September 27, 1991



Director
Office of Enforcement
U. S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D. C. 20555

License Nos. 52-01946-07 52-01946-09 52-01986-04 52-01986-01

52-10510-04 52-19434-02

Gentleman:

SUBJECT: REPLY TO NOTICE OF VIOLATION AND PROPOSED

IMPOSITION OF CIVIL PENALTY - \$6,250 (INSPECTION REPORT NOS. 52-01946-07/91-01.

52-01946-09/9101, 52-01986-04/91-01,

52-01986-01, 52-10510-04/91-01, 52-19434-02/91-01)

Enclosed please find a detailed response to each of the violations as requested in your letter dated August 28, 1991.

A Radiation Safety Improvement Plan, a schedule for completion of pending actions, and a description of the actions taken in order to maximize compliance with established plans and procedures is on preparation and will be submitted for NRC's consideration within the 60 days compliance period.

In order to develop a stronger Radiation Safety Program, the University of Puerto Rico has initiated the acquisition of personnel, equipment and materials. For this reason and due to

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Office of Enforcement NRC September 27, 1991

the fact that more than 75% of the violations have already been corrected, we are requesting NRC to reconsider reducing the amount of Civil Penalty proposed.

Sincerely,

José A. Satoana, DMD, MPH

President

Manuel Marina, MD

Chancellor

Medical Sciences Campus

arv

- Violations of License Number 52-01946-07 (Broad License) Medical Sciences Campus (Violations Assessed A Civil Penalty)
- A. 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 materials not in storage be tended under the constant surveillance and immediate control of licensee. As defined in 10 CFR 20.3(a) (17), an unrestricted area is any area to which access is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on June 18, 1991, licensed material consisting of 250 microcuries of sulfur 35 located in an unlocked refrigerator in Room 607-A of the Medial Sciences Building, an unrestricted area, was not secured against unauthorized removal and was not tended under the constant surveillance and immediate control of the licensee.

RESPONSE

The violation is admitted. The laboratory technologist inadvertently forgot to lock the refrigerator, however, he was working within the vicinity of Room 607-A at the time of the inspection. When the violation was identified by the inspector, immediate instructions were given to the technologist to lock the refrigerator and it will be kept locked as required from now on.

In order to reinforce the immediate actions taken and to avoid repetition of the same violation, the following steps are being taken:

- 1. Weekly inspections have been scheduled in areas where radioactive material is used or stored. A checklist has been designed to aid in the process. See appendix 1. The purpose of these inspections is twofold: to insure that safe conditions are maintained at all times and to keep personnel alert to the proper safety controls.
- Access locks will be installed on all doors to rooms where radioisotopes are used, and stored. We expect that full compliance will be achieved in 90 days.
- B. 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.

Contrary to the above, sealed sources containing approximately 150 microcuries of cesium 137 and 150 microcuries of barium 133 with a leak test frequency not to exceed six months, were not tested for leakage between April 3, 1990 and June 18, 1991, an interval exceeding six months.

The violation is admitted. The person performing the leak tests missed this source when carrying out the tests to other sources. The leak test was performed on June 21, 1991, and will be carried out every six months as required. To assure that all sources are leak tested, the reports will be checked against the source inventory.

C. 10 CFR 20.201(b) requires that the licensee make or cause to be made such surveys as may be necessary to comply with the requirements 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.

Contrary to the above, as of June 17, 1991, the licensee did not make surveys to assure, compliance with 10 CFR 20.101(a) that limits the radiation exposure of individuals in a restricted area. Specifically, in April and May 1990, the licensee's personnel dosimetry processor notified the licensee that four dosimetry badges (three ring badges and one whole body badge) were non-readable, and the licensee did not make necessary surveys to evaluate the radiation dose receive by the individuals who used those badges.

RESPONSE

The violation is admitted. The radiation dose received by the two persons was empirically determined and the corresponding dose added to their personal records. In order to avoid further violations the RSO will revise and sign each exposure report and indicate by his initial items missing information.

D. Condition 12.C. of License No. 52-01946-07 requires that licensed material for other than human use be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.

Contrary to the above, as cf June 18, 1991, a researcher located in Room 617-A of the Medical Sciences Building was using sulfur 35 for other than human use and was not designated by the Radiation Safety Committee to do so, nor was he using the licensed material under the supervision of an individual designated by the Radiation Safety Committee. The researcher ordered and received licensed material under his own name and was not, at that time, conducting his research under the supervision of an individual designated by the Radiation Safety Committee.

The RSO, in explaining the situation to the inspectors got confused with a second Dr. José Rodríguez, an authorized user, who was ordering and receiving licensed materials. Another doctor Rodríguez, not an authorized user, never ordered or received licensed materials and is working under Dr. George Hillyer, an authorized user.

