DEPARTMENT OF VETERANS AFFAIRS
Medical Center
Albany NY 12208

February 26, 1991

In Reply Refer To: 500/00

Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

RE: "REPLY TO A NOTICE OF VIOLATION"
(License No. 31-02755-05/Docket No. 030-10026)

(1) This correspondence, with attachments, is forwarded in response to your January 29, 1991, "Notice of Violation and Proposed Imposition of Civil Penalty - $3,150 (NRC Inspection Report No. 90-001).

(2) Your January 29, 1991, correspondence asked me to describe actions taken or planned to improve oversight of our program above the level of the Radiation Safety Officer (RSO) and by the RSO. We responded to this request, in part, in our January 29, 1991, reply to Malcolm R. Knapp, Director. To reiterate, the Radiation Safety/Radioisotope Committee (RS/RC) at the Department of Veterans Affairs Medical Center (DVAMC) meets bi-monthly; however, since the NRC Inspection on November 20 & 21, 1990, the RS/RC has met three (3) times and will continue to meet at a frequency necessary to ensure adequate oversight of the radiation safety program. Officially as of January 22, 1991, I have appointed Lawrence H. Flesh, M.D., Chief-of-Staff as RSO and Min-Fu Tsan, M.D., ACOS (Associate Chief-of-Staff for Research and Development) as Chairman, RS/RC. In addition we are actively recruiting for a qualified full-time RSO who, as of December 18, 1990, will report directly to the Chief-of-Staff who will keep me informed of all relevant radiation safety matters. The RSO shall, when and if necessary, have direct access to me. Finally, the current RSO communicates daily with the radiation safety staff and/or Health Physics Consultant to direct the radiation safety program requirements and assess their status as well as to exercise oversight of activities performed by the staff and consultant.

F/5

(3) Please communicate with me immediately if this reply is not totally responsive to your specified requests.

F. L. MALPHURS,
Director

Attachments

cc: Thomas T. Martin
Regional Administrator
U.S. Nuclear Regulatory Commission/Region 1
475 Allendale Road
King of Prussia, PA 19406

for William E. Gross, M.D.
Director, Nuclear Medicine Svc (115)

4/25/91

A. 10CFR20.207(a)

(1) A package containing 1 millicurie was left unsecured by A&MM Service (Supply and Receiving) person in the unrestricted hallway outside the Radiation Safety Storage Hot Laboratory (Room 621D). The NRC was immediately notified by telephone when the package was noted missing (August 20, 1990) and a detailed report, dated September 11, 1990, was forwarded to the NRC's Region I Administrator.

(2) The most probable reason for the violation was communicated to the NRC on September 11, 1990. In short, the then procedure for Receipt of Radioactive Material was not strictly followed.

(3) The "Procedure for Radioactive Material Receipt and Security", as noted as ITEM 4(b)5. in our correspondence to Malcolm R. Knapp, Director, dated January 28, 1991, had been implemented subsequent to the incident. An Amendment Request to Mohamed Shanbaky, Ph.D. and dated February 15, 1991 (Copy Attached), updates and modifies the ITEM 4(b)5. reply to Malcolm R. Knapp, Director. A&MM Service and Police and Security Service personnel have been instructed in the updated and modified Procedure. No further incidents have occurred to date.

(4) In addition to the Amended Procedure, formalized and documented training for the receipt, delivery, and security of packages labelled to contain radioactive material will be scheduled to be conducted for A&MM Service, Police and Security Service, and other involved personnel by the RSO and/or Consultant by February 26, 1991. New involved personnel will be trained as required and periodic refresher training (at least annually) will be conducted.

(5) Full compliance, to include training, will be achieved by February 26, 1991.

Veterans Administration

JUSTIFICATION FOR PROPOSED FIELD STATION ISSUE

(Except forms and form letters)

INSTRUCTIONS: Submit proposed issue and this form in DUPLICATE.

