

AUG 14 1991

Inspection

Docket Nos.: 030-13584 ✓
030-31462 ✓
030-01183 ✓
030-01182 ✓
030-14313
030-19550

License Nos.: 52-01946-07
52-01946-09
52-01986-04
52-01986-01
52-10510-04
52-19434-02

University of Puerto Rico
ATTN: Dr. Jose M. Saldana, President
G. P. O. Box 364984
San Juan, PR 00936-4984

Gentlemen:

SUBJECT: ENFORCEMENT CONFERENCE SUMMARY
(NRC 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 letter refers to the Enforcement Conference held at our request on July 26, 1991. The issues discussed at this conference relate to the corrective actions in response to NRC 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, and to concerns about management oversight of the radiation safety programs and the handling of storage and disposal of radioactive waste. During this meeting, the University agreed to submit to NRC Region II by August 2, 1991, an evaluation of the current hazards associated with the radioactive waste disposal areas and provide the corrective actions planned. A list of attendees (Enclosure 1) and a copy of your handouts (Enclosure 2) are provided.

We are continuing our review of these issues to determine the appropriate enforcement action.

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 enclosures will be placed in the NRC Public Document Room.

Should you have any questions regarding this matter, please contact us.

Sincerely,

ORIGINAL SIGNED BY
J. PHILLIP STOHR

J. Philip Stohr, Director
Division of Radiation Safety
and Safeguards

Enclosures: (See page 2)

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Enclosures:

- 1. List of Attendees
- 2. Licensee Handouts

cc w/encls:

Commonwealth of Puerto Rico

bcc w/encls:

Document Control Desk
 G. Jenkins, EICS

RII:DRSS <i>CConnell</i>	RII:DRSS <i>Chosey</i>	RII:DRSS <i>Wclipe</i>	RII:DRSS <i>Bsm</i>	RII:DRSS <i>GJenkins</i>
CConnell	CHosey	Wclipe	BMallett	GJenkins
08/8/91	08/8/91	08/8/91	08/14/91	08/9/91

ENCLOSURE 1

LIST OF ENFORCEMENT CONFERENCE ATTENDEES

Licensee Attendees:

J. M. Saldana, D.M.D., M.P.H., President
J. M. Roman, Dean of Administration, Medical Sciences Campus
F. L. Renaud, Radiation Safety Officer, Rio Piedras Campus

NRC Attendees:

S. D. Ebnetter, Regional Administrator
B. S. Mallett, Deputy Director, Division of Radiation Safety and Safeguards (DRSS)
C. M. Hosey, Chief, Nuclear Materials Safety Section (NMS), Nuclear Materials Safety and Safeguard Branch (NMSS), DRSS
C. A. Connell, Senior Radiation Specialist, NMS, NMSS, DRSS
H. Bermudez, Radiation Specialist, NMS, NMSS, DRSS
J. D. Ennis, Radiation Specialist, NMS, NMSS, DRSS
G. R. Jenkins, Director, Enforcement and Investigation Coordination Staff (EICS)
B. Uryc, Senior Enforcement Specialist, EICS
R. J. Delmedico, Senior Enforcement Specialist, Office of Enforcement (by telephone)



DEPARTMENT OF RADIOLOGICAL SCIENCES

**Progress Report on the Implementation of Corrective Action
Plan Submitted to the NRC in September 1990.**

Over the last 10 months there has been considerable progress in the Radiation Safety Program of the University of Puerto Rico Medical Sciences Campus. The achievements listed below are due mostly to the diligent work of Mr. José Pérez Bobonis, RSO, and the commitment to solving the problems in the Licenses by the new chancellor Dr. Manuel Marina, the Dean of Administration, Mr. John Román, and the President of the UPR, Dr. José Saldaña (the former two have only been in their positions for three months).

The major concern expressed by NRC was with regards to the major violations found in the Teletherapy License. **All violations have been corrected! No violations were found in the June 1991 inspection. All NRC standards were met.**

The teletherapy facility has been closed to patient therapy since July 1, 1991. This is due to the fact that only one authorized user-Dr. Hernando Ortiz- remains in the Radiotherapy Division. It is also due to the concerns expressed by the inspectors and acknowledge by the licensee regarding the decayed activity of the source as can be seen in the report. As new faculty and management takes over the Radiotherapy Program in Q3 and Q4 1991, a decision towards the purchase of new equipment will be finalized. Appropriate amendments will be submitted at that time.

The licensee's top priority was the full compliance with NRC standards and regulations. Since this has been achieved we are now committed to the implementation of a Total Quality Management Program in Radiotherapy Physics according to the standards of the American College of Radiology and the American Board of Medical Physicists. This program should fully in place by the end of fiscal year 1991-92.