E. 10 CFR 35.70(b) requires the licensee to survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceutical waste is stored. 10 CFR 35.70(h) requires the licensee to retain a record of this survey with specific information for three years.

Contrary to the above, between April 3, 1990, and June 19, 1991, the licensee did not survey with a radiation detection survey instrument at least once each week in areas where radiopharmaceutical waste is stored.

RESPONSE

The violation is partially admitted. The surveys were being made but the RSO failed to keep records of the results. A new form has been designed to facilitate weekly survey reports.

- F. 10 CFR 20.203(f) requires that, except as provided by 10 CFR 20.203(f)(3), each container of licensed material bear a durable, clearly visible label identifying the radioactive contents. Contrary to the above:
 - 1. On June 18, 1991, several containers of radioactive waste in the waste storage building did not bear durable, clearly visible labels identifying the radioactive contents and the containers were not excepted from such labeling; and
 - 2. On June 19, 1991 a container of radioactive materials located in the sealed source storage vault below the Health Physics Office did not bear any label identifying the radioactive contents and the container was not excepted from such labeling.

RESPONSE

Violation is admitted. An investigation made by the present RSO showed that none of the former colleagues recalls the identity of the sources and waste or whether they had ever been labeled.

The following steps have been taken in order to correct this violation:

- 1- Purchase a portable multichannel analyzer
- 2- Identify the sources and the radioisotopes in the waste container
- 3- Label the containers as required.

Full compliance is expected within six months. However if we face unexpected delays, a request for an extension of the compliance period will be applied for from NRC.

G. 10 CFR 35.22(a)(2) requires the Radiation Safety Committee to meet a least quarterly.

Contrary to the above, the Radiation Safety Committee failed to meet from December 20,. 1989 through April 4, 1990, and from December 19, 1990 through April 3, 1991, periods in excess of one calendar quarter.

RESPONSE

Partially admitted. The Committee met four times each year during 1989, 1990. They failed to meet during the NRC identified periods which constitute only a deviation of 15 days of a calendar quarter. At present the meetings have been scheduled to be held in the middle of each quarter.

H. 10 CFR 35.22(a)(3) requires the Radiation Safety Committee to establish a quorum in order to conduct business with at least one half of the Committee's membership present, including a management representative.

Contrary to the above, on December 19, 1990, April 3, 1991 and May 22, 1991 the Radiation Safety Committee met and conducted business without first establishing a quorum in that a representative of management was not present at those meetings.

RESPONSE

Violation is admitted. The management has been made aware of the importance of attending to these meetings. The Dean of Administration is made responsible for the appointment of a management representative and assuring his (her) attendance to the meetings.

- 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.
 - Attachment 11, Subparts 11.1, 11.1.2 and 11.1.6 of the licensee's application state that radioactive waste will to placed in clearly identified receptacles which are appropriately marked with the radiation standard tag or label and that under no circumstance will radioactive materials be discharged into waste baskets or other containers which would permit the contamination of the regular trash.

Contrary to the above, on June 18, 1991, phosphorus 32 waste located in Room B-316 of the Medical Science Building was placed in a receptacle of biological waste, without any radiological warning signs, and was prepared to be disposed of as biological waste.

Attachment 10.6.A.3 of the licensee's application stated that all shipments of radioactive materials are to be received in the Hot Lab (Room R-133 of the Biomedical Building) and in the Health Physics Laboratory (Room R-179 of the Biomedical Building) and inspected by the Health Physics Office staff prior to delivery to the user.

Contrary to the above, as of June 19, 1991 packages containing radioactive material had been delivered directly to the Neurobiology laboratory and had not been initially received and surveyed by the Health Physics Office staff at the Central Medical Science Campus prior to delivery to the user.

3. Attachment 8.2 of the licensee's application states that candidates for use of radioactive materials in research should submit evidence of training and experience equivalent to 40 hours academic radiation disciplines including specific subjects.

Contrary to the above, on September 19, 1990, November 8, 1990 and November 30, 1990, candidates for use of licensed materials in research were approved without submitting evidence of training and experience equivalent to 40 hours of academic radiation disciplines.

4. Attachment 10.12 of the licensee's application states that the licensee will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2 (August 1987). Item 1.e. (Records) of Appendix N specifies that the licensee will keep records which include actions taken in the case of excessive dose rates or contamination and follow up survey information.

Contrary to the above, as of June 18, 1991 records of surveys performed in the research laboratories did not indicate the actions taken and follow up survey information for cases involving excessive dose rates or contamination.

