



HOSPITAL
PAVIA

FOIA/PA REQUEST

Case No:

97-168

Date Rec'd:

5-9-97

Action Off:

Pool

Related Case:

DEPARTAMENTO DE MEDICINA NUCLEAR

José O. Morales, M.D. FACNP
DIRECTOR

April 25, 1997

Dear Sir or Ms. :

Re: FOIA Request

I would like to receive a copy of all inspection
reports with responses of :

NRC License # 52-10270-01

Docket Ref 030-03521

Damas Hospital, Ponce, PR

To cover periods from 01 January 1987 to date.

Please advise as to cost involved.

Thank you.

Sincerely,
José O. Morales M.D.

9706190022 970606
PDR FOIA
MORALES97-168 PDR

SAFETY INSPECTION

Page 1 of 1

1. LICENSEE

Hospital Damas
Ponce By Pass
Ponce, PR 00731

2. REGIONAL OFFICE

REGION II
U S NUCLEAR REGULATORY COMMISSION
101 MARIETTA STREET NW SUITE 2900
ATLANTA GA 30323

3. DOCKET NUMBER(S)

030-03521

4. LICENSE NUMBER(S)

52-10271-01

5. DATE OF INSPECTION

2/28/96

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 (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 described below or attached, were in violation of NRC requirements. This form 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),(c),(d),(e) or 34.32
- ☐ B. _____ of sealed sources were not performed at the proper frequencies. 10 CFR _____ or License Condition Number _____
- ☐ C. Records of _____ were not properly maintained. 10 CFR _____ or License Condition Number _____
- ☐ D. Documents were not properly posted or otherwise made available. 10 CFR 19.11.
- ☐ E. Reports or notification of _____ were not made in accordance with 10 CFR _____ or License Condition Number _____
- ☐ F. _____

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

4603260314

DATE

SIGNATURE - NRC INSPECTOR

DATE

2/28/96

OFFICIAL RECORD COPY

FEB 08 1993

Docket No. 030-03521
License No. 52-10270-01

Hospital Damas
ATTN: Mr. Roberto A. Rentas Ramos
Administrator
Ponce By Pass
Ponce, Puerto Rico 00731

Gentlemen:

SUBJECT: NRC INSPECTION REPORT NO 52-10270-01/92-02

Thank you for your response of January 19, 1993, to our Notice of Violation issued on December 16, 1992, concerning activities conducted at your Ponce facility.

In your response, you denied violation A and admitted the violations B and C.

After reviewing your letter and the enclosed records, we agree with your conclusion that Item A of the December 16, 1992, Notice of Violation did not constitute a violation. This information was not available to our inspector during the inspection. Accordingly, we will adjust our records to reflect that no violation of regulatory requirements occurred with respect to Item A.

We have evaluated your response to Violations B and C, and found that it meets the requirements of 10 CFR 2.201. We will examine the implementation of your corrective actions during future inspections.

We appreciate your cooperation in this matter.

Sincerely,

Original Signed By
D. M. Collins

Douglas M. Collins, Chief
Nuclear Materials Safety
and Safeguards Branch
Division of Radiation Safety
and Safeguards

cc: Commonwealth of Puerto Rico

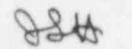
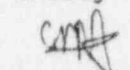
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bcc: Document Control Desk

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JHenson
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CHosey
2/7/93

Hospital Damas

PONCE BY PASS

PONCE, PUERTO RICO 00731

January 19, 1993

TEL. 840-8686

Regional Administrator
U.S. Nuclear Regulatory Commission
Region II
101 Marietta Street NW, Suite 2900
Atlanta, GA 30323

Docket No. 030-03521
License No. 52-10270-01

Reply to a Notice of Violation

Gentlemen:

This refers to the Nuclear Regulatory Commission (NRC) inspection of our facilities at the Hospital de Damas performed last November 19-20, 1992. We received on December 21, 1992 a Notice of Violation dated December 16, 1992. This letter is to comply with the provisions of 10 CFR 2.201 which requires a written statement or explanation from us to the Regional Administrator, Region II with a copy to the Document Control Desk of the U.S. Nuclear Regulatory Commission.

Before discussing the specific violations, we would like to emphasize the improvement in the performance of our radiation safety program. We had multiple violations in the inspection of February, 1992 but by the careful implementation of an extensive plan of corrective action by Dr. Rivera Luna and Mr. Carmelo Perez we have improved our performance. We will continue our efforts to comply with all the NRC regulations.

We will now discuss the specific violations in the same order that they appear in the notice of violation. We will describe the violations as they appear in the notice and answer for each one the following: 1. Admission or denial of the alleged violation, and the reasons for the violation if admitted, and if denied, the reasons why, 2&3. Corrective action taken to solve to problem, to avoid further violation and the results achieved, and 4. the date when full compliance will be achieved.

- A. 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where

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radiopharmaceuticals are routinely prepared for use, administered, or stored.