With regards to the Broad Scope License the following has been accomplished:

1. A new Radiation Safety Officer- José Pérez Bobonis- has been hired as of October 1990, and took over his responsibilities as RSO in December 1990. He has made major improvements in the Radiation Safety Program.

2. The duties of Dr. Heriberto Torres have been reduced to those of Teletherapy Physicist only (plus his duties as Associate Professor at the School of Public Health). The result has been a major improvement in solving the problems of both licenses.

3. A new Physics Section has been created in the Department of Radiological Sciences. This new section is headed by Dr. Ricardo González. Dr. González has a PhD in Biophysics and over 10 years of experience in Medical Physics (with significant expertise in radiobiology). He is in charge of supervising all Medical Physics programs in Radiological Sciences, and particularly Radiotherapy Physics. He has been given a tenured position at the Associate Professor level. This section will agglutinate all the physics personnel in the School of Medicine, and will have two tenure track positions for hiring PhD level medical physics faculty. Together with Mr. Pérez and Dr. Torres this section will provide all medical physics services, and expert consulting on radiation physics and safety campus wide. This will include comprehensive quality assurance programs in physics of Nuclear Medicine and Radiotherapy.

4. Security violations in the Nuclear Medicine Division have been resolved by the installation of electronic and high security locks in the isotope storage facilities.

5. A program for the upgrade of clerical forms and record keeping to comply with regulatory guidelines has been established by Mr. Pérez.

6. A program to revise and update all user authorizations for the broad scope license is in progress. It includes the use of expiration dates on all authorizations, something never done before at the MSC, also includes all isotope utilization protocols, and detailing of user training in isotope handling, as per regulations.

7. An educational training program has been started by Mr. Pérez. This is a three day program held every 6 months to train new users (or re-train old ones), and in future sessions will be required of all students and staff involved in isotope use. Clerical record keeping of those receiving this training is being designed. This program is required as part of the annual continuing education program for the Nuclear Medicine Staff.

8. The Radiation Safety Committee, headed by Dr. Frieda Silva, has become a very pro-active organization and has received the authority to take the actions needed to ensure regulations are observed. In particular it has taken a strong stance and interest in the solution of the waste management problem existing on campus.

9. The leak testing program has achieved full compliance with regulatory guidelines as of July '91.

10. All testing of airflow for hoods and Nuclear Medicine is fully compliant with NRC regulations.
11. Full compliance has also been accomplished in the sealed source inventory program as of July '91. The implantation source program is also fully compliant with some minor clerical aspects needing to be resolved.
12. Full compliance in the revision of the ALARA program has been achieved since Mr. Pérez assumed the position of RSO.
13. A program for the annual calibration of all survey instruments is being implemented by the RSO.
14. There is an institutional commitment for the modernization of all physics, health physics, and radiotherapy physics equipment during 1991-92.
15. There is an institutional commitment to remodel the Biomedical Building in order to provide increased safety, and modern facilities for Health Physics, Radiotherapy, Nuclear Medicine, and Physics. This building has become a property of the MSC since October 1990, although 40% of the space is still occupied by Mayagüez Campus personnel.
16. The addition of computer equipment for information management is contemplated for the Health Physics Office in fiscal 1991-92.
17. The new incinerator is installed and operational having met all of its performance specifications. It awaits permits from EPA and PR EQB for start of operations. An environmental impact statement prepared by the Department of Environmental Health (School of Public) was filed at the EQB on July 8, 1991. As soon as permits are granted an amendment will be requested from NRC to allow for the incineration of radioactive waste. Mr. Pérez attended a major USA meeting on incineration of waste in May 1991.
18. The Department of Energy of the USA will be approached for the removal of radioactive sources and waste from the old UPR Nuclear Center that was an Atomic Energy Commission contractor in the 50's, 60's and 70's. They did a major clean-up in Mayagüez in 1988, and should do so in the MSC.
19. An internal regulatory program that only allows the use of biodegradable counting materials, waste processing for limited sewage disposal is under consideration.
20. Nuclear Medicine will have its own exclusive facility for waste storage and decay, so that the waste can be disposed of as regular biomedical waste after the appropriate 10 half-life periods.

