ENCLOSURE

NOTICE OF VIOLATION

Hato Rey Community Hospital
Hato Rey, Puerto Rico

Docket No. 52-17704-01
License No. 030-13199

During the Nuclear Regulatory Commission (NRC) inspection conducted on February 6, 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 (1989), the violations are listed below:

A. License Condition 13.A states that the license is based on the licensee's statements and representations contained in the application dated October 11, 1982.

1. Item 10.1 of the application requires the licensee to calibrate survey instruments at least annually.

Contrary to the above, the Ludlum 14C survey instrument was not calibrated between December 9, 1988 and February 6, 1990.

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

2. Item 24.1.a. of the application requires that licensee management perform a formal annual review of the radiation safety program. The review shall include reviews of operating procedures, past exposure records, inspections and consultations with the radiation protection staff or outside consultants.

Contrary to the above, between April 16, 1987 and February 6, 1990, annual radiation safety program reviews were not performed by licensee management.

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

B. 10 CFR 35.22 requires that the licensee's Radiation Safety Committee meet at least quarterly.

Contrary to the above, between June 27, 1989 and October 10, 1989, the Radiation Safety Commitee did not meet.

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

C. 10 CFR 35.50(b)(3) requires the licensee to test each dose calibrator for linearity at least quarterly over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

Contrary to the above, between April 16, 1987 and February 6, 1990, the dose calibrator quarterly linearity tests were not performed over a range that included 10 microcuries.

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

D. 10 CFR 35.51(a)(3) requires the licensee to conspicuously note on the survey instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration and the date of calibration.

Contrary to the above, February 6, 1990, the Ludlum 14C survey instrument did not have a note on it indicating the apparent exposure rate from a dedicated check source or the date of calibration.

This is a Severity Level V violation (Supplement VI).

Pusuant to the provisions of 10 CFR 2.201, Hato Rey Community Hospital is hereby required to submit a written statement or explanation to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, Region II, within 30 days of the date of the letter transmitting this Notice. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) admission or denial of the violation, (2) the reason for the violation if admitted, (3) the corrective steps which 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. Where good cause is shown, consideration will be given to extending the response time. 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.

FOR THE NUCLEAR REGULATORY COMMISSION

William E. Cline, Chief
Nuclear Materials Safety and
Safeguards Branch
Division of Radiation Safety
and Safeguards

Dated at Atlanta, Georgia
this 14th day of March 1990

OFFICIAL RECORD COPY

FEB 11 1993

Docket No. 030-12483
License No. 52-17273-01

Caguas Sono-Nuclear and Vascular Center
ATTN: Carmen Caballero, M.D.
Director
P. O. Box 6960
Caguas, PR 00926

Gentlemen:

SUBJECT: NRC INSPECTION REPORT NO. 52-17273-01/92-01

Thank you for your response of January 29, 1993, to our Notice of Violation, issued on January 4, 1993, concerning activities conducted under at your Caguas, Puerto Rico facility. We have evaluated your response and found that it meets the requirements of 10 CFR 2.201.

After reviewing your letter, we agree with your conclusion that Item D of the January 4, 1993, 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 D.

Your corrective actions associated with the other items will be reviewed during future inspections.

Your cooperation in this matter is appreciated.

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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DCS

Centro Sono Nuclear y Vascular de Caguas

SEEDNI, INC.
(809) 744-5278 • 746-5232
Fax: (809) 744-5433

MEDICINA NUCLEAR
CARDIOLOGIA NUCLEAR
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SONOGRAFIA
VASCULAR ARTERIAS VENAS
CLINICA DE OSTEOPOROSIS

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

From : Carmen Caballero, MD, RSO
License No. 52-17273-01
Docket No. 030-12483

Subject : Reply to a Notice of Violation dated January 4, 1993

Date : January 29, 1993

This refers to the Nuclear Regulatory Commission (NRC) inspection of our facilities at Caguas Sono-Nuclear and Vascular Center located in Caguas, Puerto Rico, performed by Mr. J. Henson last December 8-9, 1992. We received a Notice of Violation dated January 4, 1993. 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.

We will discuss the specific violations in the same order as they appear in the notice of violation 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 the problem, to avoid further violation and the results achieved, and 4. the date when full compliance will be achieved.

A. 10 CFR 30.34(c) requires, in part, that each person licensed by the Commission pursuant to the regulations in this part and Parts 31-35 and 39 confine his possession and use of the byproduct material to the purposes authorized in the license.

