

MEDICINA NUCLEAR
CARDIOLOGIA NUCLEAR
ECOCARDIOGRAFIA

Centro Sono Nuclear y Vascular de Caguas

SEEDNI, INC.

(809) 744-5278 • 746-5232



SONOGRAFIA
VASCULAR ARTERIAS VENAS
CLINICA DE OSTEOPOROSIS

January 20th, 1988

U. S. Nuclear Regulatory Commission
Region 11, 101 Marietta St., N.W.
Atlanta, Georgia 30323

Re: Reply to a notice of Violation
License #52-17273-01

Dear Sirs:

This is in reply to the Notice of Violation dated December 21, 1987 as a result of the NRC Inspection conducted by Mr. M. P. Elliot on November 18, 1987:

- A. 1. An overall evaluation of the Radiation Safety Program (RSP) of the Center has been always performed during the regular instructions to personnel every year. There is record on our files of meetings conducted on November 28, 1984, January 21, 1985, June 10, 1986 and December 21, 1987. Enclosed please find copy of the form already made for recording the annual audit of the RSP, full compliance achieved on December 21, 1987.
- A. 2. No reason for such violation. Conscious of the importance of the Dose Calibrator quality assurance it was strongly recommended to the technologists to fully implement the Appendix C. Regulatory Guide 10.8, Revision 2 (August 1987). We have evidence on our files of the linearity tests performed on February 5 to 7, 1987; May 11 to 13, 1987; August 10 to 12, 1987 and November 16 to 18, 1987 which, as recommended by Mr. Elliot during NRC inspection conducted on November 18, 1987, was repeated on November 30, 1987. The next one due is on February 1988. To avoid any further misunderstandings, a label is being placed in the dose calibrator itself, indicating the next due date for linearity testing. Also there will be an index prepared by the RPO which will facilitate the localization of documents, reports, records and all pertinent information.

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Consolidated Mall C-1, Ave. Gautier Benitez (Carr. N° 1) • P.O. Box 6960, Caguas, P.R. 00626

Le exhortamos nos consulte. Honramos Medicare, ACA, FSE, CHAMPUS, VA, Planes Privados, Principales Tarjetas de Credito.
Acer. Maestros de PP

January 20th, 1988

- A. 3 and A. 4. Calibration check of the Dose Calibrator has been performed every day using Cs-137, Ba-133, Co-57 and Co-60 calibration sources and following the procedures as established in Appendix D, paragraphs G-1-G-6, Regulatory Guide 10.8, Revision 1, October 1980. There is record in our files to evidence this daily tests. It was missing to use the same sources for the Constancy test on all commonly used Isotope Factors of the Dose Calibration (G7). Starting February 1st, 1988, the Constancy, Linearity, Geometry and Accuracy tests will be performed according to the model on procedure and frequency published in Appendix C, Regulatory Guide 10.8, Revision 2, August 1987.
- B. Violation is denied. Written policy and procedures of the Radiation Safety Program of the Center have been included or specified in the license application documents. Concerning the procedures for receiving and opening packages, in the Renewal Application dated December 28, 1981 a copy of Appendix F, Regulatory Guide 10.8, Revision 1 was enclosed. In the License Renewal, dated April 28, 1987 it was stated that we will follow the model procedure for opening packages that was published in Appendix L, Regulatory Guide 10.8, Revision 2. This had been followed as stated.
- C. Violation is admitted and no justification can be given. Even thou, it is stated that no dose of Tc-99m had been administered containing Mo-99 in concentrations greater than 0.15 uCi of Mo-99/mCi of Tc-99m. In order to avoid any further violations in this respect, our Nuclear Medicine Technologists were fully instructed, by our Radiation physics Consultant, on the contents of Appendix M.3, Regulatory Guide 10.8. Starting January 1988, there will be registered in a log-book any action taken by the RSO when an elution of Tc-99m is found to contain concentrations of Mo-99 greater than the standard 0.07 uCi of Mo-99/mCi of Tc-99m.
- D. No reason for such violation. Inventory due to the 4th quarter of 1987 was due on December 1987 and was performed on December 21st., 1987. Starting January 1988 it had been implemented in the Center to evaluate the RSP every three months in front of a check list (model enclosed). The Radiation Physics Consultant will be in charge of performing the inventory and of making any necessary recommendations to the Physician in Charge. The actions to be taken or implemented will be notified to the corresponding personnel.

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E. Violation is denied. The rewritten ALARA Program signed by myself on July 6, 1987 includes provisions and actions to be taken to keep personnel doses as low as reasonably achievable. The only quarterly extremity radiation dose exposure recorded on September 1985 for participant No. 00020 exceeding in 2.3% of Investigational Level 1 (1875 mRems per Calendar Quarter) was due to misplacement of the ring badge within the hot room over a weekend period. In accordance with the ALARA Program (V-B1), the licensed physician and the RSO decided at that time that no action needed to be taken.