[X] THIS PROPOSED ISSUE DOES NOT REITERATE, DEVIATE FROM, CONTRADICT, OR SUPPLEMENT POLICY AND PROCEDURE PRESCRIBED BY CENTRAL OFFICE

[ ] THIS PROPOSED ISSUE CONTAINS MINOR DEVIATIONS FROM CENTRAL OFFICE PROCEDURES *(Explain fully in Item 4)*

1A. APPROVED BY SERVICE DIRECTOR/DIVISION CHIEF OF ORIGINATING ISSUE	1B. DATE	2. PROPOSED MS/DHM *(Include Issue Number assigned after final approval)*
Louis P. Nangeroni, Jr. Chief, ACMHS		
1C. TITLE AND ORGANIZATION		

3. SUBJECT

SPECIAL HANDLING PROCEDURES FOR MEDICAL CARE DELIVERIES

4. PURPOSE *(Explain fully the necessity, objective, reason for change in existing issue, etc.)*

To update Station Memorandum #90-10

5. EACH ISSUE ON SAME SUBJECT *(Except those listed in Item 6)*

Memo 90-10 dated June 22, 1987

6. AMENDMENTS OR RESCISSIONS EFFECTED BY THIS ISSUE	7. NEW (OR REVISED) FORMS REQUIRED BY THIS ISSUE	
	FORM NO.	TITLE

8A. NAME OF ORIGINATOR OF PROPOSED ISSUE *(Type or print)*	8B. ROOM NO.	8C. BUILDING	8D. TELEPHONE NO.
Louis P. Nangeroni, Jr.	C-67		2558/9

9. CONCURRENCES

SYMBOL	SIGNATURE	DATE	SYMBOL	SIGNATURE	DATE
13		2-14-91	11		2/15/91
001		2-19-91	00		

10. DISTRIBUTION

Distribution: B

11. REMARKS

12A. FORWARDED FOR APPROVAL *(Signature of Service Publications Control Officer)*	12B. DATE	13A. APPROVED FOR PUBLICATION *(Signature of Director or Designee)*	13B. DATE
M. JARLENSKI, CHIEF, BMS		F. L. MALPHURS, DIRECTOR	2/19/91

VA FORM JAN 1984 3222b

EXISTING STOCKS OF VA FORM 3222b, AUG 1949, WILL BE USED.

*U.S. GPO: 1986 — 181-822

VETERANS ADMINIS. ATION MEDICAL CENTER
ALBANY, NEW YORK 12208

MEMORANDUM NO. 90-10
MARCH 26, 1990

SPECIAL HANDLING PROCEDURES FOR MEDICAL CARE DELIVERIES

1. Purpose: To establish a uniform procedure to be followed by the V.A. Medical Center personnel for the pick-up and/or receipt of supplies ordered by Acquisition & Materiel Mgmt. Service for official use and which are delivered on weekends, holidays, and after the regular 8:00AM to 4:30PM workday.

2. Responsibility: The Chief, A&MM Service will be responsible for the compliance of the policy as stated. The Chief of Police & Security Service will be responsible for implementing procedures set forth to ensure the timely delivery of supplies received after duty hours and Saturdays, Sundays, and holidays.

3. General: In most cases, this type of delivery is of an emergent nature and the supplies are air-freighted in and are required for immediate use when received, or are required for use within two (2) days. The supplies are varied and consist mainly of drugs, pacemakers, radioisotopes, frozen pigskin for skin grafts, etc.

4. Procedure: The following procedures will be strictly observed to ensure uniformity of delivery and to ensure timely delivery of supplies.

a. After normal working hours supplies must be delivered to the Police & Security Service and processed in accordance with their internal procedures.

b. A&MM Service will notify Police & Security Service in writing of any special handling instructions that they are aware of. Other special handling instructions will be indicated on the shipping container. This information can be given only for those cases when A&MM personnel are aware that shipments will be received on weekends or after 4:30PM on workdays.

c. The Police & Security Service will notify A&MM Service by calling the Warehouse, extension 230, no later than 9:00AM of the next workday of any deliveries received, indicating number of pieces, condition, date, time and location. Police & Security Service will also record the time, date and name of individual accepting this information in A&MM Service.

d. The following areas are to be utilized for storage of supplies:

1. Supplies other than radioactive material, that require refrigeration will be stored in refrigerator in Room 622-B.

2. Supplies that require freezing will be stored in the upright deep freezer in Room 622-B. The Research Service will put up a sign on the refrigerator and freezer so that the Police will know which one to use.

e. Film Bad ⊢ Normal delivery is by gular mail, however, on occasion, new .ilm badges to be worn by V.. personnel for occupational radiation monitoring, may arrive after regular working hours. DO NOT - REPEAT - DO NOT STORE NEXT TO ANY PACKAGES MARKED RADIOACTIVE.

