U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Enforcement Conference Report No.: 030-02611/89-002

Docket No.: 030-02611

License No: 31-00032-04 Priority 1 Category G1 Program Code 02110

Licensee: V.A. Medical Center
First Avenue at East 24th Street
New York, New York 10010

Enforcement Conference Conducted: September 8, 1989

Prepared by: _____ 29 September, 1989
John M. Pelchat, Health Physicist date
Nuclear Materials Safety Section A

Approved by: _____ 10/18/1989
Mohamed M. Shanbaky, Chief date
Nuclear Materials Safety Section A

Enforcement Conference Report: The findings documented in Inspection Report No. 030-02611/89-001 were discussed. The licensee's representatives described planned and completed corrective actions. The NRC's enforcement policy was explained to the licensee representatives.

DETAILS

1. PERSONS PARTICIPATING

LICENSEE

John J. Donnellan, Associate Director
Mary Ann Musuneci, Associate Director Trainee
Murray Oratz, Ph.D., Assistant Chief, Nuclear Medicine Service
Marcus A. Rothschild, M.D., Chief, Nuclear Medicine Service

U.S. NUCLEAR REGULATORY COMMISSION

Lee Bettenhausen, Chief, Nuclear Materials Safety Branch, Region I
Keith Christopher, Enforcement Specialist, Region I
Jenny Johansen, Enforcement Specialist, Office of Enforcement
Mohamed M. Shanbaky, Chief, Nuclear Materials Safety Section A, Region I
John M. Pelchat, Health Physicist, Nuclear Materials Safety Section A, Region I

2. CONFERENCE PROCEEDINGS

a. The conference began at 10:00 a.m. on September 8, 1989 at NRC's Region I office in King of Prussia, Pennsylvania. Introductions were made and the purpose and format of the conference were explained.

b. The licensee's representatives stated that most of the violations documented in the inspection report were the result of record keeping problems and insufficient oversight of licensed activities. The licensee representatives also stated that two alternatives were being considered to correctly address these deficiencies:

Appointment of a full time Radiation Safety Officer (RSO), or

Appointment of a full time radiation safety assistant to support the RSO and to assure compliance with regulatory requirements on a daily basis.

The Chief of the licensee's Nuclear Medicine Service claimed that he did not make statements attributed to him characterizing the performance and expertise of the Medical Isotopes Committee (MIC) in the inspection report. The inspector pointed out that the NRC had not made any finding with regard to the expertise or competence of the individuals who served on the MIC; violations under discussion dealt with performance of the MIC as required by license conditions.

The licensee's representatives also presented a copy of the MIC's minutes for a meeting conducted on May 20, 1988 which was not documented in the inspection report (Enclosure 1).

c. The licensee admitted that the violations concerning the failure of the MIC to meet as required and the failure to obtain MIC approval of authorized users. Licensee representatives presented a memorandum signed by the facility director which reestablished the MIC and redesignated the committee as the Radiation Safety Committee. The document established its membership and redefined its duties in accordance with NRC guidance (Enclosure 2).

The licensee's representatives stated that the old MIC had discontinued its activities as many of its responsibilities were assumed by a reorganized quality assurance organization.

The licensee's representatives described the current procedure used for the review of radioactive material use permit applications and discussed proposed changes to those procedures to assure adequate review of all permit applications. These changes included provisions to allow rapid review and approval of permit applications. NRC representatives stated that the license would require amendment to allow these changes and that the NRC staff would review the proposed changes upon receipt of the license amendment request.

The licensee also admitted the violation regarding the failure to amend the radioactive material license to list the new RSO and presented a license amendment request to name Dr. Stephen Rudolph as the licensee's RSO.

d. The licensee representatives denied the apparent training violations discussed in the inspection report and produced letters from the supervisors of the persons who, during interviews with the inspector, stated that they had not received radiation safety training. The letters stated that the supervisors had provided radiation safety training to these individuals (Enclosures 3 and 4).

The licensee representatives stated that all persons frequenting restricted areas will be provided radiation safety training and that the training would include the requirements of the NRC's regulations and licenses. A copy of a memorandum issued to an authorized user stating the requirement for persons to receive radiation safety training from the RSO of his designee prior to entering a restricted area was provided. (Enclosure 5). The licensee's representatives also discussed the radiation safety training program for the nursing staff. A copy of the licensee's revised training program syllabus was also submitted (Enclosure 6).

e. The licensee representatives admitted the violations regarding the failure to perform adequate surveys to assure compliance with 10 CFR 20.101. The licensee representatives stated that a central clearing house had been established for the distribution and collection of radiation dosimetry on a timely basis. A copy of a memorandum sent to all principal investigators was provided (Enclosure 7). The memorandum stated that the principal investigator was responsible for ensuring that all appropriate personnel are provided and wear radiation dosimetry. A memorandum was also issued to the senior nuclear medicine technologist directing her to remind her staff of the requirement to wear extremity dosimetry.