Contrary to the above, during the weeks of February 9-15, 1992 and April 5-11, 1992, the licensee did not survey for removable contamination in the nuclear medicine laboratory, an area where radiopharmaceuticals were routinely prepared for use, administered, and stored. This is a repeat Severity Level IV violation.

1. We deny this violation. As Mr. Carmelo Perez discussed with Mr. Henson during the inspection, the survey for the mentioned weeks was performed as was identified by us in separated inspections in May and September of 1992 performed by the Nuclear Medicine Subcommittee. The possible explanation is that those reports were misplaced sometime after our September inspection. We consider that the computer datafile is a valid method of storage of survey reports and Mr. Henson agreed with it. We are including a copy of the computer printout as evidence of the performance of those tests as agreed with Mr. Henson (see addendum).
 - 2&3. As mentioned in the letter "reply to a Notice of Violation" sent by us on April 21, 1992, a chain of command was established to ensure that all duties are performed according to regulations. Upon the implementation of the chain of command, we have not missed a single survey for removable contamination once each week or a daily area survey.
 4. Date of full compliance: Immediate.
- B. Condition 15 of NRC License No. 52-10270-01 requires that licensed material be possessed and used in accordance with the statements, representations and procedures described in the license application dated June 9, 1992 and August 26, 1992.

Item 10.4 of the licensee's letter dated August 26, 1992, states that the licensee will adopt the rules for safe use of radioactive materials published in Appendix 1 to NRC Regulatory Guide 10.8, Revision 2.

Item 3 of Appendix I states that either after each procedure or before leaving the restricted area, hands are to be monitored for contamination in a low-background area with a crystal probe or camera.

Contrary to the above, as of November 20, 1992, a licensee employee routinely use a Geiger-Mueller type survey meter to survey h's hands for contamination, and

this survey meter is not a crystal probe instrument or camera. This is a repeat Severity Level IV violation.

1. We admit the violation but should clarify that the statement of adoption of the rules for safe use of radioactive materials published in Appendix 1 to NRC Regulatory Guide 10.8, Revision 2 was made in the letter of June 9, 1992 rather than of August 26, 1992. Mr. Henson asked Mr. Jose Perez about the method of survey of the hands and he answered incorrectly. Mr. Jose Perez is a newly hired technologist (Only 5 months working with us). Although he has 7-year experience working in Nuclear Medicine, upon acceptance to the job he received a full orientation about our procedures. Apparently he misunderstood the method of survey of the hands. Upon questioning the other technologists we found that survey of the hands are performed regularly with the scintillation camera by all of them.
- 2&3. A complete review of all radiation safety procedures, including the performance of surveys and the correct use of the different detectors, is being given to the technologists upon acceptance and annually. Mr. Jose Perez received a refresher orientation upon the findings of this inspection. We will implement a refresher orientation one or two months after starting in the job to all new technologists, even those with previous experience, to ensure that they are performing all procedures according to regulations.
4. Date of full compliance: Immediate.

- C. 10 CFR 20.201(b) requires that each licensee make 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), "a survey" means an evaluation of the radiation hazards incident to the production, use release, disposal, or presence of radioactive material or other sources of radiation under a specific set of conditions.

Contrary to the above, from July 5, 1992 to August 4, 1992, the licensee did not make surveys to assure compliance with that part of 10 CFR 20.201 that limits the radiation exposure to the whole body. Specifically, an individual's whole body exposure to ionizing radiation from July 5, 1992 to August 4, 1992, was not evaluated in that the whole body film badge worn by that individual during that time period was reported by the processor as unused, and the licensee did not

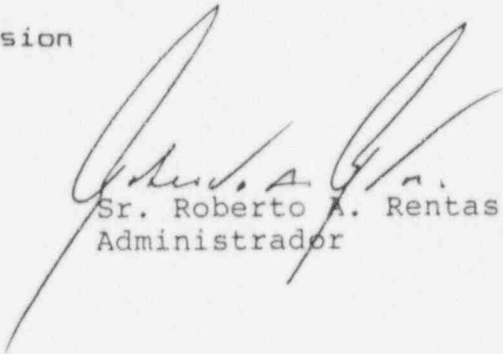
perform further surveys to determine the individual's radiation exposure.

This is a Severity Level IV violation.

1. We admit the violation. This was already identified by us in an inspection performed by the Nuclear Medicine Subcommittee in September, 1992. The preliminary information was that Mrs. Elba Caraballo lost her whole body film badge and was reported as unused. We agreed on that time to make all the necessary calculations to estimate Mrs. Caraballo exposure for the month of July. However, for unknown reasons we got involved in solving other problems in the laboratory that we missed to make those calculations. In the October meeting of the Nuclear Medicine Subcommittee we did not give follow up on the previous month findings.
- 2&3. Mr. Carmelo Perez already made all the calculations and the problem was fixed. We will implement that during each meeting of the Nuclear Medicine Subcommittee a review of the previous month findings will be made to ensure that all determinations were carried out.
4. Date of full compliance: Immediate.

