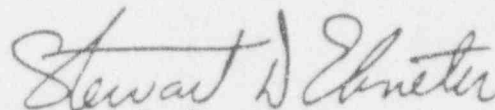
After reviewing your responses, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96.511.

Should you have any questions concerning this letter, please contact us.

Sincerely,



Stewart D. Ebnetter  
Regional Administrator

Enclosure:  
Notice of Violation and Proposed  
Imposition of Civil Penalty