RESPONSE

- Violation admitted. The laboratory technician in charge failed to segregate the radioactive waste and label it. The violation was immediately corrected and close supervision will prevent recurrences.
- Violation admitted. The reason for the violation is that the user was not aware that the license had to be amended in order to receive the radioisotopes in her new laboratory. No material will be received by the Neurobiology Laboratory until the License is amended to reflect the practice of the receiving radioactive material at the location of the Laboratory. Personnel responsible for opening packages will be trained in such procedures according to 10 CFR 20.205(b)(1).
- Partially admitted. Most of the radioisotope users have been in the campus for more than 10 years. They have taken courses and on the job training in radioisotope handling at the Medical Sciences Campus but no certificates have been issued. In the past it was not required to submit evidence of training. At present, we have updated the application procedure and requested evidence of training as indicated by 10 CFR 33.15.

In addition to this, a 20 hours course is scheduled to be held during October 1991, and all attenders will receive a certificate of attendance.

- 4- Violation partially admitted. In all occasions when high dose rates or contamination were detected the areas were initially surveyed and decontaminated until dose rates reached the approved levels; we failed to keep records of the action taken.
- J. 10 CFR 35.22(a)(5) requires the Radiation Safety Committee to promptly provide each member with a copy of the meeting minutes.

Contrary to the above, as of June 17, 1991, the Radiation Safety Committee was not providing copies of the meeting minutes to all Committee members.

Violation is admitted. It was brought into compliance on September 13, 1991 for the meeting held on August 28, 1991 and will be in compliance thereafter. The Dean of Administration will assign a secretary to the Committee that will be in charge of taking the minutes and distributing them among the members.

K. 10 CFR 35.59(g) requires the licensee to maintain inventory records of quarterly physical inventories for all sealed sources and requires those records to contain specified information including model number of each source and serial number if one has been assigned.

Contrary to the above, as of June 17, 1991, the licensee was not recording assigned source model numbers and serial numbers on its quarterly sealed source inventory records.

RESPONSE

The violation is admitted. The inventory form has been revised to include the source model and serial number.

 10 CFR 35.59(d) requires the licensee to retain leak test records of five years which contain specified information for all sources tested.

Contrary to the above, as of June 17, 1991, records of leak tests were not maintained for the sixteen Cesium 137 sources received in August 1990.

RESPONSE

The violation is partially admitted. Sealed sources were leak tested as specified by the provisions of 10 CFR 35.59(d), except that the new Cs-137 sources were not clearly identified in the form used as a permanent record.

 Violations of License No. 52-01986-04 (College of Natural Sciences) (Violations Not Assessed A Civil Penalty)

Conditions 15 of License No. 52-01986-04 requires that the licensee conduct its program in accordance with the statements, representations, and procedures described in the licensee's application received November 9, 1989, and letter dated July 24, 1990.

Procedure 5.c. of Item 10 of the licensee's application states that
the surface of the source container will be checked for contamination
using a cotton swab when initially opening packages containing
radioactive material.

Contrary to the above, as of June 20, 1991, the surface of source containers received in Room JGD 217 were not being checked for contamination when initially opening packages containing material.

RESPONSE

This violation is partially admitted, because although the packages were indeed checked for contamination but negative results were not recorded, which constitutes a violation of procedures established in our license. We have discussed this problem with the personnel in charge of receiving packages in JGD 217 and they have committed themselves to the strict compliance of all our rules and regulations. We will verify this commitment by periodic unannounced inspections to that laboratory. Compliance has already been achieved.

2. Procedure 5.d. of Item 10 of the licensee's application states that the Radiation Safety Technician is to be notified upon receipt of

the Radiation Safety Technician is to be notified upon receipt of material.

Contrary to the above, as of June 20, 1991, the Radiation Safety Technician had not been notified of all receipts of material in Rooms JGD 107 and JGD 216.

RESPONSE

The violation is partially admitted. This violation is due to a misunderstanding of the proper use of the form employed in the notification of the RST. The personnel in Room JGD 107 always notified the RST by telephone, but they failed to send the RST a copy of the proper form, which was kept in their files. On the other hand, in Room JGD 216, the RST was always notified in writing and not by telephone, because the material was usually received after working hours. These notification forms are available in the RST's files. These problems have been discussed with the appropriate personnel, and compliance with these rules will be checked by inhouse inspections.

- Procedure 10 of item of the licensee's application states that laboratories using radioactive material will perform surveys at the end of the experiment and that a permanent record would be kept of all survey results, including negative results.
 - Contrary to the above, from February 1991 until June 20, 1991, required surveys were not performed in Room JGD 217 at the end of the experiments.
 - Contrary to the above, as of June 20, 1991, a permanent record (b) of results of all surveys in Room JGD 216, including negative results, was not maintained.

