The Hospital Center at Orange
188 South Essex Avenue / Orange, New Jersey 07051

Orange Memorial Hospital Unit
New Jersey Orthopaedic Hospital Unit

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

SUBJECT: REPLY TO A NOTICE OF VIOLATION

Dear Director:

The following is our response to NRC Inspection No. 89-001; Docket Nos. 30-02464 and 30-00347.

Item A Plea Not Guilty.

Comment The area was a restricted area at the end of a dead end corridor in the Department of Nuclear Medicine that is utilized only by personnel in the department. There is a radiation logo on the door and the only other access to this region is a fire door that is locked on the outside. It is used for emergency purposes only. To reach this restricted area an individual would have to pass the secretary in the department, the hot lab, all of the technicians working in the department and two offices, that of the Chief Technologist and the Nuclear Medicine Physician before this door is reached.

Action Nevertheless we are in the process of having this door equipped with a spring hinge so that the door will close and lock automatically and we anticipate that this will be in effect by 1 June 1989. In the interim we have conducted an inservice meeting with the entire nuclear medicine staff at which we stressed the importance of not allowing any non-nuclear medicine staff beyond the reception area. The physical layout of the department is adequate for such control because of the location of this door at the end of a dead end corridor. In addition to the above all waste storage boxes have had locks installed so that even when the room door is open the waste storage boxes are locked. In addition all doors to

restricted rooms in which there is no staff present will be kept locked. This has been implemented and is under the daily supervision of the Department Manager and the Nuclear Medicine Physician.

Item B Plea 1a. Guilty.

Comment There was no Department Manager-Chief Technician available at that time. The radiation safety officer was not aware of the technician's lapse during the period of time recorded.

Action At the above inservice the staff was re-instructed concerning the necessity of performing dose calibrator constancy checks on non-routine days such as Saturdays and whenever a loaner calibrator is obtained as well as on routine days. This will be checked weekly by the Department Manager and Nuclear Medicine Physician and reviewed bimonthly by the consulting physicist and the records will be checked and reported to the quarterly radiation safety meetings.

Plea 1b. Guilty.

Comment In the future the staff will notify the consulting physicist whenever the dose calibrator is sent out for repair so that he knows immediately when a "loaner" is brought into the department which will allow the necessary linearity and geometrical variations to be determined as soon as the "loaner" arrives. It should be noted that although the consulting physicist was not informed prior to his routine monthly visit, he did perform an accuracy evaluation of the loaner calibrator during this visit which was well within specification. The department uses precalibrated unit dose syringes which verify that the loaner calibrator was performing accurately.

Action In an effort to maintain increased vigilance of all mandated radiation and safety aspects of our radioactive materials license, we have increased the visits of our consulting physicist to twice per month. In addition we now have a full time fully qualified and experienced Department Manager/Chief Technologist.

Plea 2. Guilty.

Comment Guilty for the February 2, 1989 violation of technologist who has been given a disciplinary notice which has been put in his personal file and who has since resigned and will be leaving the department effective May 12, 1989.

Action In addition we have made a ministerial change in our license so that we will open packages in accordance with the procedures of Appendix L of the Regulatory Guide 10.8, Revision 2, August, 1987 (see attached.)

We have conducted an inservice with the staff concerning all phases of Appendix L. Department Manager/Chief Technologist will monitor technologists and report to radiation safety officer concerning compliance.

New employees will immediately be instructed and monitored by the Chief Technologist.

Plea 3. Guilty.

Comment Guilty to the February 2, 1989 violation by the same technologist as mentioned under Item B2. We have made a ministerial change to our license in which radioactive materials would be used in accordance with the procedure in Appendix I of the Regulatory Guide 10.8, Revision 2, August, 1987 (see attached.)

Action We have conducted and will continue to conduct an inservice with the staff concerning all phases of Appendix I.

Plea 4. Guilty.

Comment Guilty of Saturday violations from December 3, 1988 through February 28, 1989 at a time when we had no Chief Technologist and the consulting physicist and radiation safety officer were unaware of the lapse in technique of the Saturday technologists who were not doing quality control.

We have made a ministerial change to our license in which area surveys will be performed in accordance with the procedure of Appendix N, Regulatory Guide 10.8, Rev. 2 August, 1987 (see attached.)

Action — We have conducted and will continue to conduct an inservice for the staff concerning all phases of Appendix N in which it was stressed that surveys must be performed on non-routine days, such as Saturdays, Sundays or Holidays as well as weekdays. The recommended action levels of the Table N-1 were discussed in detail during the above mentioned inservice.

The Department Manager/Chief Technologist is monitoring weekly and reporting to the radiation safety officer immediately if violations occur.