F. and G. - Violations are admitted. Possible reasons for such violation may be the information sent to us by the Suppliers of the Lung Aerosol Units and a delay in forwarding the NRC documents to the Nuclear Technologists. The following corrective steps had being taken:

1. Enclosed please find license amendment to request permission from the NRC to use aerosols in the Center.
2. No aerosols are to be used at the Center until the license amendment is approved by the NRC.
3. Model Procedure 0.1 of Appendix O, Regulatory Guide 10.8 will be followed. Record of the calculations of workers dose from concentrations of aerosols in working areas are to be kept for NRC review during inspections. Full compliance is expected for February 1st, 1988.
4. Starting January 1988, every person who received a document will indicate on the document the date received and its initials. This will provide timing evidence.

H. Violation is denied. Notice of Employees (Form NRC-3) including notice of where the mentioned documents might be examined at anyone time, had always being posted in the bulletin board located in the Hot-Room.

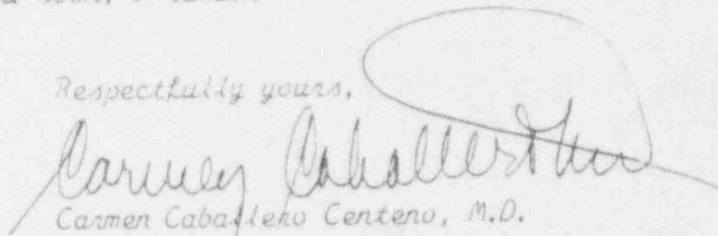
Hope, in the best of my knowledge, to satisfactorily replied to this notice of Violation. Please contact me at any time for any additional details or information. On January 21st, 1988, Mr. Earl G. Wright was notified over the phone that this reply was on its way.

U. S. Nuclear Regulatory Commission

January 20th, 1988

Hoping to hear from you soon, I remain

Respectfully yours,


Carmen Caballero Centeno, M.D.
Director

CCC/emv

c. Mr. Santiago Gomez, RSO
Nuclear Medicine Physicians and Technologists

Licensee: _____ Lic. No.: _____

Place: _____

Attendants: _____

Date: _____ Hour: _____

TOPICS:

1.0 Operating Procedures:

1.1 New Personnel Trained: Yes _____ No _____

1.2 Safety Equipment Changes: Yes _____ No _____

1.3 New Laboratories: Yes _____ No _____

2.0 Exposures Reports: (See Attached Annual Summary)

2.1 Results Exceeding ALARA: Yes _____ No _____

2.2 Level I: _____ Times
Level II: _____ Times

2.3 Highest Exposure: F.B. (Whole body) _____ TLD (Pin) _____

2.4 Average Exposure: F.B. (Whole body) _____ TLD (Ring) _____

3.0 Radiation Safety Inspections:

3.1 Results, required to be reported: Yes _____ No _____

3.2 Highest Rad. Level _____ Highest Contamination _____

4. Spills and Radiation Incidents:

Required to be notified: Yes _____ No _____

5.0 Misadministrations:

5.1 Therapy: Yes _____ No _____ Diagnostic: Yes _____ No _____

5.2 Required to be notified: Yes _____ No _____

6. Quarterly Check (list):

Violations corrected: Yes _____ No _____

7.0 Hints to Improve the Radiation Protection Program for Adherence to ALARA

Concepts:

7.1 New regulations: Yes _____ No _____

7.2 NRC Inspections: Reported Violations Yes _____ No _____
Enforcement Conference Yes _____ No _____

8. Amendments to Lic. Requested:

Yes _____ No _____

9. Comments, attached:

Yes _____ No _____

10. Recommendations, attached:

Yes _____ No _____

To: _____

From: _____

Date: _____

The following Items related to the Radiation Protection Program and NRC Regulations require your consideration to take immediate action, comply and document:

- _____ Copy of the License and Amendments
- _____ Copies of 10CFR-Parts 19,20,21,30,35,40,50
- _____ Radioactive Materials shipments Radiation Survey and Records
- _____ Daily Radiation Survey to the Hot Room
- _____ Calibration check of the Dose Calibrator
- _____ Mo-99 Breakthrough Test
- _____ Linearity Test of the Dose Calibrator ; *Constancy, Geometry and Accuracy Test*
- _____ Film Badges Service and Radiation Exposure Records
- _____ Radiation Sources Leak Test and Inventory
- _____ Instructions to Personnel and Continued Education
- _____ Weekly Radiation Survey and Contamination Control
- _____ I-131 Therapeutic Treatments radiation surveys and records
- _____ Radioactive Waste collection and disposal
- _____ Radiation Detection Instruments Calibration
- _____ Up-takes and/or Bioassays
- _____ Radiation Labels, Emergency Procedures, Notice to Employees...etc.
- _____ Manuals: Nuclear Medicine Procedures____, Radiation Protection____
- _____ Radiation Safety Committee meetings
- _____ Reports on Radiation Incidents and Missadministration
- _____ Quality Control Programs: a) Sensitivity _____
 b) Field Flood (Uniformity) _____
 c) Resolution (Weekly) _____
 d) Others: _____
- _____ Others

REMARKS: Full Compliance due to " _____