NRC Form 591
(12-81)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION

1. LICENSEE	2. REGIONAL OFFICE
University of Puerto Rico Office of the Chancellor Medical Science Campus GPO Box 5067 San Juan, PR 00936	U.S. Nuclear Regulatory Commission 101 Marietta St. NW Suite 2900 Atlanta, GA 30323

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE OF INSPECTION
030-13584	52-01946-07	3/3/88

Licensee:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission's (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews, with personnel, and observations by the inspector. The findings as a result of this inspection are as follows:

☐ 1. Within the scope of this inspection, no violations were observed.

☑ 2. The inspector also verified the steps you have taken to correct the violations identified during the last inspection. We have no further questions on those actions at this time.

☑ 3. During this inspection certain of your activities, as checked below, were in violation of NRC requirements. THIS IS A NOTICE OF VIOLATION which is required to be posted in accordance with 10 CFR 19.11.

☐ A. _____ was not properly posted to indicate the presence of a _____. 10 CFR 20.203(b), (e), (d), (e) or 34.42.

☐ B. Containers located in _____ were not properly labeled to indicate the presence of radioactive material. 10 CFR 20.203(f)(1), or (f)(2).

☐ C. _____ of sealed sources were not performed at the proper frequencies. 10 CFR _____ License Condition Number _____.

☐ D. Records of _____ were not properly maintained. 10 CFR _____ or License Condition Number _____.

☑ E. Documents were not properly posted or otherwise made available. 10 CFR 19.11.

☐ F. Reports or notifications of _____ were not made in accordance with 10 CFR _____ or License Condition Number _____.

☐ H. _____

☐ I. _____

☐ J. _____

☐ K. _____

I hereby state that within 30 days the actions described by me to the inspector will be taken to correct the violations identified in the items checked above. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201. No further response will be submitted unless required by the NRC.

SIGNATURE - LICENSEE	DATE	SIGNATURE - NRC INSPECTOR	DATE

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

JUL 19 1990

Docket Nos. 030-13584 and 030-31462
License Nos. 52-01946-07 and
52-01946-09(08)

EA 90-076

University of Puerto Rico
Office of the Chancellor
ATTN: Jose M. Saldana, D.M.D., M.P.H.
Medical Science Campus
G.P.O. Box 5067
San Juan, PR 00936

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $12,500 (NRC INSPECTION REPORT NOS. 030-13584/90-01 AND 030-31462/90-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted on April 2-3, 1990, at the University of Puerto Rico, of activities authorized by NRC License Nos. 52-1946-07 and 52-1946-09(08). The report documenting this inspection was sent to you by letter dated April 25, 1990. As a result of this inspection, the NRC identified significant failures to comply with NRC regulatory requirements. NRC concerns relative to the inspection findings were discussed in an Enforcement Conference held on May 3, 1990. The letter summarizing this Conference was sent to you on May 14, 1990.

The violations described in Sections I and II of the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice), include failures: to maintain control and surveillance of licensed material; of the therapy physicist to perform full calibration of the teletherapy system; to perform various types of required surveys; to perform leak tests and physical inventories for sealed sources; of the Radiation Safety Committee to perform an annual review of the radiation safety program; of the therapy physicist to review monthly spot checks of the teletherapy system; and of the Radiation Safety Officer (RSO) to review and sign records of dose calibrator tests. Although Violations F and J in Section I of the Notice were inadvertently left out of of the NRC's April 25, 1990 inspection report, they were discussed with you at both the inspection close out interview and the Enforcement Conference, and therefore these violations are documented in the enclosed Notice.

The large number of violations identified during this inspection is of concern to the NRC. However, of even greater concern is your apparent inability to develop, implement, and maintain an adequate management oversight program to assure lasting corrective actions for previously identified radiation safety program deficiencies. Your inability to assure lasting corrective action is demonstrated by the fact that Violations C, D, E, G, H, and I in Section I and Violations A and B in Section II of the Notice have been previously

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identified during inspections in 1985, 1987, or 1989. Repetitious violations are of particular concern and cannot be tolerated. The NRC expects its licensees to take effective and lasting corrective actions when violations are identified.

Violation C in Section I of the Notice, failure to maintain constant surveillance and immediate control of licensed material in an unrestricted area, is a safety significant violation, and could be considered for separate action. However, the NRC considered all the violations in Section I of the Notice collectively, as they are indicative of lack of management control and supervisory oversight of your nuclear medicine program, as well as lack of an effective audit program to detect and correct violations of NRC requirements. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), 10 CFR Part 2, Appendix C, the violations in Section I of the enclosed Notice are classified in the aggregate as a Severity Level III problem.

