Centro Sono Nuclear y Vascular de Caguas

SEEDNI, INC.

(809) 744-5278 • 746-5232

MEDICINA NUCLEAR
CARDIOLOGIA NUCLEAR
ECOCARDIOGRAFIA

SONOGRAFIA
VASCULAR ARTERIAS VENAS
CLINICA DE OSTEOPOROSIS

April 20, 1988

J. Phillip Stohr, Director
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region II
101 Marietta St. N.W.
Atlanta, Georgia 30323

Sir:

Ref. Report No. 52-1723 / 01-87-01

This is in response to your letter dated March 3, 1988, requesting supplemental clarification on some violations found during the Nuclear Regulatory Commission inspection conducted on November 18, 1987.

Item 1

A-2 Violation has been admitted and as previously stated on our response on Janaury 20, 1988, we cannot give a reasonable explanation for such violation. Our records are in full compliance since November 30, 1987. The linearity test corresponding to the first quarter of this year was performed on February 22, 1988.

Item 2

Violation B was denied because the written procedures for safely receiving and opening packages of byproduct material are included in our license (copy enclosed - Appendix F). These procedures has always been followed by our personnel. Upon interviewing our representatives during the inspection, Dr. James W. Scott Cora and Ms. Grisel Alejandro, they stated that at the time they did not recall the document. Since I cannot give a reasonable explanation for their answer, I have no other alternative than to admit the violation, since it was based on the incorrect answer given by our representatives.

Item 3

Violation D as stated by Nuclear Regulatory Commission Inspector was previously admitted. In order to be in full compliance, the 4th quarter physical inventory was performed on December 21, 1987 and will be performed thereafter by the RSO every three months.

Item 4

Violation E - Enclosed please find copy of the written ALARA Program which was included as part of the license renewal application dated July 6, 1987. Again the violation was based on the incorrect answer given by our representatives at the time of the inspection. Even thou our representatives were totally wrong in their answer, the violation was objectively based on their answer and there is no other alternative than to admit it.

Violation H - This violation was and is still denied because notice to Employees including notice of where to examine other required documents has always been posted in the Bulletin Board of the Hot Room. The newly revised Form NRC - 3 (11-85) is being posted now and it contains the following notice to workers:

"At any one time, copies of the following documents may be examined at the RSO and Radiation Physic's Consultant files":

a. Nuclear Regulatory Commission license No. 52-17273-01 and license application documents.

b. 10 CFR - Part 35 - Medical use of Byproduct Material.

c. Regulatory Guide 10.8 Revision 2, August 1987.

d. 10 CFR - Parts 19, 20 and ALARA Program.

e. Radiation Dosimetry Reports.

I consider pertinent to clarify that on our previous communication the statement: "No reason for such violation", meant that no reasonable explanation for the violation could be given and that it was accepted.

Unfortunately, I realize that our representatives during the inspection did not provide the correct answers to several items. I cannot give an objective and reasonable explanation for their action but I realize that I have to assume full responsability for their representation. To prevent any further similar situations, adequate corrective actions had been taken and we commit ourselves to their full implementation.

Thanking You in advance, I await your communication and remain.

Respectfully Yours,

Carmen Caballero

Carmen Caballero, MD

APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES
CONTAINING RADIOACTIVE MATERIAL

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205(a)(1) and (c)(1) of 10 C.F.R. Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours, or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 μCi/100 cm^2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).

2. For all packages, the following additional procedures for opening packages will be carried out:

a. Put on gloves to prevent hand contamination.

b. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

c. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If >10 mR/hr, stop procedure and notify Radiation Safety Officer.

d. Measure surface exposure rate and record. If >200 mR/hr, stop procedure and notify Radiation Safety Officer.

e. Open the package with the following precautionary steps:

(1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.

(2) Open inner package and verify that contents agree with those on packing slip. Compare requisition,* packing slip, and label on bottle.

(3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).

(4) Check also that shipment does not exceed possession limits.

f. Wipe external surface of final source container shield and remove wipe to low background area. Check wipes with a thin-end-window G-M survey meter, and take precaution against the spread of contamination as necessary.

g. Monitor the packing material and packages for contamination before discarding.

(1) If contaminated, treat as radioactive waste.

