Boston University
School of Medicine

80 East Concord Street
Boston, Massachusetts
02118-2394
617-638-5300

Aram V. Chobanian, M.D.
Dean

June 14, 1989

United States Nuclear Regulatory Commission
Attn: Malcolm R. Knapp, Director
Region I
475 Allendale Road
King of Prussia, PA 19406

Dear Mr. Knapp:

We are responding to your letter of May 8, 1989, regarding violations discovered during the March 8 and 9 inspection of our institution.

With respect to the individual issues raised in your letter:

Item A. The loss of the 15 millicurie Ni-63 source was reported to the Commission on February 26, 1988. In that letter we discussed the generic problem of these units not being labeled properly by the manufacturers as well as our corrective action to label such units with a radioactive label prominently on the outside of the unit. This corrective action was confirmed by one of your inspectors during the inspection.

Item B. We confirm that licensed material stored in an unrestricted area should be secured against unauthorized removal from the place of storage by the Radiation Protection Office. Compliance was achieved by June 1, 1989.

Item C. Corrective action was instituted on March 8, 1988, during the inspection. This was confirmed by Mr. Pelchat of your staff during our telephone conversation of May 31, 1989.

Item D. The leak tests that were inspected were determined to be NDA (no detectable activity) since the wipe of the source was within the 95% confidence interval of the variation in background counting. A LLD (a lower limit of detection) had been determined so that all leak tests could detect 0.005 microcuries of removable contamination. We confirm that the results of all leak tests will be recorded in units of microcuries even if there is no detectable activity on the leak test. Compliance was achieved March 1989.

Item E. We have notified the Radiation Medicine/Radiation Physics group of this citation relating to the units of measurements (millirems/hour) of surveys. They have responded that all their survey forms contained preprinted units of measurement (mR/hr) which we have enclosed for your consideration. Based on this information, it appears that this item should not have been cited during the inspection.

With regard to...

Item A - The GC manufacturer labels the devices in conformance w/ Part 20 requirements. The RSO wishes a bigger label were required. Am satisfied w/ corrective actions

Item B - OK

Item C - OK

Item D - OK

Item E - Review of my notes & recollection of the inspection are not of any help. ~~Entry~~ I only wonder why the RSO or staff didn't mention the units when I discussed it with them. Am willing to give them the benefit of doubt.