Amendment to NRC license 52-17273-01 dated September 29, 1992, authorizes the possession of byproduct material for storage only.

Contrary to the above, between September 29, 1992 and October 30, 1992, byproduct material was used for purposes not authorized in the license, in that radiopharmaceuticals were administered to patients for diagnostic medicine purposes.

(Carr. No. 1) P.O. Box 6960, Caguas, P.R. 00726

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

1. We admit this violation but prefer to call it a self identify oversight. On September 14, 1992, the RSO, Dr. Carmen Caballero, had a telephone communication with the NRC License Fee and Debt Collection Branch, and requested information regarding and extension of the license annual fee payment dates. The reason for such a request was due to the possibility of selling and closing the facilities by mid or the end of October, 1992. She was then informed that the annual fee was charged in advance in October first and that no credit would be given if the facilities did not operate for the whole year. She was told that in order to avoid being charged for the year 1993, in the event that the closing of the facilities went through, a license for possession and storage should be requested at once, prior to the deadline date of October 1st., 1992. On that same date, September 14, 1992, Dr. Carmen Caballero had a telephone communication, regarding the same topic, with the NRC Licensing Branch (please refer to attached copy of written communication) and on September 15, 1992 requested the license amendment for possession and storage, which was received by September 29, 1992. It is obvious that there was a misunderstanding between our RSO, Dr. Carmen Caballero and the NRC officials. It was not our intention to violate any of the NRC regulations. We have had an NRC license since 1977, without any major negative events what solver. Since we are the only Nuclear Medicine facilities in the region and we service several hospitals in the area, we kept operating the facilities until October 30, 1992, when the situation was recognized.

2&3. On October 30, 1992 our physicists, Mr. Santiago Gomez, called the NRC to clarify the status of the fee of $1,000.00 paid on July 30, 1992 for the license renewal and of other amendments fees paid afterwards. The oversight of the license for possession and storage was then recognized. As instructed over the phone we proceed with the immediate cancellation of all operations regarding Nuclear Medicine services. That same day multiple telephone and Fax communications were carried over between Dr. Carmen Caballero and NRC Officials. The license renewal application of July 30, 1992, was sent over the Fax, together with an emergency request to continue operations. That same day, after several communications with Mr. John M. Pelchat, from the NRC, we were authorized to continue operations and the license renewal document was received over the

Fax. The original document was received early in November, 1992.
I would like to suggest to the NRC that in order to issue a license for possession and storage, that the specific official day of cessation of operations must be stated in the request and the license be issue to be in effect from that day on.

4. Date of full compliance: October 30, 1992.

B. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

Contrary to the above, on twelve occasions between October 8, 1988 and August 4, 1992, dose calibrator linearity tests were not performed down to 10 microcuries.

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

1. We admit the violation. Linearity tests are performed quarterly utilizing the decay method described in Appendix C to Regulatory Guide 10.8, Revision 2. We usually take a Monday morning eluate and measure the activity for four days, however, the initial activity varies because sometimes we used the elution from the previous week generator, giving a starting activity slightly higher than 100 mCi, and other times used part of the elution from the new generator utilizing a starting activity close to 300 mCi. Apparently, due to the routine testing for four days, sometimes we got to less than 10 uCi, and others we did not depending on the starting activity. The technologists did not realize that the goal was not being achieved.

2&3. The test is already being performed always with the old generator eluate and ensuring that both the maximum and the minimum activity of 10 uCi are achieved. A complete review of all radiation safety procedures, including the proper way to perform the linearity test, was given to the technologists.

4. Date of full compliance: Immediate.

C. 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, on twenty-five occasions, between January 6, 1991 and November 21, 1992, the licensee did

not survey once each week for removable contamination in the hot lab and imaging room, areas where radiopharmaceuticals were routinely prepared, administered, or stored.

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

1. We admit this violation. Upon discussion of this violation with the technologists and Mr. Santiago Gomez, our physicist, we found out that many times the technologists thought that Mr. Santiago Gomez performed the test while he thought the technologists performed it. We should have detected this violation in the regular review performed by Mr. Santiago Gomez but somehow it was missed.
2&3. We have appointed the technologists responsible for the performance of the weekly tests for removable contamination, and Mr. Santiago Gomez responsible to ensure that all tests are being performed on time according to regulations.
4. Date of full compliance: Immediate.