This will cause exposure of the film badges and would create many unnecessary problems. The film badges will be delivered to room 616-D.

f. Radioactive Material - When radioactive packages are received by A&MM Service (Supply & Receiving) during normal work hours and by the Police & Security Service after normal working hours, on weekends, and holidays, (non-normal work hours) the following procedures should be strictly followed:

NORMAL WORK HOURS

1. A&MMS personnel shall immediately examine the package to determine if damage or leakage has occurred during transit.

2. If the package is visibly damaged or leaking A&MM Service shall:

(a) Immediately notify the RSO or a member of the RSO staff at Extension 2524, or by paging the operator.

(b) Attempt to detain the carrier until it can be determined that neither the driver nor the vehicle is contaminated. If not, the name of the driver, delivery company or other identifying information required by the Radiation Safety Officer (RSO) should be obtained by person accepting the delivery.

(c) Isolate the damaged package from further handling.

(d) Keep all personnel away from the immediate vicinity of the package and under no circumstances shall anyone, other than Radiation personnel, attempt to open the package.

If the package is intact:

(a) Deliver the unopened package to the RSO's Room (618D) immediately or at least within three (3) hours of delivery or;

(b) If the RSO is unavailable, unlock the door to the Radiation Safety Storage/Hot Laboratory (Room 621D), place the unopened package on top of the counter, or, if package markings indicate that refrigeration is needed, the unopened package shall be placed in the large upright refrigerator in Room 621D. Relock the door and notify the RSO's secretary of delivery and record the date, time, and name of the individual notified.

NON NORMAL WORK HOURS

1. V.A. Police and Security personnel shall immediately examine the package to determine if damage or leakage has occurred during transit.

2. If the package is visibly damaged or leaking V.A. Police and Security personnel shall:

(a) Immediately notify the RSO or a member of the RSO staff,

(b) Attempt to detain the carrier until it can be determined that neither the driver nor the vehicle is contaminated. If not, the name of the driver, a delivery company or other identifying information required by the RSO shall be obtained by the person accepting the delivery.

(c) Isolate the damaged package from further handling.

(d) Keep all personnel away from the immediate vicinity of the package and under no circumstances shall anyone, other than Radiation Safety personnel, attempt to open the package.

If the package is intact:

(a) Deliver the unopened package immediately to Room 621D. Place the unopened package on top of the counter, or, if the package indicates that refrigeration is needed, the unopened package shall be placed in the large upright refrigerator in Room 621D.

(b) Notify A&MM Service by following Procedure 4.C.

3. Under no circumstances should anyone other than Radiation Safety Personnel attempt to open the shipment.

5. References: None

6. Rescission: Memorandum No. 90-10 dated June 22, 1987

7. Follow-Up Responsibility: Chief, A&MM Service

8. Automatic Rescission Date: March 26, 1992

F. L. MALPHURS
Director

DISTRIBUTION: B

B. 10CFR35.315(a)(8)

(1) The Nuclear Medicine Technologist and Physician involved in the preparation and administration of a therapeutic quantity of Iodine-131 to a patient hospitalized in accordance with 10CFR35.75 on July 13, 1990, failed to have their thyroid burden measurements performed.

(2) The violation occurred during the time period when the Chief of Nuclear Medicine had been named Radiation Safety Officer (RSO). It appears that the RSO was not familiar with the requirements of 10CFR35.315(a)(8) at the time thereby creating a noncompliant situation.

(3) The technologist and physician involved, as well as all technicians and physicians likely to be involved, have been instructed in the proper procedures to follow in the administration of therapy doses of radiopharmaceuticals and the requirements for bioassay measurements. No Iodine-131 therapy doses, pursuant to 10CFR35.75, have been administered since July 13, 1990.

(4) To prevent future noncompliance in this area, the RSO will be responsible to implement all applicable requirements for unsealed therapeutic procedures. In addition, the RSO must be notified whenever a patient who will be hospitalized is scheduled to receive a radiopharmaceutical for therapeutic purposes as specified in 10CFR35.300. This will allow the RSO sufficient time to perform room preparation, nursing instructions and oversight of the radiopharmaceutical administration to ensure that regulatory compliance is maintained. Individuals involved in the preparation and administration of I-131 will have thyroid burden bioassays performed within 24-72 hours.