It should be noted that if background values were subtracted from recorded values that all past values were within guide line requirements.

Plea — 5. Guilty.

Comment — Guilty due to change of employees and passage of time since 1979. We will review our license on an annual basis in the future.

Action — We have made a ministerial change to our license to change the frequency of xenon trap monitoring from weekly to monthly.

If any of the above items need further clarification please notify us. Both of our goals are the same, which is to operate a first class Nuclear Medicine Department in which all phases of our operation are in full compliance with federal and state requirements.

Yours very truly,

WNM:jmb

WADE N. MILLER, M.D.
DIRECTOR
DEPARTMENT OF NUCLEAR MEDICINE

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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APPENDIX L

Model Procedure for Safely Opening Packages Containing Radioactive Material
(See §§ 35.23, 30.51, 20.203(f)(4), and 20.205.)

You may use the following model procedure for opening packages. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2."

If you develop your own package opening procedure for review, you should consider for inclusion all the features in the model. Say on your application, "We have developed a package opening procedure for your review that is appended as ATT 10.7," and append your package opening procedure.

MODEL PROCEDURE

1. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in paragraph 20.205(b) of 10 CFR Part 20 (e.g., more than 20 curies of Mo-99, Tc-99m, uncompressed Xe-133, or more than 3 curies of Xe-133, I-131, Cs-137, Ir-192, I-125, or more than 0.001 curie of Ra-226). Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). The NRC Regional Office must be notified if removable contamination exceeds 0.01 microcurie (22,000 dpm)/100 cm^2.

2. For packages received under the specific license, the following procedure for opening each package will be followed:

   a. Put on gloves to prevent hand contamination.

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

   c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface (see § 71.4 of 10 CFR Part 71); the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour at the package surface. (See § 172.403 of 49 CFR Part 172.))

   d. Open the package with the following precautionary steps:

      (1) Remove the packing slip.

(2) Open the outer package following the supplier's instructions, if provided.

(3) Open the inner package and verify that the contents agree with the packing slip.

(4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

(5) If anything is other than expected, stop and notify the RSO.

e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. [The licensee should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.] Take precautions against the potential spread of contamination.

f. Check the user request to ensure that the material received is the material that was ordered.

g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.

(1) If contaminated, treat this material as radioactive waste.

(2) If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.

h. Make a record of the receipt.

3. For packages received under the general license in § 31.11, the following procedure for opening each package will be followed:

a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.

b. Check to ensure that the material received is the material that was ordered.

See Exhibit 12 for a sample record form you may want to use.

APPENDIX I

Model Rules for Safe Use of Radiopharmaceuticals
(See § 35.21.)

You may use the following model rules as they appear here, saying on your application, "We will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own rules for safe use of radiopharmaceuticals for review. If you do so, you should consider for inclusion all the items in the model rules and carefully review the requirements of Part 35. Say on your application, "We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as ATT 10.4," and append your model rules for the safe use of radiopharmaceuticals.

MODEL RULES

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with a crystal probe or camera.

4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.

7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.

8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.

9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

10. Never pipette by mouth.

11. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.

12. With a radiation detection survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.

14. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it is more than 10 percent off from the prescribed dosage, except for prescribed dosages of less than 10 microcuries. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.

15. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.

16. Because even sources with small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

APPENDIX N

Model Procedure for Area Surveys
(See § 35.70.)

You may use the following model procedure to perform area surveys. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of § 35.70. Say on your application, "We have developed survey procedures for your review that are appended as ATT 10.12," and append your survey procedures.

MODEL PROCEDURE

Ambient Dose Rate Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.

   c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.

   d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurement survey meter.

2. Immediately notify the RSO if you find unexpectedly high or low levels.

Removable Contamination Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.

c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200 dpm/100 cm^2 for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm) to disintegrations per minute or dpm.

3. Immediately notify the RSO if you find unexpectedly high levels.

Records

1. Keep a record of dose rate and contamination survey results. It must include the following information:

   a. The date, area surveyed, and equipment used.

   b. The name or initials of the person who made the survey.

   c. A drawing of the areas surveyed with contamination and dose rate action levels as established by the RSO. (Recommended removable surface contamination action levels are published in Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions." See Regulatory Guide 8.23 or Table N-1 below for guidance in establishing your action levels.)

   d. Measured dose rates in mR/hr or contamination levels in dpm/100 cm^2, as appropriate.

   e. Actions taken in the case of excessive dose rates or contamination and followup survey information.

2. The RSO will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

The following information is not part of the model procedure.

See Exhibit 16 for a sample record form.

Table N-1

Recommended Action Levels in dpm/100 cm^2 for Surface Contamination by Radiopharmaceuticals

	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
1. Unrestricted areas, personal clothing	200	2,000
2. Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000