D. 10 CFR 35.70(b) requires that a licensee survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

Condition 15 to License No. 52-17273-01, Amendment No. 14, requires, in part, that the licensee conduct its program in accordance with statements, representations, and procedures contained in the letter with attachments dated October 30, 1992. This letter includes a statement that the most recent amendment to the license is based on the license renewal application dated July 30, 1992.

Item 10.12 of the license renewal application requires that the licensee establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2. Item 1.c of the removable contamination surveys section of Appendix N requires, in part, that the licensee survey weekly for removable contamination in radiopharmaceuticals waste storage areas.

Contrary to the above, as of December 9, 1992, the licensee routinely did not survey weekly with a radiation detection survey instruments or survey weekly for removable contamination, the closet next to the hot lab, an area where radiopharmaceutical waste stored.

1. We deny this violation. Dr. Rivera Luna did not know that the closet next to the hot lab is not used for

radiopharmaceutical waste storage. We place in that closet old generators that have decayed in storage in the hot lab for over sixty days and are ready to be discarded as regular waste, based on background readings. We placed them in that closet, awaiting for the lead to be sold.

2&3. Despite of the above explanation, we have included the mentioned closet in the areas for weekly surveys to ensure background levels in the room at all times.

4. Date of full compliance: Immediate.

E. 10 CFR 35.92(a) permits a licensee to dispose of byproduct material with a physical half life of less than 65 days in ordinary trash, provided, in part, that the licensee first holds such byproduct material for decay a minimum of ten half-lives.

Contrary to the above, on July 1, 1991, June 22, 1992, and October 2, 1992, the licensee disposed of Iodine-131 in ordinary trash without first holding this material for decay a minimum of ten half-lives.

This is a severity Level IV violation (Supplement VI).

1. We admit this violation. Apparently, there was a misunderstanding about the requirements for disposal. Although it should be decay-in-storage for ten half-lives and background levels, the technologist considered it to be an or rather than an and situation. Most of the times both requirements were met.

2&3. We have already oriented the technologists about the regulations emphasizing that both requirements must be met before disposing in ordinary trash, any radiopharmaceutical with a physical half life of less than 65 days.

4. Date of full compliance: Immediate.

We want to emphasize that we are putting of all our efforts to comply with all NRC regulations. 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

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Docket No. 030-12483
License No. 52-17273-01

Caguas Sono-Nuclear and Vascular Center
ATTN: Carmen Caballero, M.D.
Director
P. O. Box 6960
Caguas, PR 00926

Gentlemen:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 52-17273-01/92-01)

This refers to the inspection conducted by Mr. J. Henson of this office on December 8-9, 1992. The inspection included a review of activities authorized for your Caguas, Puerto Rico facility. At the conclusion of the inspection, the findings were discussed with Hiram Rivera-Luna, M.D., acting director. The findings were also discussed on January 4, 1993, in a telephone conversation between the inspector and 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 (Notice). 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 the failure to perform a quarterly linearity test of the dose calibrator on two occasions, failure to post some required documents, and failure to include all required information in sealed source inventory, patient dose and radioactive waste disposal records. These items were discussed with Hiram Rivera-Luna, M.D., during the meeting at the conclusion of the inspection.

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.

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

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

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

Sincerely,

Original Signed By
D. M. Collins

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

Enclosure:
Notice of Violation

cc w/encl:
Commonwealth of Puerto Rico

ENCLOSURE

NOTICE OF VIOLATION

Caguas Sono-Nuclear and Vascular Center
Caguas, Puerto Rico

Docket No. 030-12483
License No. 52-17273-01

During an NRC inspection conducted December 8-9, 1992, 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, the violations are listed below:

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D. 10 CFR 35.70(b) requires that a licensee survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

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Item 10.12 of the license renewal application requires that the licensee establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2. Item 1.c of the removable contamination surveys section of Appendix N requires, in part, that the licensee survey weekly for removable contamination in radiopharmaceutical waste storage areas.
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E. 10 CFR 35.92(a) permits a licensee to dispose of byproduct material with a physical half-life of less than 65 days in ordinary trash, provided, in part, that the licensee first holds such byproduct material for decay a minimum of ten half-lives.

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

Pursuant to the provisions of 10 CFR 2.201, Caguas Sono-Nuclear and Vascular Center 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 (Notice). 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, 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 as to why the 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 4th day of January, 1993