f. The licensee representatives admitted the violations regarding security of radioactive material in research areas. Self locking doors will be installed on each doorway to a research laboratory in which radioactive materials are used. A copy of a memorandum from the chairman of the Radiation Safety Committee to the chief of the engineering service was provided requesting installation of the locks and offering assistance in identifying which laboratories required these locks. A copy of a memorandum sent to all principal investigators reviewing radioactive material security requirements was also submitted (Enclosures 8).

g. The licensee's representatives admitted the violation regarding the failure to adequately assay patient radiopharmaceutical doses prior to administration. The chief of the nuclear medicine service stated that patient doses were now being assayed immediately prior to administration and that the assay results were now being recorded. A copy of the new dose assay record was submitted by the licensee's representatives. Since this record contained confidential patient information, NRC staff reviewed and returned the document to the licensee's representatives during the conference.

h. The licensee's representatives admitted the violation regarding improper radioactive material package receipt survey procedures. Training in radioactive material package receipt survey procedures was provided to the nuclear medicine staff during a weekly nuclear medicine service staff meeting.

i. The licensee's representatives admitted the violation regarding the failure to test dose calibrator constancy and linearity in accordance with license procedures. Copies of a revised dose calibrator test procedure and a memorandum to the senior nuclear medicine technologist directing use of these revised procedures was submitted (Enclosures 9 and 10).

j. The licensee's representatives admitted the violation regarding the failure to perform monthly area radiation surveys in research areas where radioactive materials were used and stored. The licensee's representatives also admitted the violation regarding the presence of food, beverages, and related utensils in areas where radioactive materials were used and stored. The licensee provided a copy of a memorandum to research users of radioactive material restating the monthly survey requirement and the prohibition against the consumption or storage of food in radioactive material use and storage areas (Enclosure 11). Investigators are now required to provide copies of the monthly area radiation survey results to the RSO. The memorandum stated repeat violations of these requirements would result in the closure of the offending laboratory.

The licensee representatives also stated that increased surveillance of research laboratories would be a primary duty of either the RSO in his new expanded role or the proposed radiation safety assistant.

k. The licensee's representatives admitted the violation regarding the failure to maintain records of radioactive waste disposed of by decay-in-storage. A copy of a memorandum to the senior nuclear medicine technologist directing the maintenance of these records and a copy of these records was submitted (Enclosures 12 and 13).

l. Members of the NRC staff reviewed the NRC's enforcement policy with the licensee and the options the policy provided. The licensee representatives were advised that the licensee would be notified of the NRC decision on appropriate enforcement action under separate cover.

ENCLOSURE 1

VETERANS ADMINISTRATION MEDICAL CENTER
NEW YORK, NEW YORK 10010

SEPTEMBER 15, 1988

Medical Isotope Committee Meeting

Convened: 1:00 pm Adjourned: 2:00 pm

Present:	M.A. Rothschild M.D.	Chief, Nuclear Medicine
	M. Oratz Ph.D.	Asst Chief Nuclear Medicine
	S.S. Schreiber M.D.	Physician, Nuclear Medicine
	V.J. Fisher M.D.	ACOS for R&D
	A. Benoff M.D.	Physician, Radiology Service
	N. Cooper M.D.	Chief, Laboratory Service
Excused:	J.H. Ayvazian M.D.	Chief of Staff
	S. Rudolph Ph.D.	Radiation Safety Officer

The meeting was held in Room 18099S at 1:00 pm on September 15, 1988.

1. Equipment Status:
All equipment are functioning. We have not received the SPECT upgrade as yet.

2. Personnel:
A situation has occurred where a newly hired Nuclear Medicine Technologist was hired at a salary rate higher than what is presently paid to our technologists. Personnel has informed us that they would try to mollify this situation.

3. Quality Management:
Nuclear Medicine's Quality Management Program was looked upon favorably by JCAH.

4. Adverse Incidents:
There were no adverse incidents to report since the last meeting.

5. Workload:
No change since the last meeting. The most frequently requested studies are Gallium, Bone and Gated Heart Pool.

Respectfully submitted,

M. Oratz

Murray Oratz, Ph.D.
Secretary

ENCLOSURE 2

VETERANS ADMINISTRATION MEDICAL CENTER
NEW YORK, NEW YORK
September 1, 1989

POLICY MEMORANDUM NO. 115-1

SUBJECT: Radiation Safety Committee

I. PURPOSE

The Radiation Safety Committee will function as the Medical Radioisotope Committee for this Medical Center as described in VA Manual M-2, Part XX, U.S. NRC Rules and Regulations and JCAHO standards.

II. POLICY

The Radiation Safety Committee will promote the best practice in safe handling and use of radioactive sources at this Medical Center. In addition, the Medical Center is committed to a program described below for keeping individual and collective doses as low as is reasonably achievable (ALARA).