In summary , > 90% compliance has been achieved with NRC regulatory guidelines. We are hoping to have a Total Quality

Program in place by the end of fiscal year 91-92. We will need the collaboration of NRC in doing a 100% inspection, to be able to identify any citations that may have been overlooked by our program or by prior inspections. We believe that the success of the program shows a major institutional commitment to appropriate management and oversight of the Licences at the MSC by the new administration and personnel.

prepared by:
Ricardo González Méndez, PhD

General Weaknesses Due to Inadequate Management Oversight	
Cited Program Weakness	Corrective Actions In Progress
Lack of effective oversight by University management	Direct access to Medical Sciences Campus Chancellor and Dean of Administration as needed since 12/90 Authority on Radiation Safety Committee to order and implement any corrective or disciplinary action needed to comply with regulations
Lack of effective oversight by Radiation Safety Committee	Requirement of RSC to have all actions by Radiation Safety Officer reported to the committee for review Also see above #2
Lack of knowledge of NRC regulations by Staff	Training programs at all staff and student levels as of 10/90 Publication of revised Radiation Safety Manual including regulations as official MSC publication by 1992
Failure to have an effective program for the identification and correction of violations of NRC regulations	New MSC RSO and New Physics Division started a comprehensive program on 2/91
Waste storage and disposal problems	Incinerator installed and tested in 3/91. Awaits final permits for operation by EPA and PR EQB, then NRC permit. New program to use biodegradable counting materials and waste preparation that can be disposed by standard means.
Failure of management representative to attend RSC meetings	RSC will not hold meetings if management representative is not present Chain of command identified to ensure management presence at meetings

<p>Failure to secure licensed material from unauthorized removal</p>	<p>All prior major citations corrected. New incident is minor compared to past. More stringent inspection and disciplinary actions will be implemented</p>
<p>Use of licensed material by unauthorized personnel</p>	<p>User cited was actually under the direct supervision of authorized user. Incident due to misunderstanding by user of questions by inspector</p>
<p>Failure to perform training or inadequate training of the staff</p>	<p>New training program in place since 10/90</p> <p>Improved clerical record keeping being designed</p> <p>Program to identify untrained personnel in progress-particularly students in research labs.</p> <p>Revision and publication of revised radiation safety manual</p>
<p>Failure to have a Quality Assurance Program to prevent misadministrations</p>	<p>Programs being designed and in the beginning stages of implementation since 3/91. Should be fully in place by end of 1991-92</p>
<p>Failure to test sealed sources for leakage</p>	<p>Program >90% compliance by June '91 inspection. Only two small sources not tested. Leak testing done on them in July '91. Program currently in full compliance.</p> <p>Clerical record keeping for leak tests, and source inventories in process of being upgraded to meet regulatory standards for the first time in more than 15 yrs.</p>

prepared by:
Ricardo González Méndez, PhD

Specific Findings of Apparent Violations in Broad Scope License at The
Medical Sciences Campus of the University of Puerto Rico

Apparent Violation	Explanation	Immediate Corrective Action	Long Term Corrective Action
1. Failure of RSC to meet quarterly	Admitted. One meeting was late by 3 days (April 91) due to inadvertently being scheduled on Good Friday	Proper scheduling taking into account holidays is in progress	Annual schedule of meetings for following year to be set at Q4 meeting.
2. Management representative not present at RSC meetings	Admitted.	A chain of command is being identified at University management to ensure the presence of a management representative at all RSC meetings	Publication to all people involved of annual schedule of meetings.
3. Minutes of RSC meetings not distributed to members	Admitted. Minutes always available at RSC meetings. Has been this way for 19 years. First time MSC is cited for this.	In process of allocating clerical staff to transcribe and distribute the minutes to committee members	Preliminary minutes of meetings to be distributed to members prior to RSC meeting. Corrected/approved minutes to mailed within 2 weeks of their approval.

<p>4. Failure to ensure licensed material was used under supervision of authorized user</p>	<p>NOT ADMITTED! Researcher cited works under the supervision of Dr. George Hillyer-an authorized user. There was a misunderstanding on the part of the researcher of what was being asked by the inspector.</p>	<p>NONE</p>	<p>Researcher will apply for his own user authorization.</p>
<p>5. Failure to assure specific training had been received before issuing authorization for material use</p>	<p>Admitted with qualification. RSC always makes sure that specific training required has been received by prospective users. The application form in use since 1972 did not include the item of basic academic training. This item has never been cited before as a violation.</p>	<p>New application form conforming to regulatory guide has been made. All authorized users have been ordered to re-apply for authorization using new forms.</p>	<p>Clerical record forms will be evaluated every two years (or sooner if needed) to ensure they conform to regulations.</p>
<p>6. Failure to evaluate individual radiation dose when personal badge was unreadable in April-May 1990</p>	<p>Admitted.</p>	<p>Appropriate calculations were performed to estimate individual radiation doses, and these were included in the persons records. Fully compliant-July '91.</p>	<p>Estimates of individual dose will be performed when personal badge is unreadable. Written procedure for this will be established.</p>