AM

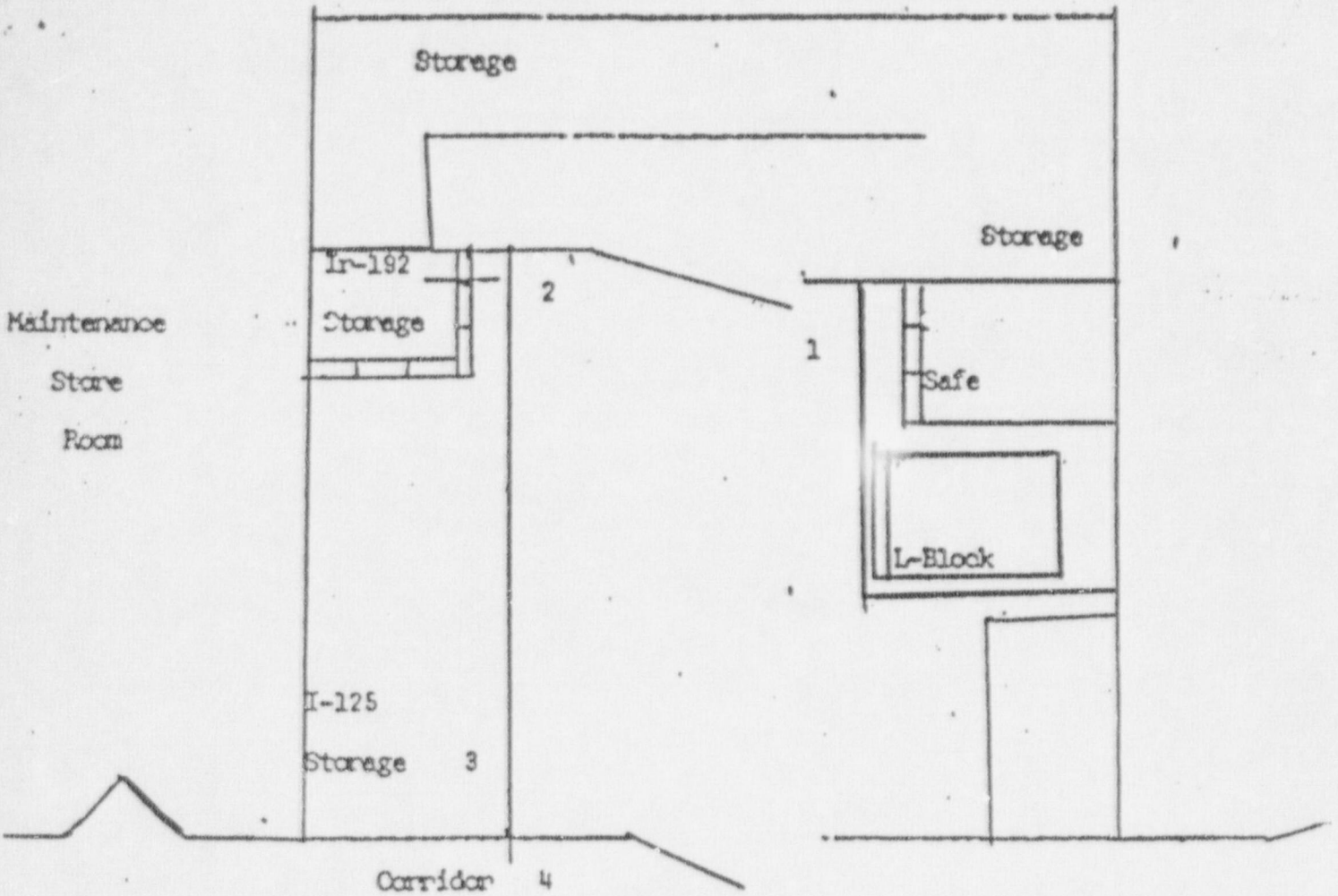
Should you desire further information, please do not hesitate to contact me.

Sincerely,

Aram V. Chobanian, M.D.
Dean

AVC/dcl

UNIVERSITY HOSPITAL RADIATION ROOM SURVEY



Surveys were performed in the above indicated areas. The results are:

1. safe area wrist level / eye level _____ mR/hr
2. Ir-192 area _____ mR/hr
3. I-125 area _____ mR/hr
4. outside entrance door _____ mR/hr
5. BACKGROUND _____ mR/hr

Signature _____

Date: _____

IMPLANT SURVEY RECORDS

UNIVERSITY HOSPITAL DEPARTMENT OF RADIATION PHYSICS

Patient name: Date of Implant:

Floor, room #: Isotope:

Anatomic location: Total activity:

Survey in Operating Room (mR/hr)

Exposure rate @ 1 meter from implant _____

Patient removed, list any readings above background of _____

Suction _____ Floor _____ Table _____ Other, specify _____

Disposition and Co-e #'s of any unimplanted sources not returned to the Radium Room:

Physicist signature _____

Surveys in Patient's Room (mR/hr)

First day Site _____ Visitor area _____

Bedside _____ Adjacent wall _____

1 meter from site _____ Other, specify _____

Physicist signature _____

Day of discharge Site _____ 1 meter from site _____

Patient removed, list any readings above background of _____:

Room _____ Laundry _____ Waste materials _____

Others, specify _____

See back of page for additional relevant information such as surveys of other rooms, unusual precautions or occurrences

Physicist signature _____

Date _____

SUMMARY OF NURSING PRECAUTIONS FOR RADIOACTIVE IMPLANT OF RADIUM-226, and IRIDIUM-192

(Refer to Nursing Manual for greater details)

PATIENT NAME _____

The patient has received _____ mCi of _____

Patient exposure mR/hr	
Site	_____
Bedside	_____
1 meter from site	_____

1) Your exposure depends on the distance from the implant and time you spend caring for the patient. By working as quickly as possible and maximizing distance, your exposure will be minimized.

2) No one under 18, or pregnant, shall attend or visit with the patient. Visits: no more than 30 minutes.