III. RESPONSIBILITIES

A. The responsibilities of the Radiation Safety Committee are to:

1. Ensure that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

2. Ensure that all use of radioactive material is conducted in a safe manner in accordance with the ALARA policy and in accordance with NRC regulations and the conditions of the license.

B. The responsibilities of the Radiation Safety Officer are to:

1. Review and report quarterly a summary of the occupational radiation dose records of all personnel working with byproduct material.

2. Review and report quarterly all incidents involving byproduct material with respect to cause and subsequent action taken.

3. Review and report annually on the radiation safety program.

4. Review and report quarterly on radiation safety training.

POLICY MEMORANDUM NO. 115-1

IV. PROCEDURES

A. The Committee shall:

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.

2. Review the training and experience of any individual who uses radioactive material (including physicians, technologists, physicists and pharmacists) and determine that the qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security and housekeeping personnel) are properly instructed as required by Section 19.12, of 10 CFR Part 19, and that such work is consistent with the ALARA philosophy and program (Sec. 3.5).

4. Review and approve all requests for use of radioactive material within the institution. The review process will include review of application forms and where indicated, site visits to document the adequacy of facilities and equipment, operating, handling, and emergency procedures, and the experience and training of the proposed users. Since this institution does not have a broad license for human use we will employ the appropriate review committees at the Bronx VAMC whenever an application for use of a new or non-recognized use of radioactivity in human subjects is received.

5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users and special monitoring.

6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, results of NRC inspection, written safety procedures and management control system, and reports from the radiation safety officer to include procedures for maintaining inventories, possession limits, procurement and transfer of radioactive material. The written report of the annual review will be submitted to the CEB.

7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

8. Maintain written records of all committee meetings, actions, recommendations and decisions.

9. Ensure that the byproduct material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures and personnel.

B. The Radiation Safety Committee will meet as often as necessary to conduct business, but not less than once a calendar quarter.

C. The minutes of each Radiation Safety Committee meeting will be signed by the Chairperson and counter signed by the Chief of Staff. A copy of all meeting minutes will be sent through the Director to the Quality Management Office by the 15th day of the month after the month in which

the meeting was held. Committee meeting minutes will include the following:

1. Date of the meeting.
2. Members present and absent.
3. Summary of deliberations and discussions (e.g., Old Business, New Business, etc.).
4. Recommendations to the CEB.
5. ALARA program reviews.

D. A copy of all committee meeting minutes will be maintained in the Office of the Chief, Nuclear Medicine Service for the duration of the NRC license.

E. The appointed members of the Radiation Safety Committee are as follows:

Chief, Nuclear Medicine Service	Chairperson
Asst. Chief Nuclear Medicine Service	Member
Radiation Safety Officer	Member
Representative, Research Service	Member
Representative, Nursing Service	Member
Staff Assistant/Director	Member
Physician, Research Service	Member
Chief, A&MM Service	Member, Ex-Officio
Chief, Laboratory Service	Member

V. REFERENCES

Regulatory Guide 10.8, Revision 2
U.S. NRC Rules and Regulations, Title 10, Chapter 1, Part 35.22.
Accreditation Manual for Hospitals, JCAHO, 1989.

VI. RESCISSION

None.

SANFORD GARFUNKEL
Director

DIST: 5C
(115) 11
00A-8 copies

ENCLOSURE 3

Medical Center

First Avenue at East
24th Street
New York NY 10010

Veterans Administration

Stephen Richardson MD
Department of Medicine.

9/6/89

In Reply Refer To:

Marcus Rothschild MD
Chief Nuclear Medicine

Ms Teri Laya, who is a medical graduate from the Philipines and has recently begun to work in my laboratory, was interviewed by the inspectors from the NRC. At that time she had not performed any studies involving radioactive materials although she had observed and been instructed in radioimmunoassay techniques. She had received informal training concerning the use of gloves when handling radioactivity and radioactive waste disposal. At the time of the above interview, she had been employed for only one week and subsequent training in this area is continuing.

S Richardson

Stephen Richardson MD
Chief Diabetes Research Laboratory

ENCLOSURE 4

Veterans Administration

Memorandum

Date: August 29, 1989

From: Assistant Chief, Infectious Disease Section (111)

Subj: USE OF RADIO ISOTOPES

To: Dr. Rothschild, Chief, Nuclear Medicine Service (115)

1. The purpose of this memo is to inform you that I have personally trained Joe Szmulewicz in the proper handling and disposal of the radio isotopes ^{35}S and ^{3}H.

2. I have directly supervised Joe while performing experiments involving the use of these radio isotopes.

Phyllis Flomenberg

PHYLLIS R. FLOMENBERG, M.D.

VA FORM SEP 1984 2105

ENCLOSURE 5

Veterans Administration

In Reply Refer To:

DATE: August 28, 1989

FROM: M. A. ROTHSCHILD, M.D.
CHIEF, NUCLEAR MEDICINE /115/

SUBJ: Radiation Safety

TO: V. J. FISHER M.D., ACOS for Research /151

1. Following a recent Nuclear Regulatory Commission (NRC) inspection this Medical Center was found not to be in compliance with NRC Rules and Regulations.