(5) Full compliance with this item was achieved in early December 1990 upon employment of a Health Physics Consultant who revised the current procedures for therapeutic administration which was included as ITEM 4(b)4. of our correspondence to Malcolm R. Knapp, Director dated January 28, 1991.

C. 10CFR35.22(b)(6)

(1) As of November 21, 1990, the Radioisotope/ Radiation Safety Committee (RS/RC), with the assistance of the Radiation Safety Officer (RSO), did not perform an annual review of the radiation safety program for 1989.

(2) It appears that the annual review of the radiation safety program for 1989 did not occur due to an oversight or lack of time/personnel, or a combination of these factors, on part of the RSO at the time.

(3) Subsequent to obtaining the services of an independent consultant the RSO, with additional time and direction, completed a most comprehensive RADIATION SAFETY ANNUAL REPORT FOR 1989.

This REPORT was reviewed in detail at the RS/RC Meeting on January 24, 1991, and submitted in our correspondence dated January 28, 1991, to Malcolm R. Knapp, Director (EXHIBITS 7 & 10).

(4) Material for the 1990 REPORT is now being collated and reviewed by the RSO staff for preparation by the RSO for submission to the RS/RC.

(5) Full compliance for 1989 was achieved on January 24, 1991.

D. 10CFR35.205(c)

(1) As of November 21, 1990, no calculation was performed of the time needed after a spill of Xenon-133 to reduce the concentration in Imaging Room 626D to the applicable limit.

(2) It appears that calculations were not performed due to an oversight or lack of time/personnel, or a combination of these factors, on part of the Radiation Safety Officer (RSO) at the time. A License Amendment to use Room 626D (See Item M of this correspondence) was not submitted for these same apparent reasons.

(3) An Amendment Request for the "Use of Xenon-133 Gas for Pulmonary Ventilation Studies in Room 626D" dated February 19, 1991, has been submitted to the NRC under separate cover. Room 626D will not be used for radioactive aerosols or gases unless the Amendment Request is granted.

NOTE: In support of the Amendment Request calculations of spilled gas clearance time have been performed by our current RSO and Health Physics Consultant according to the procedure that was published in Appendix O.4 to Regulatory Guide 10.8, Revision 2. A record of the calculations, to include assumptions and measurements, shall be retained for the duration of use, if the request is granted, of Room 626D. A copy of the calculated time and safety measures to be instituted in the case of a spill in Room 626D, as well as the calculations, will be posted in Room 626D when and if the Amendment Request is granted.

(4) Room 626D will not be used for radioactive aerosols or gases unless the Amendment Request referred to in (3) above is granted. If and when the Amendment Request is granted, calculations and the calculated gas clearance time as noted in (3) above, shall be posted. Finally, the attached RSO Memorandum, dated February 19, 1991, details and defines "Xenon-133 Requirements" and responsibilities.

-OVER-

Veterans Administration

Memorandum

Date: February 19, 1990

To: Andrew Kang, M.D.
Chief, Nuclear Medicine Service (115)

From: Lawrence H. Flesh, M.D.
Radiation Safety Officer (11R)

Subj: Xenon-133 Requirements

This is a reminder for you and your staff regarding Xenon-133 use requirements:

XENON-133 USE REQUIREMENTS

1. Volatile radiopharmaceuticals and radioactive gases shall be stored in the shipper's radioactive shield and containers. A multi-dose container shall be stored in a fume hood after drawing the first dosage from it. [10CFR35.90]

2. Radioactive gases shall only be administered in rooms that are at negative pressure compared to surrounding rooms. [10CFR35.205(b)]

3. Before receiving, using, or storing a radioactive gas, the user (licensee) shall calculate the amount of time needed after a spill to reduce the concentration in the room to the occupational regulatory limits. The calculation must be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available exhaust rate. [10CFR35.205(c)]

(*) 4. The user (licensee) shall make a record of the calculations required in 3. above that includes the assumptions, measurements, and calculations made and shall retain the record for the duration of use of the area. <u>The user (licensee) shall make a record of the calculated time and safety measures to be initiated in case of a spill at the area of use.</u> [10CFR35.205(d)]

OVER

VA FORM 2105
MAY 1983
☆ U.S. GOVERNMENT PRINTING OFFICE: 1984-421-488/0348

PROCEDURE FOR MONITORING OR CHECKING TRAP EFFLUENT (*)

Charcoal traps can significantly reduce air contamination. They can also become saturated or be spoiled by improper use, humidity, chemicals, or inadequate maintenance.