The violation is admitted. Apparently additional training should be given to students and technicians involved in radioisotope research to enhance awareness of the established procedures and regulations. We are requiring that all the personnel and students involved in radioisotope research have a thorough knowledge of all the procedures established in our license by attending compulsory one day workshops. Permanent records will be kept of the training of students and technicians in the proper procedures. Each person will receive a certificate upon passing of a written examination. These workshops will be followed by unamounced in-house inspections. The first workshop was already held on August 16, 1991 (see addendum) and will repeated at least twice a year. Compliance has already been achieved.

4. The licensee's letter dated July 24, 1990, states that the Radiation Safety Techinician will verify that the researchers complete forms for receiving and handling radioactive material in compliance with the standards and regulations established in the license.

Contrary to the above, as of June 20, 1991, the licensee's Radiation Safety Technician was not verifying that the forms for receiving and handling radioactive material were completed properly. Specifically, the technician was not verifying that the forms demonstrated that packages were routinely surveyed for contamination prior to opening, that the technician was being notified of all material receipts and that laboratory surveys were being performed and recorded as required.

RESPONSE

This violation is admitted. This violation is mostly due to the fact that the current RST has other responsibilities in addition to his responsibilities as RST. A person will be identified that will devote additional time to the RST duties. In addition, the RSO has been given a two credit-hour release time from his teaching duties in order to dedicate more time to enforcement of the license's rules and regulations.

- 111. Violations of License No. 52-01986-01 (Agricultural Experiment Station) (Violations Not Assessed a Civil Penalty)
 - A. Condition 17 of License No. 52-01986-01 requires the licensee to conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.

Contrary to the above, from October 17, 1990 until June 20, 1991, an interval in excess of 6 months, the licensee did not perform inventories to account for all sources and/or devices received and

RESPONSE

The violation with condition 17 is admitted. The last correspondence received by the RSO, Dr. J. Singmaster, for verification of an NRC inspection was in 1982, in which no violation was stated with almost the same situation as present. At that time, the 6 months wipe tests for nickel-63 functioned as the inventory. In 1985, the NRC allowed wipe tests to be done very 3 years resulting in inventories every 6 months no longer being recorded, but all the detectors and hydrogen-3 and nickel-63 sources were being seen or used by the RSO every month or more often.

An inventory book and dated labeling of all hydrogen-3, carbon-14, and nickel-63 containers were initiated by July 1, 1991, and inventories will be done every 6 months thereafter.

B. 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 materials not in storage be tended under the constant surveillance and immediate control of the license. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area to which access is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on June 20, 1991, licensed material consisting of eleven vials of carbon 14 ranging from 50 microcuries to 386 microcuries per vial stored in an unlocked refrigerator in an open hallway, an unrestricted area, was not secured against unauthorized removal, and was not tended under the constant surveillance and immediate control of the licensee.

RESPONSE

Security under 10 CFR 20.207(a) requires licensed material to be in a secured area as defined in 10 CFR 20.3(a)(17). The violation of CFR 20.207(a) is admitted for having carbon-14 sources in unsecured area.

The last letter received by the RSO for verification of a NRC inspection was in 1982 in which no violation was cited with some of the sources in the exact same unsecured area. No letters were received by the RSO after later inspections to state this violation until the present letter following the June 1991 inspection.

By July 1, 1991, the carbon-14 sources were secured in locked room with the unused hydrogen-3 and nickel-63 sources and will remain there until final disposed can be arranged.

C. 10 CFR 20.203(e) requires that rooms or areas in which specified amounts of licensed material are used or stored be conspicuously posted "Caution - Radioactive Material".

Contrary to the above, on June 20, 1991, a refrigerator which contained eleven vials of carbon 14 ranging from 50 to 386 microcuries per vial and which was located in an open hallway was not posted as required.

RESPONSE

Posting and Labeling under 10 CFR 20.203(e) indicate that posting of a sign warning "Caution Radioactive Material" for more than one millicurie of carbon-14 (10 times the 0.1 mc for carbon-14 as stated in Appendix C) is required. (Letter from NRC August 8, 1991) The violation on posting warning (10 CFR 20.203) for the carbon-14 sources is denied.

By checking the old papers on the sources for the inventory, the RSO found that all 11 vials had 0.1 mci or less with 3 nearly empty vials, and seven with 0.05 mci or less in one case. The total is a maximum of 0.8 mci less the used amounts of the initial 0.35 mci in the nearly empty vials. The sample indicated as having 386 microcuries was per millimole with only 20 microcuries (0.02 mci) actually present.