2. In order to be in compliance : No employee will be allowed to handle radioactive material until he/she has received training in radiation safety from the RSO or designate, and he/she has received the proper personnel monitoring device.

3. Failure to comply will result in withdrawal of all privileges relating to the use of radioactive isotopes.

M. A. ROTHSCHILD, M.D.
Chief, Nuclear Medicine

ENCLOSURE 6

RADIATION SAFETY TRAINING

The Nuclear Medicine Service staff receives a radiation safety orientation upon employment and the Radiation Safety Officer provides informal radiation safety training during monthly meetings 3-4 times per year. The attached documentation outlines safety instructions given during orientation and safety training meetings.

PERSONNEL TRAINING PROGRAM

All persons who work in or frequent a restricted area shall receive instruction to include the following:

1. Areas where radioactive material is used or stored.

2. Potential hazards associated with radioactive material.

3. Radiological safety procedures appropriate to their respective duties.

4. Pertinent Nuclear Regulatory Commission regulations.

5. The rules and regulations of the license.

6. The pertinent terms of the license.

7. Their obligation to report unsafe conditions.

8. Appropriate response to emergencies or unsafe conditions.

9. Their right to be informed of their radiation exposure and bio-assay results.

Personnel will be properly instructed in the following situations:

1. Before assuming duties in a restricted area. The extent of instruction will be determined by previous radiation safety training and the scope of the program.

2. Wherever there is significant change in duties, regulations, terms of the license, or scope of the program.

Instruction will be given by the Radiation Safety Officer (RSO), Deputy Radiation Safety Officer, or when appropriate, by the authorized user.

In addition to the above, a three-hour radiation safety lecture will be given no less than once a year by the Radiation Safety Officer or Deputy Radiation Safety Officer. All persons working in or frequenting a restricted area will be required to attend.

Competency determinations of persons working in or frequenting a restricted area will be made through observation, written or oral testing, as appropriate.

Records of all training, testing and competency determination will be maintained.

LABORATORY RULES FOR THE USE OF RADIOACTIVE MATERIALS

1. Before any work is undertaken with quantities of radioisotopes which may produce a significant external or internal exposure, attention shall be given by the user to precautionary measures including the use of shielding hoods, remote handling equipment and air monitoring. The Radiation Safety Officer shall be consulted for recommendations on initial or unusual operations.

2. Work which may result in contamination of work areas shall be done over stainless steel trays or trays lined with heavy absorbent paper.

3. Personnel working in areas containing radioactive materials shall wash their hands thoroughly, using plenty of soap, before eating, smoking or leaving work. Those working with unsealed sources should monitor hands and shoes upon completing operations.

4. Eating, storing, or preparation of food is forbidden in a laboratory or rooms where work with unsealed radioactive sources is taking place or where contamination may exist.

5. Smoking is not permitted in areas where work with unsealed radioactive sources is in progress or where contamination may exist. Under no circumstances should cigarettes, cigars or pipes be left on tables or benches where radioactive work has been or is in progress.

6. Pipetting by mouth is forbidden.

7. Impervious gloves shall be worn whenever hand contamination is likely, and should be seriously considered whenever qualities requiring a radioactive materials area sign are being handled.

8. Laboratory coats shall be worn by all individuals handling radioactivity. In cases where millicurie amounts of activity are being handled and there is likelihood of spillage and personal contamination, the laboratory coat should be removed before leaving the isotope laboratory and kept in the laboratory.

2.

LABORATORY RULES FOR THE USE OF RADIOACTIVE MATERIALS

9. Where contamination is noted during a laboratory survey, or there has been a spill of radioactive material which may have produced contamination of a person or clothing, both the person and the clothing shall be monitored. Personal contamination should be removed as soon as possible. Clothing which shows contamination producing surface levels less than the levels indicated in Section 7.2.5 may be released to the institutional laundry. Clothing showing higher count rates shall either be stored until the count is less than the levels indicated in Section 7.2.5 laundered by an approved decontamination laundry or disposed of through a commercial disposal company, at the discretion of the Radiation Safety Officer.

10. Suitable lead barriers, containers, and syringe shields should be used for preparation of patient doses and administration to patients except in circumstances, such as pediatric cases where the use of syringe might compromise the patient's well-being.

11. Assay each patient dose in the dose calibrator prior administration. Do not use any doses that differ from the prescribed dose by more than 10%.

12. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These should be worn at chest or waist level.

13. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

14. Dispose of radioactive waste only in specially designated receptacles.

15. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

16. Confine radioactive solutions in covered containers plainly identified and labelled with name of compound, radionuclide, date, activity, and radiation level if applicable.

17. Always transport radioactive material in shielded containers.

18. Forceps, tongs or other suitable remote handling devices should be used in handling significant quantities of hard based and/or gamma emitting materials.