Violation B in Section II, failure of the qualified and NRC authorized Teletherapy Physicist to perform the annual calibration of the teletherapy system was previously cited in NRC inspections of September 1987, April 1989, and August 1989. This violation is of significant concern to the NRC because in your response to the NRC's September 30, 1987, Notice of Violation, involving the failure of the teletherapy physicist (qualified expert) to perform the annual full calibrations conducted on June 9, 1986 and June 9, 1987, you stated (in the letter dated October 29, 1987) that the individual who performed the annual calibration "... does not meet the minimum academic requirements as stated in 10 CFR 35.961." The letter further stated that your corrective action included "...the appointment of a half time teletherapy physicist as defined by the new 10 CFR Part 35, paragraph 35.691 with the specific duty of performing full calibration measurements every year...," that "...We do not foresee any further violation in this respect," and that "...Full compliance is expected for January 15, 1988." Notwithstanding, your stated corrective actions were ineffective, as you did not assure that a Therapy Physicist qualified in accordance with 10 CFR 35.691, and authorized by the NRC by name on License No. 52- 01946-09(08) performed the annual full calibrations of the teletherapy unit on June 9, 1988 and June 9, 1989. In fact, the teletherapy physicist did not perform a full calibration of the teletherapy unit until April 6, 1990, three days after the NRC's April 2-3, 1990 inspection. The calibrations prior to April 6, 1990, were performed by the same individual you stated in your October 29, 1987 letter, did not meet the qualifications in 10 CFR 35.691, and was later denied authorization to be the Therapy Physicist by the NRC on July 26, 1989, in response to your requests for an exception to 10 CFR 35.961, dated April 13, 1987 and January 29, 1988. This violation, which could have been considered for separate action, was considered collectively with Violations A and C in Section II of the Notice as they are associated with your teletherapy program. Collectively these violations demonstrate a significant failure to assure that the duties of the Therapy Physicist are performed by a qualified and authorized individual. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), 10 CFR Part 2, Appendix C, the violations in Section II of the enclosed Notice are classified in the aggregate as a Severity Level III problem.

To emphasize the need for stronger management oversight, more effective controls of your licensed radiation program, and to assure a qualified and NRC authorized individual performs the duties of the Therapy Physicist, 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 Penalties in the amount of $12,500 for the violations described in Sections I and II of the enclosed Notice. The base value of a civil penalty for a Severity Level III problem is $2500. The escalation and mitigation factors in the Enforcement Policy were considered for each Severity Level III problem.

For the Severity Level III problem in Section I of the Notice, the base civil penalty has been increased by 50 percent because the violations were identified by NRC. Had an effective management review program been implemented, these violations may have been identified and corrected internally. The base civil penalty has also been increased by an additional 100 percent because of your poor past performance. In addition to the repetitive violations discussed above, 32 violations have been identified during NRC inspections over the past three years. As a result of the NRC's concerns about implementation of your management controls, an enforcement conference was held with you on April 15, 1987. However, violations continued to occur, including an employee over-exposure of 1.82 rem which occurred during the third quarter of 1989. For the Severity Level III problem in Section II of the Notice, the base civil penalty has also been increased by 50 percent because the NRC identified the violations and by an additional 100 percent because of your poor past performance. Neither escalation nor mitigation of the base civil penalty for the violations in Section I or II of the Notice was warranted for your corrective action to prevent recurrence. Although it was considered comprehensive, it was not prompt. The planned actions which you described at the enforcement conference, if effectively implemented, should substantially improve your safety program. These actions include retaining a new teletherapy physicist and minimizing the teaching responsibilities of the Radiation Safety Officer (RSO) in order that he may apply more time and attention to the RSO duties, and assigning an experienced technician to perform more radiation safety functions, as well as certain procedural and facility changes. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty of the violations in Sections I and II of the Notice is considered appropriate.

Therefore, based on the above, the base civil penalty of each Severity Level III problem in the enclosed Notice has been increased by 150 percent.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, 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 Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and 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, Public Law No. 96-511.