1. If the trap effluent is monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions and keep a record of the checks.

2. If you do not monitor the trap effluent, check it on receipt and once each month. Collect the effluent from the trap during one patient study in a plastic bag and then monitor the activity in the bag by holding the bag against a camera, with the camera adjusted to detect the noble gas, and compare its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm.

3. If you measure a significant increase in the bag cpm, TWO (2) TO THREE (3) TIMES THE BACKGROUND CPM, the trap is breaking down and must be replaced. NOTIFY THE RSO.

4. Follow the trap manufacturer's instructions for replacing the Drierite and/or the trap.

Mark Horan, M.D. for
LAWRENCE H. FLESH, M.D.
CHIEF OF STAFF
RADIATION SAFETY OFFICER

8/21/91
DATE

(*) Adapted from Appendix O.3 to Regulatory Guide 10.8, Revision 2

IMAGING ROOM 626D

*** XENON-133 ***

EMERGENCY PROCEDURES

The following EMERGENCY PROCEDURES shall be implemented in the event that there is an accidental release of Xenon-133 in Imaging Room 626D:

=1= REMOVE THE PATIENT FROM THE IMAGING ROOM.

=2= ENSURE THAT THE EXHAUST FAN* IS OPERABLE AND ALL DOORS* ARE CLOSED.

=3= VACATE (ALL PERSONNEL) THE IMAGING ROOM FOR 1/2 HOUR.

=4= SURVEY, UPON RE-ENTRY, THE IMAGING ROOM WITH A THIN WINDOW GM SURVEY METER TO ENSURE THAT RADIATION LEVELS HAVE RETURNED TO NORMAL.

---

* The EXHAUST FAN shall be "ON" CONTINUOUSLY (i.e. never "OFF") and the DOORS shall remain closed during Xenon-133 procedures to ensure that the Imaging Room is a negative pressure area.

LAWRENCE H. FLESH, M.D.
CHIEF OF STAFF
RADIATION SAFETY OFFICER

2/15/91
(DATE)

E. 10CFR20.303/10CFR20.401(c)(3)

(1) Adequate records were maintained as required under 10CFR20.401 for both 1988 and 1989 for radioactive materials released into the sanitary sewerage system.

(2) Records of the releases for 1989 were present in the Radiation Safety Office and contained in the Authorized User's Utilization Logs, they had not yet been collated at the time of the inspection on November 20-21, 1990. A total of 12.6mCi (388 x 10^{-10}uCi/ml) was released in 1989; this was summarized in our correspondence to Malcolm R. Knapp, Director on January 28, 1991. (EXHIBIT 10, Attachment I).

The Annual Report record for 1988 did indicate a conflicting quantity of radioactivity released to the sewer. The REPORT was accurate in indicating that the total activity released was 24.015 mCi (24,014.9mCi). However, the concentration of radioactivity released into the sanitary sewer should have indicated 971.4 x 10^{-10}uCi/ml; the exponential term (x 10^{-10}uCi/ml) was inadvertently omitted.

(3) The above was fully explained at the Enforcement Conference conducted December 13, 1990, at the King of Prussia; we honestly thought that the explanation was understood and accepted.

(4) Since records were maintained, no corrective action is deemed necessary. Nevertheless we will check more carefully as to the accuracy of formal tabulated data.

(5) Not applicable.

F. 10CFR35.70(d)

(1) Ambient radiation dose rate trigger levels had not been formally established for dose preparation, administration, and radioactive waste areas to achieve compliance with 10CFR35.70(d). However, until the date of November 20-21, 1990, any ambient dose rates twice background levels in the dose administration area was cause to perform a more intensified survey. For radioactive waste and dose preparation areas any radiation levels above normal was cause for further surveys to be performed.

(2) It appears that the Radiation Safety Officer (RSO) at the time was not aware of the 10CFR35.70(d) requirements.