THE FOLLOWING PROCEDURES WILL BE FOLLOWED:

MINOR SPILLS

1. Notify all persons in the room at once.

2. Permit only the minimum number of persons in the area necessary to deal with the spill.

3. Confine the spill immediately.

4. Don protective gloves.

5. If a liquid, drop absorbent paper on the spill.

6. If dry material, dampen thoroughly taking care not to spread the contamination. (Water may generally be used except where chemical reaction with the water would generate an air contaminant. (Oil would then be used.)

7. Notify the Radiation Safety Officer as soon as possible.

8. Decontaminate using a monitor to check the progress of the work.

9. Monitor all persons involved in the spill and cleaning.

10. Permit no person to resume work in the area until a survey is made and approval of the Radiation Safety Officer is secured.

STORAGE

1. Radioisotopes requiring "Radioactive Materials" label must be stored in areas under the control of the user, which may be locked or otherwise secured against unauthorized removal of the material.

2. The radioisotopes shall be stored in a container, shielded if necessary, such that radiation a distance of one foot from the container does not exceed 100 mrem/hour, i.e. the area may be classified as no more than Radiation Area.

3. Containers must be properly installed and area signs posted where necessary.

4. Suitable precautions hall be taken so that the probability of an explosion in the storage area which would cause the dispersion of the radioactivity is very small.

TRANSPORTATION ON HOSPITAL PREMISES

1. Radioisotopes requiring a "Radioactive Materials" label must be enclosed in non-shatterable carrying case or container, preferably metallic, before being transported through corridors or between buildings.

2. Containers for the transportation of beta sources requiring a "Radioactive Materials" label must provide shielding thicker than the maximum range of the beta rays.

3. Gamma-ray emitters shall be transported in closed containers, shielded if necessary, such that the dose-rate at the surface does not exceed 200 mrem per hour, and the dose-rate at one meter does not exceed 10 mrem per hour. (This rule follows the Department of Transportation shipping regulations.)

RADIOACTIVE WASTE DISPOSAL

STORAGE OF WASTE

a. Special 5-gallon pails suitably identified with the radioisotopes warning sign shall be supplied through arrangement with the Nuclear Medicine Service to each laboratory in which isotopes are used. Larger containers (30 gallon or 55 gallon capacity) may be obtained through special arrangement with the Radiation Safety Officer, where required.

b. Radioactive wastes must be stored only in restricted areas where they can be secured against unauthorized removal.

c. Waste that contains short-lived radioactive material should be stored temporarily in a marked area to permit substantial decay before ultimate disposal.

d. Liquid waste should be stored in unbreakable inner containers preferably in polyethylene bottles. All liquid waste pails shall in addition have polyethylene inserts with sufficient absorbent material to absorb the liquid contents in the event of leakage from an inner container. There must be no possibility of a chemical reaction during storage that might cause an explosion or cause the release of radioactive gases or vapors. Liquids shall be neutralized before deposition in a waste container.

CATEGORIES THAT CAN BE ACCEPTED FOR COMMERCIAL RADIOACTIVE WASTE DISPOSAL ARE:

(D) Dry (separated as above - no decantable (freely movable) liquid. Aqueous liquids in hardened cement are accepted as dry.

(L) Aqueous liquid - infirmly sealed containers, capable of being poured into larger can in waste room. Liquids should be neutralized and preservative added before disposing.

(S) Liquid Scintillation vials and contents. Please ensure that vial caps are tightly sealed.

(R) Biological (animal) waste - This must be packed in lime. The animals gut must be exposed to the lime. (Lime is supplied by this office.)

SOLID WASTE

All solid waste material including wipes, paper towels, broken glassware, etc., which may be contaminated must be placed in the special radioactive waste pails. Non-radioactive waste should not be placed in these containers since special handling costs are involved.

WASTE COLLECTION

Arrangements for regularly scheduled radioactive waste collections (weekly, bi-weekly, monthly, etc., depending on needs) are made through the Nuclear Medicine Service. Those users not requiring routine collections must notify the Nuclear Medicine Service at least five working days in advance of having a full container to be included in the next regular collection. Each department is billed according to the type and number of containers removed.

WASTE DISPOSAL RECORDS

Records shall be kept by the user of all radioisotopes disposed of via any of the above methods. If disposition is made by administration to humans or animals, or by transfer to an authorized recipient, the laboratory use records must show these amounts. In order to maintain releases to the outside via sink or hood within institutional limits such disposals shall be recorded on Form WD-1 and a copy sent to the Nuclear Medicine Service at the end of each month.