3) Save all linen, dressings, waste, etc. in the room until it is checked by the Radiation Physics Dept. Written and oral precautions for Radiation Safety can only be removed by the Radiation Physics Dept.

4) The Radiation Physics Dept. will designate where the patient's bed is to be placed as well as the visitor's chairs so that exposure to other patients and visitors will be minimized.

5) Patient movement should be minimized and limited to their room.

6) If sources become dislodged, use forceps to return to lead storage container in room. Contact Radiation Medicine Dept. (x-7070) and Radiation Physics Dept. (x-7192) immediately.

7) Dosimeter readings should be taken at the beginning and at the end of each shift and recorded on the data sheet on the wall. (DO NOT TAKE DOSIMETERS OFF THE FLOOR).

In case of any questions, contact Radiation Physics (x-7192) or:

Mr. David Cail	894-1730
Mr. Harry Bohrs	566 3556
MR NAGESH RAO	661-3513

In case of emergency surgery or death, notify immediately the Radiation Safety Office (x-7052) or Mr. Victor Evdokimoff at home, 444-8564

NOTICE OF VIOLATION

Boston University Medical Center
Boston, Massachusetts 02118

Docket No. 030-01845
License No. 020-02215-01
EA 89-81

During an inspection conducted on March 8-9, 1989, 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, 53 Fed. Reg. 40019 (October 13, 1988), the violations are set forth below:

A. 10 CFR 20.301 requires that no licensee dispose of licensed material except by certain procedures specified in 10 CFR 20.301(a) or (b).

Contrary to the above, at some time in December 1987, a gas chromatograph containing an approximately 15 millicurie nickel-63 source within an electron capture device, was disposed of in the normal trash, a method of disposal not authorized by 10 CFR 20.301.

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

B. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area not in storage be under constant surveillance and immediate control of the licensee. As defined in 10 CFR Part 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, in December 1987, a gas chromatograph containing a 15 millicurie nickel-63 source within an electron capture device was stored in an unrestricted area, and at the time, the device was not secured against unauthorized removal, nor was it under constant surveillance and immediate control of the licensee.

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

C. 10 CFR 20.205(d) requires that each licensee establish and maintain procedures for safely opening packages in which licensed material is received and shall assure that such procedures are followed. The licensee's procedures for safely opening packages are set forth in Item 14.1.7 of the license application dated November 25, 1980. Item 14.1.7 sets a contamination limit of 20,000 disintegrations per square centimeter (dpm/cm^2).

Contrary to the above, on March 8, 1989, the procedure for safely opening packages was not followed in that, although a wipe test sample was collected as required by the procedure, the wipes were not adequately evaluated for contamination prior to opening the package. Specifically, the evaluations

were inadequate in that they lacked sufficient sensitivity to detect the 20,000 dpm/cm² limit set forth in the procedure.

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

D. 10 CFR 35.59(d) requires that records of leak test results contain, among other things, the measured activity of each test sample expressed in microcuries.

Contrary to the above, as of March 9, 1989, although leak test sample results were recorded, they were not recorded in units of microcuries.

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

E. 10 CFR 20.401(b) requires that each licensee maintain records in the same units used in 10 CFR 20, showing the results of surveys required by 10 CFR 20.201(b). 10 CFR 20.201(b) requires the performance of surveys to ensure compliance with all requirements in 10 CFR Part 20.

Contrary to the above, as of March 9, 1989, adequate records were not maintained of the brachytherapy surveys made to assure compliance with 10 CFR 20.105. Specifically, the records of survey results did not include the units of measurement (e.g., millirems).

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

Pursuant to the provisions of 10 CFR 2.201, Boston University is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within thirty days of the date of the letter transmitting this Notice. The reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation; (2) the corrective steps which have been taken and the results achieved; (3) corrective steps which 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 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. Consideration may be given to extending the response time for good cause shown.

MR Knapp

Malcolm R. Knapp, Director
Division of Radiation Safety
and Safeguards

Dated at King of Prussia, Pennsylvania
this 8th day of May 1989

BOSTON UNIVERSITY MEDICAL CENTER

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Aram V. Chobanian, M.D., Dean
Office of the Dean

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Charlie G.