(2) If not contaminated, obliterate radiation labels before discarding in regular trash.

3. Maintain records of the results of checking each package using "Radioactive Shipment Receipt Record" (see next page) or a form containing the same information.

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*In the case of special orders (e.g., therapy doses), also compare with physician's written request.

ATTACHMENT 10.2

PROGRAM FOR MAINTAINING OCCUPATIONAL

RADIATION EXPOSURES ALARA

License's Name: CAGUAS SONO-NUCLEAR AND VASCULAR CENTER

NRC LICENSE NO: 52-17273-01

Date: July 6, 1987

I. Management Commitment

a. We, the management and licensed physicians of this Center are committed to the program described in this paper for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). In accord with this commitment, we hereby establish an administrative organization for radiation safety and develop the necessary written policy procedures and instructions to foster the ALARA concept within our Center. The organization will include a Radiation Safety Officer (RSO).

b. We will perform a formal audit annually to determine how exposures might be lowered. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgement, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

II. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

1. Annual review of the Radiation Safety Program. The RSO will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

2. Quarterly review of Occupations Exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph VI of this program.

3. Quarterly review of records of Radiation Level Surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

II. Radiation Safety Officer (RSO)

b. Education Responsibilities for an ALARA Program

1. The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

2. The RSO will assure that authorized users, workers and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, outside safety consultants and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers wil be given opportunities to participate in formulation of the procedures that they will be required to follow.

1. The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

2. The RSO will establish procedures to receive and evaluate the suggestions of individual workers for the improvement of health physics practices. He will also encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices; and, if possible, determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

III. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

1. The authorized user will consult the RSO and Licensed Physicians before using radioactive materials for a new procedure.

2. The authorized user will consider all procedures thoroughly before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of the Authorized User to Those He Supervises

1. The authorized user will thoroughly explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises

2. The authorized user will ensure that his occupational workers are trained and educated in good health physics practices and in maintaining exposures ALARA.

3. The authorized user will be responsible to the radiation safety concerns of the individuals that he supervises.

III. Authorized Users

c. Continuing Review of ALARA Concepts by the Authorized User

1. The authorized user will continuously review his procedures to ensure that his ALARA program is optimal.

2. The authorized user will maintain contact with the RSO to ensure that he is aware of and employs the most current methods to maintanin exposures ALARA.

IV. Persons Who Receive Occupational Radiation Exposure

a. The worker will be instructed in the ALARA concept and its relationship to his working procedures and work conditions.

b. The worker will know that recourses are available if he feels that ALARA is not being promoted on the job.

V. Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures.

The Caguas Sono-Nuclear and Vascular Center hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Officer and/or the Radiation Physics Consultant. The Investigational Levels that we have adopted are listed in Table I below. These levels apply to the exposure of individual workers.

TABLE I

	Investigational Levels - (mrems per calendar quarter)	
	LEVEL I	LEVEL II
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body	750	2250

The Radiation Safety Officer will review and record the results of personnel monitoring, as provided by the Dosimeters Processor and not less than once in any calendar quarter, as is required by 10 CFR Part 20, 20.401. The following actions will be taken at the Investigational Levels as stated in Table I:

a. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table I values for the Investigational Level I.

b. Personnel dose equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly dose equals or exceeds Investigational Level I. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Licensed Physicians, the RSO himself and/or the Radiation Physics Consultant.

c. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel doses equaling or exceeding Investigational Level II and, if warranted, take action. A report of the investigation, actions taken, if any, and a copy of the individual's doses records will be presented to the Licensed Physicians. The details of these reports will be recorded. Copy of the reports containing details of the investigation, will be made available to NRC inspector for review at the time of the next inspection.

d. Re-establishment of an individual occupational worker's Investigational Level II Above That Listed In Table I.

In cases where a worker's or a group of worker's exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

VI. Signature of Certifying Official (Licensed Physician)

I hereby certify that the Caguas Sono-Nuclear and Vascular Center has implemented the ALARA Program set forth above.

Carmen Caballero

Signature

Name: Carmen Caballero, MD

Physician

Title

Laboratory Name and Address:

Caguas Sono-Nuclear and Vascular Center
Box 6960
Caguas, P.R. 00626