ENCLOSURE 7

Veterans Administration

In Reply Refer To:

DATE: August 28, 1989

FROM: M. A. ROTHSCHILD, M.D.
CHIEF, NUCLEAR MEDICINE /115/

SUBJ: Distribution of Film Badges and Finger Rings

TO: V. J. FISHER M.D., ACOS for Research /151

1. Following a recent Nuclear Regulatory Commission (NRC) inspection this Medical Center was found not to be in compliance with NRC Rules and Regulations concerning personnel monitoring as a consequence of undisciplined badge pickup and return. To be in compliance we are establishing the following procedure with respect to badge pickup and return:

All Principal Investigators who have permission to use radioactive isotopes, or their designee are responsible for picking up and delivering all dosimeter badges and finger rings within 5 working days of the beginning of each month. Upon receipt of the new monthly badges, the person picking up the badges will be required to sign a log book.

If a badge is lost, a report detailing that individual's daily exposure to radiation will have to be submitted in order to estimate exposure.

The Principal Investigator must notify the Nuclear Medicine Service of any personnel changes. Notification must be received within 7 working days of such action.

Failure to comply with the above will be deemed as non-compliance and will result in loss of priveleges for that laboratory.

M.A. Rothschild, M.D.
Chief, Nuclear Medicine Service

ENCLOSURE 8

Veterans Administration

In Reply Refer To:

DATE: September 6, 1989

FROM: M. A. ROTHSCHILD, M.D.
CHIEF, NUCLEAR MEDICINE /115/

SUBJ: Securing areas containing radioisotopes

TO: J.WALSH, CHIEF, ENGINEERING /138/

1. Following a recent Nuclear Regulatory Commission (NRC) inspection this Medical Center was found not in compliance with NRC License Condition 19 which states that "radioisotopes labeled as radioactive material must be stored in areas under the control of the user, which may be locked or otherwise secured against unauthorized removal of the radioactive material."

2. In order to be in compliance it is requested that the doors of all laboratories using radioactive materials be equipped with a snap-lock.

3. The Chief or Asst Chief of Nuclear Medicine will cooperate with your Service in identifying these areas.

M. A. Rothschild, M.D.
Chief, Nuclear Medicine

ENCLOSURE 8

Veterans Administration

In Reply Refer To:

DATE: Proposed memo

FROM: M. A. ROTHSCHILD, M.D.
CHIEF, NUCLEAR MEDICINE /115/

SUBJ: Restricted Areas

TO: V. J. FISHER M.D., ACOS for Research /151

1. Following a recent Nuclear Regulatory Commission (NRC) inspection this Medical Center was found not to be in compliance with NRC Rules and Regulations.

2. Herewith is an excerpt from the report of inspection dealing with lack of security in areas containing radioactivity: "...Failure to secure radioactive material against unauthorized use or removal is an apparent violation of License Condition 19."

3. It is incumbent upon all users of radioactivity that when they leave their area where there is radioactivity to see to it that the radioactive material is secured. In many cases closing the door (equipped with a self-locking lock) of the laboratory may be sufficient.

4. Periodic checks will be made by Nuclear Medicine to see if security is maintained. Laboratories that are inspected will be required to sign a log book.

5. Failure to comply will result in a loss of privileges.

M. A. Rothschild, M.D.
Chief, Nuclear Medicine

ENCLOSURE 9

Medical Center

First Avenue at East
24th Street
New York, NY 10010

Veterans Administration

In Reply Refer To:

DATE: August 18, 1989

FROM: M. A. ROTHSCHILD, M.D.
CHIEF, NUCLEAR MEDICINE /115/

SUBJ: Calibration of Dose Calibrator

TO: P. DIXON, Supervisor Technologist, Nuclear Medicine

1. As discussed in our monthly Clinic meeting (August 17, 1989), the NRC inspector indicated that our calibration of the dose calibrator does not exactly conform to the Rules & Regulations (10 CFR 35.50)

2. Effective Aug 21, 1989 the dose calibrator will be calib ated according to the attachment.

3. Effective Aug. 21, 1989 all doses administered to patients will be assayed in the dose calibrator prior to injection.

M. A. Rothschild, M.D.
Chief, Nuclear Medicine

ENCLOSURE 9

Medical Center

First Avenue at East
24th Street
New York, NY 10010

Veterans Administration

In Reply Refer To:

DATE: August 18, 1989

FROM: M. A. ROTHSCHILD, M.D.
CHIEF, NUCLEAR MEDICINE /115/

SUBJ: Calibration of Dose Calibrator

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2. Effective Aug 21, 1989 the dose calibrator will be calib ated according to the attachment.

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M. A. Rothschild, M.D.
Chief, Nuclear Medicine

Appendix 10

Procedure for Calibrating Dose Calibrator

1. Test for the following at the indicated frequency. Consider repairs, replacement, or arithmetic correction if the dose calibrator fails outside the suggested tolerances. (These recommended tolerances are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances.)

a. Constancy at least once each day prior to assay of patient dosages (± 5 percent).
b. Linearity at installation and at least quarterly thereafter (± 5 percent).
c. Geometry dependence at installation (± 5 percent).
d. Accuracy at installation and at least annually thereafter (± 5 percent).