(3) Corrective action has included formalization of ambient dose rate trigger levels which have been placed on the daily survey forms. Trigger limits have been established at five times background or 0.1mR/hr for dose administration areas. (This is the lower level of detectability required by 10CFR35.70(c)). The trigger level for preparation and radioactive waste areas will be two times the average radiation levels in these areas averaged for the last three (3) months. No ambient dose rate levels to date have exceeded the trigger levels.

(4) Future noncompliance shall be avoided by review of the surveys conducted in accordance with 10CFR35.70 and periodic independent measurements performed by the RSO.

(5) Initial compliance with this item was achieved on November 27, 1990, when interim trigger levels were established. Final trigger levels were evaluated and implemented on February 15, 1991.

G. 10CFR35.59(b)(2)

(1) Sealed sources containing licensed material were not tested for leakage from October 14, 1989, to November 21, 1990.

(2) It appears that the required leak tests were not performed due to an oversight or lack of time/ personnel, or a combination of these factors, on part of the Radiation Safety Officer (RSO) at the time.

(3) Leak tests, on all sealed sources requiring the tests, were conducted by our Consultant Health Physicist on 12/4/90 and completed on 1/3/91. Leak Test Certificates showing no removable activity exceeding 0.005μCi are being maintained in the Radiation Safety Office.

(4) Periodic leak tests, not to exceed six (6) months, shall be performed by our Radiation Safety Officer (RSO) and/or the Consultant Health Physicist.

(5) Full compliance was achieved on January 3, 1991.

H. 10CFR35.205(e)

(1) The ventilation rates available in Room 609D had not been measured during the last twelve (12) months and, during that period, radioactive Xenon gas was used in that Room.

(2) It appears that the Radiation Safety Officer (RSO) at the time was not familiar with the requirements of 10CFR35.205(e).

(3) The ventilation rates were measured by Engineering Service personnel on 12/26/90 and the following results were obtained: Supply Air Flow (0 Vents) and Exhaust Air Flow Rate (130 CFM).

(4) Nuclear Medicine Service shall be responsible, as reminded by a February 19, 1991, Memorandum from the RSO, to notify and have completed a measurement of the ventilation rates in areas of radioactive gas storage and use each six (6) months. Nuclear Medicine Service shall also be responsible for maintaining the measurements and, if necessary, revising any necessary calculations.

(5) Full compliance was achieved on December 26, 1990.

I. 10CFR35.315(a)(7)

(1) A room used on July 16, 1990, for a radiopharamecutical therapy which required patient hospitalization in accordance with 10CFR35.75 was not surveyed prior to being reassigned to ensure that removable contamination was less than 200dpm/100cm^2.

(2) As indicated in the response to ITEM B above, the Radiation Safety Officer (RSO) at the time did not appear to be familiar with the Regulatory and License requirements thereby creating a noncompliant situation.

(3) The procedure for "Radiation Safety During Iodine Therapies Over 30 millicuries" has been revised and was submitted as ITEM 4(b)4. of our January 28, 1991 correspondence to Malcolm R. Knapp, Director. No therapy, which required patient hospitalization in accordance with 10CFR35.75, has been performed since July 16, 1990.

(4) The RSO and associated staff will be required to read and be familiar with the requirements specific to iodine therapies. The current RSO is knowledgeable with respect to the requirements and will ensure compliance is achieved during any future therapies involving unsealed radiopharmaceuticals.

(5) Full compliance was achieved January 22, 1991, when a new interim RSO was named to our License.

J. 10CFR19.12

(1) Individuals frequenting or working in any portion of a restricted area had not had recent and adequate training as described.

(2) It appears that the Radiation Safety Officer (RSO) at the time was either not aware of the training requirements or did not have the time to adequately perform the training tasks.

(3) The Health Physic Consultants, as detailed in ITEM 2. of my correspondence to Malcolm R. Knapp, Director dated January 28, 1991, have performed training for those items noted in ITEM 2. of Mr. Knapp's correspondence to me dated November 29, 1990. Training has been completed for Research and Nuclear Medicine personnel and has specifically included the following areas: (a) applicable NRC requirements, (b) procedural requirements to include personnel and area surveys and the use of daily utilization logs, and (c) appropriate radiological safety precautions. Documented attendance to date has been nearly 100% of the radioactive material users at the Department of Veterans Affairs Medical Center (DVAMC).