<p>7. Failure to receive all material not associated with Nuclear Medicine at Health Physics Office</p>	<p>Admitted. This procedure has been in place for a few years and was not cited as a violation previously.</p>	<p>All orders and shipments of licensed material by/to Neurobiology Institute have been halted effective July '91</p>	<p>Appropriate procedures will be identified and implemented. License amendments will be requested if necessary.</p>
<p>8. Presence of licensed material in unsecured refrigerator</p>	<p>Admitted. Only unsecured material found on campus. Minor incident compared to prior citations which have been fully corrected.</p>	<p>Material removed to secure area immediately. Fully compliant-June '91.</p>	<p>More stringent inspections will be performed by the Health Physics Staff. Immediate removal of unsecured material is authorized. Violators' user authorization will be revoked.</p>
<p>9. Failure to place radioactive material waste in properly marked containers</p>	<p>Admitted.</p>	<p>Waste is being properly labeled and marked at this time.</p>	<p>Program to provide pre-marked bags and containers for radioactive waste will be introduced. Violators' user authorization will be revoked.</p>

<p>10. Failure to label source containers at MSC source storage vault</p>	<p>Admitted with qualification. Several unknown sources and waste material exist at the MSC from the Old Nuclear Center - an Atomic Energy Commission contractor. These were not removed in 1988 by Department of Energy when Mayagüez campus clean-up was performed.</p>	<p>Containers are being labeled as radioactive at this time</p>	<p>Negotiations between UPR and D of E must take place to have these sources removed from the MSC.</p>
<p>11. Failure to leak test all sealed sources</p>	<p>Admitted. These two sources had never been leak tested, and were not part of prior citations.</p>	<p>Sources have been leak tested. 100% compliance-July '91.</p>	<p>All sealed sources will be leak tested regardless of prior history of program.</p>
<p>12. Failure to maintain complete records of source leak tests 16 Cs-137 sources</p>	<p>Admitted. Problem is one of clerical record keeping. Form has been used for 15 years. It does not conform to regulatory guide. Was never cited before.</p>	<p>New leak test record form designed and implemented as per regulatory guide</p>	<p>As #4 above.</p>
<p>13. Failure to record all required information on inventory of sealed sources</p>	<p>Admitted. As #12.</p>	<p>As #12.</p>	<p>As #4 above.</p>

14. Failure to document actions taken where radiation and/or contamination exceed action levels, and follow-up survey information	Admitted.	New and more stringent procedures are being designed for implementation. Report of all incidents, actions taken, and follow-up to RSC for adequate review will be required	To be included as part of comprehensive action plan within the Radiation Safety Program. Quarterly review of actions by RSC.
15. Failure to perform weekly surveys of radiopharmaceutical waste storage area	Admitted.	Weekly survey program established- July '91	Identification of area for exclusive use as a radiopharmaceutical waste storage area.
16. Failure to label containers in radioactive waste building as required	Admitted. See #10.	All waste material is being labeled properly.	See #15, and #9, and #10.

prepared by:
Ricardo González Méndez, PhD



Universidad de Puerto Rico

Recinto de Río Piedras
Río Piedras, Puerto Rico 00931

Departamento de Biología

July 24, 1991

J. Philip Stohr, Director
Division of Radiation safety and Safeguards
Nuclear Regulatory Commission
101 Marietta Street, NW
Atlanta, Georgia 30323

Dear Dr. Stohr:

I wish to respond to the NRC Inspection Report involving the recent inspection to our campus (License No. 52-01986-04):

1. First apparent violation:

Audits and Surveys. "Failure to perform contamination surveys of packages of radioactive materials upon receipt, to perform adequate contamination surveys, to perform surveys at the end of experiments, to record the results of all surveys performed, and to ensure that researchers were properly completing forms for receiving and handling radioactive materials were identified as apparent violations of condition 15 of License No. 52-01986-04."

Response. These facts are admitted. The information on the proper way to perform audits and surveys had been communicated to all the laboratories using radioactive materials; evidently we need to be more rigorous in the local inspections and in the training of the personnel involved in the surveys and audits of isotopes. With this in mind we have scheduled an all day workshop for August 16, 1991, the attendance of this workshop will be compulsory for all the students and technicians working with radioisotopes and for all personnel in charge of surveys. We also plan to have additional activities during the semester, such as showing films that educate about the safe handling of radioisotopes. Furthermore we propose to have monthly in-house inspections.