Sincerely,

Stewart D. Ebneter

Stewart D. Ebneter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

DISTRIBUTION
PDR
SECY
CA
H. Thompson, DEDS
J. Sniezek, DEDR
J. Lieberman, OE
L. Chandler, OGC
J. Goldberg, OGC
R. Bernero, NMSS
R. Cunningham, NMSS
Enforcement Coordinators
RI, RII, RIII, RIV, RV
F. Ingram, GPA/PA
B. Hayes, OI
D. Williams, OIG
V. Miller, GPA/SP
E. Jordan, AEOD
OE: CHRON
OE: EA
OE: ES
DCS
Commenwealth of Puerto Rico

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

University of Puerto Rico
San Juan, Puerto Rico

Docket Nos. 030-13584 and 030-31462
License Nos. 52-01946-07 and
52-01946-09(08)
EA 90-076

During the Nuclear Regulatory Commission (NRC) inspection conducted on April 2-3, 1990, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, (1990), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations of License No. 52-01946-07 (Broad License)

A. 10 CFR 35.415(a)(4) requires, in part, that for each patient receiving implant therapy, a licensee promptly, after implanting the material, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 10 CFR 20.

Contrary to the above, on April 13, 1989, October 11, 1989, and January 4, 1990, the licensee did not conduct any surveys for dose rates in the contiguous restricted and unrestricted areas to demonstrate compliance with the requirements of 10 CFR 20 after implanting the material in a patient receiving implant therapy.

B. 10 CFR 35.404(a) requires, in part, that immediately after removing the last temporary implant therapy source from a patient, a licensee make a radiation survey of the patient to confirm that all sources have been removed.

Contrary to the above, on April 17, 1989, the licensee did not make any survey of an implant therapy patient immediately after the removal of iridium-192 temporary implant therapy sources to confirm that all the sources had been properly removed.

C. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under the constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of

protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on April 2, 1990, licensed materials located in the the radiopharmaceutical storage and preparation laboratory (hot lab) of the Nuclear Medicine Department, an unrestricted area, was not secured against unauthorized removal and were not under the constant surveillance and immediate control of the licensee in that the laboratory was left open and unattended

This is a repeat violation (Inspection 89-01).

D. 10 CFR 35.59(b)(2) requires that a licensee in possession of any sealed sources or brachytherapy sources test the sources for leakage at intervals not to exceed six months or other intervals approved by the Commission and described in the manufacturer's label or brochure that accompanies the sealed sources.

Contrary to the above, between June 1989 and April 3, 1990, an interval exceeding six months, the licensee did not test any sealed source or brachytherapy source in its possession for leakage and no other intervals for testing these sources had been approved by the Commission.

This a repeat violation (Inspection 87-01).

E. 10 CFR 35.59(g) requires, in part, that a licensee in possession of any sealed sources or brachytherapy sources shall conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, between December 12, 1988 and May 3, 1989 (the 1st quarter of 1989), and between May 3, 1989 and October 6, 1989 (the 3rd quarter of 1989), the licensee did not conduct quarterly physical inventories of any sealed sources and brachytherapy sources in its possession.

This is a repeat violation (Inspection 85-01).

F. 10 CFR 35.59(h) requires, in part, that a licensee in possession of any sealed sources or brachytherapy sources measure the ambient dose rates quarterly in all areas where such sources are stored.

Contrary to the above, between June 1989 and April 3, 1990 (the 3rd and 4th quarter of 1989, and 1st quarter of 1990), the licensee did not measure the ambient dose rates in any areas where sealed or brachytherapy sources are stored.

G. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the regulations of Part 20, and which are reasonable under the circumstances to evaluate the extent

of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions. When appropriate, such an evaluation includes physical survey of the location of materials and equipment, and measurements of levels of radiation and concentrations of radioactive material present.

10 CFR 20.103(b)(1) requires, in part, that a licensee, as a precautionary procedure, use process or other engineering controls to limit concentrations of radioactive material in air to the extent practicable.

Contrary to the above, between January 1989 and April 3, 1990, the licensee's surveys made to verify compliance with the requirements of 10 CFR 20.103(b)(1) were inadequate in that air flow rates in fume hoods used as process and engineering controls for the handling and storage of multiple dose vials containing millicurie quantities of iodine-131 were not being measured and evaluated.

This is a repeat violation (Inspection 87-01)

H. 10 CFR 35.205(e) requires that a licensee measure the ventilation rates available in areas of radioactive gas use each six months.

Contrary to the above, between January 1989 and April 3, 1990, the licensee did not measure the ventilation rates available in the room where xenon-133 gas was used.

This is a repeat violation (Inspection 87-01)

I. Condition 20 of License No. 52-01946-07 requires that the licensee conduct its program in accordance with the statements, representations, and procedures described in the licensee's application dated August 29, 1988.

Item 10.7, page 30, of the licensee's application dated August 29, 1988, states that packages containing radioactive material will be opened in accordance with the procedures described in Appendix L of Regulatory Guide 10.8, Revision 2, "Guide for the Preparation of Applications for Medical Use Programs" (August 1987) (RG 10.8). Step 2.c of Appendix L requires that radiation dose rate measurements be made at one meter from the package and on contact with the package surface.