(4) Corrective steps that have been taken to avoid further violations include the following: (a) refresher training will be provided for individuals working or frequenting restricted areas; this training will include newly hired radiation workers; (b) present arrangements include training of A&MM Service (Supply and Receiving) and Police and Security Service personnel by February 26, 1991; (C) nursing personnel shall be instructed in applicable provisions just prior to the next sealed or unsealed source therapy procedure to ensure timely familiarity with radiation safety preecautions since these therapies occur only 1-2 times each year.

(5) Full compliance, except for Nursing personnel training, is scheduled to be completed by February 26, 1991.

K.1. LICENSE CONDITION 18

(1) The NRC inspector did find evidence of drinking and eating in the five (5) research laboratories noted.

(2) The Department of Veterans Affairs Medical Center's (DVAMC)'s findings seem to indicate that the following main reasons contributed to the inspection findings: (a) lack of adequate training as noted in my response to ITEM J. (10CFR19.12) above and (b) several of the individuals in the laboratories invalided were new employees (started after 10/88 when the previous full-time Radiation Safety Officer (RSO) had left) who were not trained and were not totally familiar with the Regulations and License Conditions.

(3) Corrective steps that have been taken to-date include the following: (a) an initial "audit" of each laboratory by our Health Physics Consultant (the purposes of the "audit" were to notify all users of the availability of an active Radiation Safety Office, to post in each laboratory an updated "Notice-to-Employees" which stated the location and availability of the Materials License and associated documents and to answer questions; the attendance for the audit at each laboratory is documented), (b) reinforcement of the Regulations and License Conditions by Min-Fu Tsan, M.D., Ph.D., Associate Chief of Staff for Research and Development (ACOS) and Chairman of the Radiation Safety/Radioisotope Committee. (Dr. Tsan has appointed "User RSO's" to facilitate compliance with the Regulations and communicate with the Radiation Safety Office) and (c) training as noted above in my response to ITEM J. (10CFR19.12). Results achieved to date as noted by most recent visits by the Radiation Safety staff to a number of the laboratories, indicate no evidence of eating or drinking in the laboratories.

(4) Corrective steps that will be taken to avoid further violations include increased communication, quarterly audits of the research laboratories by the Radiation Safety staff, and a yearly audit of each Authorized User's protocol once a full-time qualified RSO is employed.

(5) Full compliance was achieved on January 28, 1991.

K.2. LICENSE CONDITION 18

(1) As of November 21, 1990, two authorized users did not notify the Radiation Safety Office of changes in laboratory locations.

(2) It is more than apparent that the main reasons for this violation are (a) lack of adequate communication between the users and the Radiation Safety Office and (b) lack of knowledge of the requirement on part of the users.

(3) Enhanced communication and training efforts have been noted above (J.10CFR19.12 and K.1. LICENSE CONDITION 19). Additional corrective steps to date have included: (a) a reminder to all research users of the requirements by Min-Fu Tsan, M.D., Ph.D., Associate Chief for Research and Development (ACOS) and Chairman, RS/RC and (b) an "Update of Radioactive Material Approvals and Lab Personnel" initiated by the Radiation Safety Officer (RSO) on January 31, 1991. We are confident all users are quite aware of the requirements to notify the Radiation Safety Office whenever there is a change in laboratory personnel or location.

(4) To avoid further violations the Radiation Safety Office shall maintain communication and training efforts, shall perform quarterly audits of the research laboratories, and shall conduct a yearly audit of each Authorized User's protocol once a full-time qualified RSO is employed.

(5) Full compliance was achieved on January 31, 1991.

K.3. LICENSE CONDITION 18

(1) The Department of Veterans Affairs Medical Center's (DVAMC's) findings, with respect to the inventory records for radioactive material use in Room A607 (607A), showed that the radioactive waste disposal forms were maintained by the Authorized User as part of the Authorized User's Daily Utilization Log.

(2) The violation is denied since adequate inventory records were and are being maintained according to Section 3.1.4.A. of the License Application dated December 5, 1985 for use of radioactive material in Room 607A. (It is speculated that the inspector may have believed that the radioactive waste container required a list stating the quantity and type of radionuclide contained therein; this information is attached at the time the container is taken to the Radiation Safety's Radioactive Waste Room.)