Before finishing, we want to emphasize that we are putting of our efforts to comply with all the NRC regulations as you could corroborate by the significant improvement in the performance of our radiation safety program. Please feel free to contact us if we can be of further assistance.

fc: U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington D.C. 20555



Sr. Roberto A. Rentas, MHSA
Administrador

official

DEC 16 1992

Docket No. 030-03521
License No. 52-10270-01

Hospital Dan
ATTN: Mr. Rolando A. Rentas Ramos
Administrator
Ponce By Pass
Ponce, PR 00731

Gentlemen:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 52-10270-01/92-02)

This refers to the inspection conducted by Mr. J. Henson of this office on November 19-20, 1992. The inspection included a review of activities authorized for your Ponce, Puerto Rico facility. At the conclusion of the inspection, the findings were discussed with you.

The inspection was an examination of activities conducted under your license with respect to radiation safety and compliance with NRC regulations and the conditions of your license. It included selective examinations of procedures and representative records, interviews with personnel and direct observations by the inspector.

Based on the results of this inspection, certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notice of Violation. In addition, the inspector identified activities that violated NRC requirements that will not be subject to enforcement action because the licensee's efforts in identifying and/or correcting the violations meet the criteria specified in Section VII.B of the Enforcement Policy. These noncited violations included failure to maintain records of dose calibrator tests and surveys and failure to properly post caution signs and other required documents. These items were discussed with you during the meeting at the conclusion of the inspection.

Violations A and B described in the enclosed Notice are similar to violations contained in the Notice sent to you by our letter dated March 27, 1992. Recurring violations are of particular concern because the NRC expects licensees to learn from their past failures and to take effective corrective actions. Although NRC does not normally consider monetary civil penalties for Severity Level IV violations, the Enforcement Policy states that such penalties may be imposed for Severity Level IV violations that are similar to previous violations for which the licensee did not take effective corrective action. In this case, we have decided not to hold an enforcement conference nor to propose a civil penalty because the violations represent isolated occurrences and because of your extensive corrective action. In your response to the enclosed Notice, you should document the specific actions taken and any

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additional actions you plan to prevent recurrence. We will review your response, including your proposed corrective actions, and the results of future inspections to determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

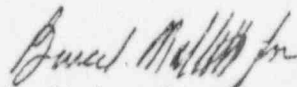
You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this 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 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's 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,

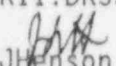


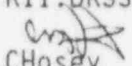
J. Philip Stohr, Director
Division of Radiation Safety
and Safeguards

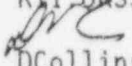
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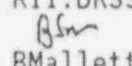
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DCollins
12/15/92

RII:DRSS

BMallett
12/15/92

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GJenkins
12/16/92

ENCLOSURE

NOTICE OF VIOLATION

Hospital Damas
Ponce, Puerto Rico

Docket No. 30-03521
License No. 52-10270-01

During an NRC inspection conducted on November 19-20, 1992, several violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Action," 10 CFR Part 2, Appendix C, the violations are listed below:

- A. 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

Contrary to the above, during the weeks of February 9-15, 1992 and April 5-11, 1992, the licensee did not survey for removable contamination in the nuclear medicine laboratory, an area where radiopharmaceuticals were routinely prepared for use, administered, and stored.

This is a repeat Severity Level IV violation (Supplement VI).

- B. Condition 15 of NRC License No. 52-10270-01 requires that licensed material be possessed and used in accordance with the statements, representations and procedures described in the license application dated December 29, 1989, and letters dated June 9, 1992 and August 26, 1992.

Item 10.4 of the licensee's letter dated August 26, 1992, states that the licensee will establish and implement the model rules for safe use of radiopharmaceuticals published in Appendix I of NRC Regulatory Guide 10.8, Revision 2.

Item 3 of Appendix I states that either after each procedure or before leaving the restricted area, hands are to be monitored for contamination in a low background area with a crystal probe or a camera.

Contrary to the above, as of November 20, 1992, a licensee employee routinely used a Geiger-Mueller type survey meter to survey his hands for contamination, and this survey meter is not a crystal probe instrument or a camera.

This is a repeat Severity Level IV violation (Supplement VI).

- C. 10 CFR 20.201(b) requires that each licensee make 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 material or other sources of radiation under a specific set of conditions.

Contrary to the above, from July 5, 1992 to August 4, 1992, the licensee did not make surveys to assure compliance with that part of 10 CFR 20.101 that limits the radiation exposure to the whole body. Specifically, an individual's whole body exposure to ionizing radiation from July 5, 1992 to August 4, 1992, was not evaluated in that the whole body film badge worn by that individual during that time period was reported by the processor as unused, and the licensee did not perform further surveys to determine the individual's radiation exposure.

This is a Severity Level IV violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Hospital Damas is hereby required to submit a written statement or explanation to the Regional Administrator, Region II with a copy to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, within 30 days of the date of the letter transmitting this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, Hospital Damas if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or Demand for information may be issued to show cause why this license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Dated at Atlanta, Georgia
this 16th day of December , 1992