Contrary to the above, on April 11, 1989, no radiation survey measurements were made either at one meter from the package or at contact with the package, upon receipt of a package containing iridium-192 implant therapy sources.

This is a repeat violation (Inspection 85-01)

J. 10 CFR 35.22(b)(6) requires that to oversee the use of licensed materials, the Radiation Safety Committee must review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

Contrary to the above, an annual review of the radiation safety program was not performed by the Radiation Safety Committee and the Radiation Safety Officer for 1988. The last two reviews were performed in March 1990 (for 1989) and in April 1988 (for 1987).

K. 10 CFR 35.50(e)(2), (3), and (4) require that records of dose calibrator accuracy, linearity, and geometric dependence tests, include the signature of the Radiation Safety Officer.

Condition 20 of License No. 52-01946-07 requires that the licensee conduct its program in accordance with the statements, representations, and procedures described in the licensee's application dated August 29, 1988.

Item 9.3 of the application dated August 29, 1988, requires that the model procedures in Appendix C, RG 10.8, be followed for calibration of the dose calibrator. Procedure 8. of Appendix C requires that the RSO review and sign the records of all geometry, linearity, and accuracy tests.

Contrary to the above, between April 1989 and April 3, 1990, the Radiation Safety Officer did not review or sign the dose calibrator accuracy, linearity, and geometric dependence test records.

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

Cumulative Civil Penalty - $6,250 (assessed equally among the 11 violations).

II. Violations of License Number 52-01946-09 (Teletherapy License)

A. 10 CFR 35.634(a) requires, in part that a licensee authorized to use teletherapy units for medical use perform output spot checks on each teletherapy unit once in each calendar month. 10 CFR 35.634(c) requires, in part, that a licensee have the teletherapy physicist review the results of each spot check within 15 days.

Contrary to the above, between April 1989 and April 3, 1990, the licensee did not have the teletherapy physicist (Radiation Safety Officer) review the results of each spot check either within the 15 days required or at anytime during the 12-month period from April 1989 to the date of the inspection.

B. 10 CFR 35.632(a)(3) and (f) require, in part, that a licensee authorized to use a teletherapy unit for medical use perform full calibration measurements at intervals not to exceed one year and that these full calibration measurements be performed by the licensee's teletherapy physicist.

License Condition 11.B of License No. 52-01946-09 specifies the licensee's designated teletherapy physicist by name.

Contrary to the above, between April 1, 1987 and April 3, 1990, the designated teletherapy physicist did not perform the annual full calibration measurements of the teletherapy system documented for June 9, 1987, June 9, 1988 and June 9, 1989. Instead, these annual full calibrations were performed by an individual not meeting the qualifications of a teletherapy physicist and not designated by License No. 52-01946-09 to perform such measurements.

C. 10 CFR 35.59(b)(2) requires, in part, that a licensee in possession of any sealed sources test the sources for leakage at intervals not to exceed six months or at other intervals approved by the Commission and described in the label or brochure that accompanies the sealed sources.

Contrary to the above, between June 1989 and April 3, 1990, an interval exceeding six months, the licensee did not test the teletherapy system sealed source in its possession for leakage and no other intervals for testing this source had been approved by the Commission.

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

Civil Penalty - $6,250 (assessed $1,500 for Violation A, $4,250 for Violation B and $500 for Violation C).

Pursuant to the provisions of 10 CFR 2.201, the University of Puerto Rico (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the violation, (2) the reasons for the violations if admitted, (3) the corrective steps that have been taken and the results achieved (4) the corrective steps which will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalties in whole or in part by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting m[illegible]tion of the proposed penalties, the factors addressed in Section V.B o[illegible]R Part 2, Appendix C (1990), should be addressed. Any written answe[illegible]ordance with 10 CFR 2.205 should be set forth separately from the stat[illegible] explanation in reply pursuant to 10 CFR 2.201 but may incorporate pa[illegible] the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing civil penalties.

Upon failure to pay any civil penalties due, which has been subsequently determined in accordance with the applicable provisions of 10 CFR 2.[illegible] this matter may be referred to the Attorney General, and the penalties, [illegible]s compromised, remitted, or mitigated, may be collected by civil action [illegible]uant to Section 234c of the the Act, 42 U.S.C 2282c.

The responses noted above (Reply to a Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II.

FOR THE NUCLEAR REGULATORY COMMISSION

Stewart D Ebneter

Stewart D. Ebneter
Regional Administrator

Dated at Atlanta, Georgia
this 19th day of July 1990