(3)(4)(5) Although no corrective action is required, the Radiation Safety Officer (RSO) forwarded a memorandum to all Authorized Users on January 23, 1991, reminding them and reinforcing the Section 3.1.4. requirements.

L. 10CFR20.103 and 20.106

(1) As of November 21, 1990, Xenon airborne concentrations in restricted areas (Room 626D) and in release to unrestricted areas were not established to demonstrate compliance with the requirements of 10CFR20.103 and 20.106.

(2) It appears that calculations were not performed due to an oversight or lack of time/personnel, or a combination of these factors, on part of the Radiation Safety Officer (RSO) at the time.

(3) See the reply to D. 10CFR35.205(c) (3) of this correspondence. In addition, airborne concentration of Xenon-133 in Room 626D (restricted area) and in release to unrestricted areas were calculated by our current RSO and Health Physics Consultant according to the model procedures published in Regulatory Guide 10.8, Revision 2 (Appendix 0.1 and Appendix 0.2). A record of the calculations, to include assumptions and measurements, shall be retained for the duration of use of Room 626D if the Amendment Request is granted.

(4) Room 626D will not be used for radioactive aerosols or gases unless the Amendment Request referred to in (3) above is granted.

(5) The use of Xenon-133 in Room 626D was terminated on December 14, 1990.

M. 10CFR35.13(e)

(1) Radioactive Xenon gas had been used in Room 626D without applying for or receiving a License Amendment.

(2) A License Amendment to use Room 626D for radioactive Xenon gas was apparently not submitted through an oversight or lack of time/personnel, or a combination of these factors, on part of the Radiation Safety Officer (RSO) at the time.

(3) An Amendment Request for the "Use of Xenon-133 Gas for Pulmonary Ventilation Studies in Room 626D" dated February 19, 1991, has been submitted to the NRC under separate cover. Room 626D will not be used for radioactive aerosols or gases unless the Amendment Request is granted. (See the Reply for ITEM D. 10CFR35.205(c) (3).

(4) See the Reply for ITEM D 10CFR35.205(c) (4).

(5) See the Reply for ITEM D 10CFR35.205(c) (5).

N. 10CFR35.50(e)(3)

(1) As of November 21, 1990, records of the quarterly dose calibrator linearity tests did not contain the serial number of the dose calibrator nor the signature of the Radiation Safety Officer (RSO).

(2) It appears that the RSO at the time was unaware that his review and signature were required; the omission of the serial number on the records was an oversight.

(3) The Nuclear Medicine Technologists, who perform the tests, have been reminded to have the RSO review and sign future test records. Serial numbers have been added to all the records to date.

(4) The Nuclear Medicine Technologists, who perform the tests, the Chief of Nuclear Medicine Service (also the most recent RSO), and the current RSO have been informed of the requirements of 10CFR35.50(b)(3) and (e)(3).

(5) Full compliance will be achieved at the time of the next scheduled Linearity Tests on February 25, 1991.

O. 10CFR35.50(e)(1)

(1) The Department of Veterans Affairs Medical Center's (DVAMC's) findings, with respect to records of daily constancy checks and inclusion of the model and serial numbers for each dose calibrator, showed that 10CFR35.50(b)(1) and (e)(1) requirements have been met to date.

(2) The violation is denied since past dose calibrator records did fulfill the 10CFR35.50(b)(1) and (e)(1) requirements.

(3)(4)(5) No action required.

P. 10CFR35.50(e)(4)

(1) As of November 21, 1990, the records of tests for dose calibrator geometrical dependence did not include the serial number of the dose calibrator nor the signature of the Radiation Safety Officer (RSO).

(2) It appears that the RSO at the time was not aware that his review and signature were required; the omission of the serial number on the records was an oversight.

NOTE: It does appear from previous records that the dose calibrators were tested for geometry dependence upon installation (or at least subsequent to installation), as required by 10CFR35.50(b)(4) and reviewed and signed by the then RSO as required by 10CFR35.50(e)(4).

(3) Serial numbers have been added to all of the records to date.

(4) The Nuclear Medicine Technologists, who perform the tests, the Chief of Nuclear Medicine Service (also the most recent RSO) and the current RSO have been informed of the requirements of 10CFR35.50(b)(4) and 10CFR35.50(e)(4).

(5) Full compliance will be achieved on or before March 1, 1991