In case the Station has misunderstood the claimed violation, the RSO has relabeled all sample containers of the carbon-14 containing herbicides and stored them before, July 1, 1991, in a cabinet in the locked room mentioned above with the warning sign posted on the cabinet door.

All violations at the Agricultural Experimental Station are in compliance since July 1, 1991.

IV. Violations of License No. 52-10510-04 (Payaguez Campus) (Violations Not Assessed a Civil Penalty)

Even though license activities have been minimal at the Mayaguez Campus, the Administration has decided to hire a part time Radiation Protection Techinician to carry out the routine activities for compliance with the NRC regulations, eventually it is foreseen that the RPI will be a full time employee. The responsibilities of RPT will include maintenance of a current inventory carry out surveys and monthly inspections of the areas where the radioisotopes are being used and other related responsibilities.

- A. Condition 20 of License No. 52-10510-04 requires that the licensee conduct its program in accordance with the statements, representations, and procedures described in the licensee's application dated August 9, 1983, which includes the licensee's Radiation Safety Regulations Manual, and letter dated April 11, 1986.
 - Section 2.2.7.7 of the Radiation Safety Regulations Manual requires that the Radiation Safety Committee perform an annual audit of the radiation safety programs.

Contrary to the above, the Radiation Safety Committee failed to perform annual audits of the radiation safety program for the calendar years 1989 and 1990.

RESPONSE

This violation is admitted. An audit form has been prepared and a commitment has been made to carry out annual audits as indicated in the Manual. The first one has been scheduled for the third week of October 1991.

 Section 2.5 of Appendix 2 of the Radiation Safety Regulations Manual requires that the Radiation Protection Officer perform inventories of licensed material every six months.

Contrary to the above, between January 1989 and March 1990 and between May 1990 and June 17, 1991, intervals which exceed six inventories of licensed material, the Radiation Protection officer failed to perform inventories of licensed materials

RESPONSE

The violation is admitted and the inventory has been carried out. Due to the limited use of radioactive material the movement of sealed sources is restricted to those used for routine check of survey meters; for this reason, variations of the inventory are limited to the incoming H-3, S-35 and I-25 used in the research laboratories. Each researcher maintains a current inventory of the amount received, used and remaining in the laboratory. At least one of these inventories was shown to the NRC inspectors on site.

 Section 4.3 of Appendix 4 of the Radiation Safety Regulations Manual require that laboratory areas where less than 100 microcuries of licensed material are used he surveyed monthly by each user. Contrary to the above, from January 1989 to June 17, 1991, monthly surveys had not been performed in Biology and Chemistry laboratories which frequently use licensed material in amounts less than 100 microcuries.

RESPONSE

The violation is admitted and the surveys have already been performed as required. As indicate before, the RST will carry out this surveys.

4. The licensee's letter dated April 11, 1986 states that the Radiation Safety Committee will meet no less than once each fiscal year.

Contrary to the above, the Radiation Safety Committee failed to meet during the fiscal year 1989.

RESPONSE

This violation is partially admitted. After consulting the members of the Radiation Safety Committee it was agreed that we have met at least once every year. We failed to keep a record of the meeting held during 1989. The chairman of the Committee will make sure that minutes of the meetings are made and are properly maintained.

B. 10 CFR 19.11(a) and (b) required, in part, that the licensee post current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments and operating procedures; or that the licensee post a notice describing these documents and where they may be examined. 10 CFR 19.11(c) requires that a licensee post Form NRC-3, "Notice to Employees".

Contrary to the above, on June 19, 1991, the licensee did not have posted any of the required documents or notices at the Marine Sciences Laboratory.

RESPONSE

The violation is admitted. The apparent reason for it is that during a cleanup of the laboratory, somebody removed it. A copy of Form NRC-3 "Notice of Employees" has been provided to the principal investigator using radioisotopes in the Marine Sciences Laboratory with instructions to permanently post it as required. This will be verified by the RST. The violation has already been corrected.

AFFIRMATION.

I, the undersigned, Dr. José M. Saldaña, of legal age, married, doctor as President of the University of Puerto Rico, solemnly affirm that the above "Reply to a Notice of Violation" are true the best of my knowledge and belief and also according to and based upon information given to me which I believe to be true. In San Juan, Puerto Rico, the 27th day of Septembrer, 1991.

José M. Satoria, DMD, MPH

University of Puerto Rico

Affidavit No. 62

Affirmed and suscribed before me by José M. Saldaña of the personal circumstances stated above, whom I personally know.

In San Juan, Puerto Rico, the 27th day of September, 1991

Notary Pobly

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