2. After repair, adjustment, or relocation of the dose calibrator, repeat the above tests as appropriate.

3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, Co-57, or Ra-226 using a reproducible geometry each day before using the calibrator. Use the following procedure:

a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).

b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit of it is used.

c. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.

d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.

e. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The regulation requires repair or replacement if the error exceeds 10 percent.

4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

5. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

Decay Method

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and new activity on the Dose Calibrator Linearity Test Form . This first assay should be done in the morning at a regular time, for example, 8 a.m.

b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 10 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.

c. Convert the time and date information you recorded to hours elapsed since the first assay.

d. On a sheet of semilog graph paper label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Then plot the data.

e. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/(A-line) = deviation.

f. If the worst deviation is more that $\pm$0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

g. Put a sticker on the dose calibrator that says when the next linearity test is due.

6. Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmeceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmecutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that you syringes and vials are tested throughout the range of volumes commonly used.

a. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.

b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated on the Dose Calibrator Geometry and Accuracy Form.

c. Remove the syringe from the calibrator, draw an additional 0.5 cc on nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

d. Repeat the process until you have assayed a 2.0-cc volume.

e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume."

f. If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that ill allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

g. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.

j. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume."

k. If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." if this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

7. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Bureau of Standards (NBS) or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) should be used. The regulations require that one must have a principal photon energy between 100 keV and 500 keV. The regulations also require that, if a Ra-226 source is used, it must be at least 10 microcuries; other sources must be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.

a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57). Then remove the source and assay background. Subtract the background from the indicated activity to obtain the net activity. Record this measurement on the Geometry and Accuracy Form. Repeat for a total of three determinations.

Calculate the three determinations. The average value should be within 5 percent of the activity of the reference source mathematically corrected for decay.

c. Repeat the procedure for other calibrated reference sources.

d. If the average value does not agree, within 5 percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent.

e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (is need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.

f. Put a sticker on the dose calibrator that says when the next accuracy test is due.

8. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

ENCLOSURE 11

...ical Center
First Avenue at East 24th Stre...
New ... 100...

Veterans Administration

In Reply Refer To:

DATE: August 28, 1989

FROM: M. A. ROTHSCHILD, M.D.
CHIEF, NUCLEAR MEDICINE /115/

SUBJ: Violation of NRC Rules and Regulations

TO: V. J. FISHER M.D., ACOS for Research /151

1. Following a recent Nuclear Regulatory Commission (NRC) inspection this Medical Center was found not to be in compliance with NRC Rules and Regulations.

2. Herewith is an excerpt from the report of inspection dealing with food in areas of radioactivity: "...During a tour of the research areas, the inspector noted several instances of food and beverage storage in areas where radioactive materials were stored and used. In room 16029-W, an area where I-125 is handled, the inspector found a tin containing loose tea, a tea cup, several utensils, and dishes. In room 16013F-W, the inspector found a beverage container in a refrigerator where radioactive material including up to 5 millicuries of P-32 is stored. Item 15.4 of the radioactive material license application states that eating, storage, or preparation of food is forbidden in laboratories or other rooms where work with unsealed radioactive material is performed or where radioactive contamination may exist.

The storage of food and associated utensils in areas where radioactive materials are used or stored is an apparent violation of License Condition 19. This finding is a repeat violation which was initially documented during the December 16, 1987 inspection."

Failure to remove food and associated utensils in areas where radiactive materials are used or stored is non-compliance with NRC Rules & Regulations and will result in closure of the offending laboratory until such violation is corrected.

3. Herewith is another excerpt with respect to radiation surveys: "...Several research technologists and investigators in the research area where radioactive materials are used and stored confirmed that monthly area radiation surveys were not performed." "...Failure to perform monthly area radiation surveys of laboratory areas in which radioactive materials are used is an apparent violation of License Condition 19."

Attached to this memorandum is an outline of what the "Area of Survey" should include.

4. In order to comply with NRC Rules and Regulations all Principal Investigators who are authorized to receive and use radioactive isotopes will have to submit to the Nuclear Medicine Service a monthly report of package receipt and monitor log. A sample copy is attached to this memo.

5. All reports are due no later than the first 7 working days of each month. Failure to comply will result in withdrawal of all privileges relating to the use of radioactive isotopes.

M. A. Rothschild, M.D.
Chief, Nuclear Medicine

ENCLOSURE 12

Medical Center

First Avenue at East
24th Street
New York, NY 10010

Veterans
Administration

In Reply, Refer To

DATE: August 18, 1989

FROM: M. A. ROTHSCHILD, M.D.
CHIEF, NUCLEAR MEDICINE /115/

SUBJ: Radioactive Waste Disposal

TO: P. DIXON, Supervisor Technologist, Nuclear Medicine

1. As discussed in our monthly Clinic meeting (August 17, 1989), the NRC inspector indicated a failure to maintain survey records of decayed radioactive waste prior to disposal into ordinary trash.

