

MAR 14 1990

OFFICIAL RECORD COPY"

Docket No. 030-31223  
License No. 52-25058-01

Mennonite General Hospital  
ATTN: Mr. Ramon Alvarado  
Administrator  
GPO Box 1379  
Aibonito, PR 00609

Gentlemen:

SUBJECT: NOTICE OF VIOLATION  
(NRC INSPECTION REPORT NO. 52-25058/90-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by M. Elliott on February 6, 1990. At the conclusion of the inspection, the findings were discussed with Sandra Gracia-Lopez, M.D.

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.

The inspection findings indicate that certain activities appeared to violate NRC requirements. The violations, references to pertinent requirements, and elements to be included in your response are described in the enclosed Notice of Violation.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and its enclosure 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.

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Mennonite General Hospital

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

Sincerely,

*for W. E. Cline*

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

Enclosure:  
Notice of Violation

cc w/encl:  
Commonwealth of Puerto Rico

bcc w/encl:  
Document Control Desk

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ENCLOSURE  
NOTICE OF VIOLATION

Mennonite General Hospital  
Aibonito, Puerto Rico

Docket No. 030-31223  
License No. 52-25058-01

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. 10 CFR 35.60(b) requires the licensee to conspicuously label each syringe or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

Contrary to the above, since October 1989, syringes or syringe shields containing radiopharmaceuticals were not labelled.

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

- B. 10 CFR 35.59(b)(2) requires the licensee to test each sealed source for leakage at intervals not to exceed six months.

Contrary to the above, between July 18, 1988 and February 6, 1990, leak tests on the Cs-137 sources were not performed.

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

- C. 10 CFR 35.92(a) requires a licensee to hold byproduct material for decay a minimum of ten half-lives and monitor the material at the surface before disposal as trash to determine that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding.

Contrary to the above, on February 6, 1990, four cotton swabs measuring approximately 2 mR/hr on contact were disposed of as normal trash.

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

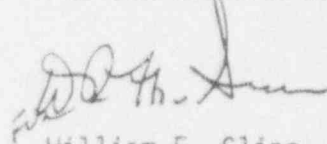
Pursuant to the provisions of 10 CFR 2.201, Mennonite General Hospital is hereby required to submit a written statement or explanation to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, Region II, within 30 days of the

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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 17 day of March 1990

Henson



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

MAY 13 1993

Docket No. 030-13584  
License No. 52-01946-07

University of Puerto Rico  
ATTN: Dr. Francisco Hernandez Oquendo  
Chancellor  
Medical Sciences Campus  
G.P.O. Box 5067  
San Juan, PR 00936-4984

Gentlemen:

SUBJECT: NOTICE OF VIOLATION  
(NRC INSPECTION REPORT NO. 52-01946-07/93-01)

This refers to the inspection conducted by Messrs. J. Henson and H. Bermudez of this office on March 17 - April 23, 1993. The inspection included a review of activities authorized for your Medical Sciences Campus 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 (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. The non-cited violations were failure to include all the required information in records of brachytherapy sealed source inventories and decay-in-storage waste disposal and failure to post the required caution sign on the brachytherapy source storage area door. These items were discussed with you 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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University of Puerto Rico

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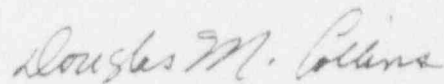
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In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and any reply will be placed in the NRC Public Document Room.

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,



Douglas M. Collins, Chief  
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

University of Puerto Rico  
San Juan, Puerto Rico

Docket No. 030-13584  
License No. 52-01946-07

During an NRC inspection conducted March 17 - April 23, 1993, 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:

- A. 10 CFR 35.75(a) requires that a licensee not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either the measured dose rate from the patient is less than 5 millirems per hour (mr/hr) at a distance of one meter or the activity in the patient is less than 30 millicuries (mCi).

Contrary to the above, on four occasions between March 17 and October 2, 1992, the licensee released patients who had received up to 29.1 mCi of iodine-131 each day for three to four consecutive days, and, at the time of release on those days following the initial administration of up to 29.1 mCi, the licensee neither measured the dose rate at a distance of one meter from the patient to determine if the dose rate was less than 5 mr/hr nor adequately assessed the activity in the patient to ensure it was less than 30 mCi.

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

- B. 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 February 2, 1993, the licensee disposed of a package containing iodine-131 waste in ordinary trash without first holding this material for decay a minimum of ten half-lives. Specifically, the package was placed in storage on November 25, 1992, and held for seventy days, which is less than the ten half-lives period of eighty days for iodine-131.

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

- C. Condition 28.A. to License No. 52-01946-07 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the license application dated August 29, 1988, including any enclosures. Item 9.2.2 of Attachment 9 to the application states that the licensee will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2

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(August 1987). Appendix B to Regulatory Guide 10.8, Revision 2, requires, in part, that radiation survey meters be calibrated at least annually.

Contrary to the above, a Ludlum Model 2 radiation survey meter, serial number 20904, which was routinely used to perform surveys in room 663 of the Medical Sciences Building, was not calibrated between August 30, 1991 and March 18, 1993, a period in excess of the annual requirement.

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

Pursuant to the provisions of 10 CFR 2.201, University of Puerto Rico is hereby required to submit a written statement of 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 ~~13<sup>th</sup>~~ day of May, 1993