2. Effective Aug 21, 1989 survey records of all disposed radioactive waste into ordinary trash will be maintained. A copy of the survey will be posted on the inside door of the room where we store the radioactive material and a copy will be kept in your files.

M. A. Rothschild, M.D.
Chief, Nuclear Medicine

DECAY → TRASH
after B.G. subtraction

Feedback #3
44-3 probe.

ISOTOPE	DATE	BG is mR/hr	Date	BG is mR/hr	Date	mR/hr
131 I - Lever	7/24/89	11.5	9/6/89	0.25		
Te 4:30pm	9/1/89		9/6/89	0.00	discard	

ENCLOSURE 1

VETERANS ADMINISTRATION MEDICAL CENTER
NEW YORK, NEW YORK 10010

MAY 20, 1988

Medical Isotope Committee Meeting

Convened: 1:00 pm Adjourned: 2:00 pm

Present:	M. A. Rothschild M.D.	Chief, Nuclear Medicine
	M. Oretz Ph.D.	Asst Chief, Nuclear Medicine
	S.S. Schreiber M.D.	Physician, Nuclear Medicine
	V.J. Fisher M.D.	ACOS for R & D
	M. Basti R.N.	Chief, Nursing Service
	A. Benoff M.D.	Physician, Radiology Service
	N. Cooper M.D.	Chief, Laboratory Service
Excused:	J.H. Ayvazian M.D.	Chief of Staff
	S. Rudolph Ph.D.	Radiation Safety Officer

The meeting was held in Room 18099S at 1:00 pm on May 20, 1988

1. Equipment Status:

All equipment are functioning. The Medical Center has placed an order with GE for SPECT upgrading of the GE LFOV camera. Personnel will be trained at NYU Medical Center as well as at GE in Minneapolis, MN.

2. Personnel:

Victor Zee has returned to active duty. A replacement was found for Mrs. Swan. The Service is now at full strength. All Technologists are being roteted through all the modalities of the Service. Thus, at any time any Technologist can do a Gated Heart Pool, or run a program on the computer.

Dr. Rudolph was approved for an extra visit/week in order to handle the waste disposal.

3. Quality Management:

Nuclear Medicine is formalizing a Quality Assurance-Quality Control program as part of the Medical Center's overall Quality Management Program.

4. Adverse Incidents:

There were no adverse incidents to report since the last meeting.

ENCLOSURE 1

5. Workload:

There has been a doubling in requests for Gated Heart Pool studies which is a consequence of this Medical Center's appointment as a Cardiac Center. Also, there has been an increase in the number of RIA requests.

Respectfully submitted,

M. Oretz

Murrey Oretz, Ph. D.
Secretary

ENCLOSURE 1

[illegible]

[illegible]

[illegible] Meeting

Convened: [illegible]   Adjourned: [illegible]

Present:	[illegible] Ph.D.	Asst Chief, Nuclear Medicine
	S.B. Schneider M.D.	Nuclear Medicine
	[illegible] M.D.	ACOS for R & D
	A. Benoff M.D.	Radiology Service
Excused:	M.H. Rothschild M.D.	Chief, Nuclear Medicine
	J.H. [illegible] M.D.	Chief of Staff
	[illegible] Ph.D.	Radiation Safety Officer
	V. [illegible] M.D.	Chief, Laboratory Service

The meeting was held in Room 1[illegible] at [illegible] p.m. on February 2[illegible], 1988.

1. NRC Inspection

The Medical Isotope Committee (hereinafter referred to as The Committee) was informed that the Nuclear Regulatory Commission (NRC) conducted a surprise inspection on December 1[illegible], 1987. The report identified 3 violations. Fortunately they were of a minor severity. The violations were:

a. Failure to assay thyroid glands of personnel who perform monthly iodinations with I-125;

b. A cup of coffee was stored on a bench adjacent to equipment contaminated with radioactivity.

c. Wipe test were not performed by some [illegible] on packages containing radioactive material prior to their being opened.

2. Remedial Action to item #1:

a. A Ludlum [illegible] monitor was purchased and routine thyroid monitoring is now being done on personnel who iodinate.

b. The individuals in question were instructed as to NRC regulations concerning food in areas where there is radioactivity.

c. Wipe tests are being performed on all radioactive containing packages.

ENCLOSURE 1

[illegible]. Adverse Incidents:

There were no adverse [illegible] to report since the last meeting.

[illegible]. Equipment Status:

[illegible] the last meeting [illegible] report the receipt of a new GE portable camera [illegible], the table to the camera [illegible], we have received a [illegible] developing system [illegible] the old Kodak [illegible] [illegible] for BREDT.

[illegible]. Personnel:

The individual that we hired to replace Mrs [illegible] Swan has decided to return to his prior place of employment (Montrose VA). Active recruiting is underway.

Victor [illegible] is returning to active duty after a [illegible] tour of duty in the Air Force as an Air Evac [illegible].

Respectfully submitted,

M. Oratz

Murray Oratz, Ph.D.
Secretary