March 10, 1986

W. L. Axelson, Chief Nuclear Materials Safety and Safeguards Branch U.S. Nuclear Regulatory Commission 799 Roosevelt Road Glen Ellyn, Illinois 60137

Re: Lic. #34-16763-01

Dear Mr. Axelson:

Enclosed please find the responses and corrective actions we have taken pursuant to your inspection conducted on January 15, 1986. The following paragraphs correspond numerically to the items in that letter.

- The Medical Isotopes Committee shall meet at least quarterly, more often if necessary. We will try to arrange these meetings to coincide with our visiting consultants (Nuclear Medicine Associates, Cleveland, Ohio) if possible.
- 2. Please refer to Supplement A attached.
- No food, drink, or personal items shall be consumed or stored within the Nuclear Medicine Department. Periodic checks for compliance with this statement will be performed by our visiting consultants.
- 4. All survey instruments will be calibrated at least annually by our visiting consultants. Calibration certificates shall be maintained on file within the Nuclear Medicine Department.
- 5. The dose calibrator willbe calibrated as follows:
 - A. Sealed sources will be used to e ablish accuracy. They will consist of:

Nuclide	Suggested Activity	Activity (mCi)	Accuracy
Co-57	3 - 5 mCi	1 mCi or more	Within ± 5%
Ba-133	0.1 - 0.5 mCi	100 uCi or more	Within ± 5%
Cs-137	0.1 - 0.3 mCi	100 uCi or more	Within ± 5%

- B. The accuracy of the assay of the above standards will be at least ± 5% and traceable to National Bureau of Standard sources.
- C. The dose calibrator will be checked for accuracy at annual intervals and following repair using sealed sources having energies which encompass that portion of the spectrum of energies for which the

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dose calibrator is used. Nuclides that will be used are listed in Item 1 above.

- D. The activity displayed by the dose calibrator must agree with the stated assay within ± 5% of the limits of the standard's calibration accuracy. If the unit displays readings with an error greater than ± 5%, arrangements will be made for immediate repair or adjustment.
- E. The dose calibrator will be checked for constancy each day of use. This will be accomplished using a Cs-137 standard. The sealed source will be placed in the chamber and the unit set to measure that nuclide. The activity displayed with background and decay considered, must fall within ± 5% of the predicted activity based on the balue obtained at the time of the original accuracy test.
- F. The daily constancy check will be extended to include verification of displayed activities using the same standard but with the dose calibrator set to measure each of the different nuclides to be assayed on that day. With background and decay considered, variation in displayed activities must fall within ± 5% of the activity shown at the time of the most recent accuracy check. If variations greater than ± 5% are noted, arrangements will be made for immediate repair or adjustment.
- G. The dose calibrator will be checked for activity linearity at quarterly intervals and following repair. This test will be performed using the maximum dose received from a Radiopharmacy.

By following the above described procedure, along with help from Nuclear Medicine Associates, future problems in this area should not occur.

- 6. A wipe of all final source containers, as described in Appendix F of our current license, will be performed. Records of such wipes shall be maintained on file within the Nuclear Medicine Department.
- 7. All personnel preparing, assaying, and injecting radiopharmaceuticals have now been issued both whole body and TLD finger badges. Every effort will be made to ensure all individuals involved utilize monitoring devices (film badges) whenever radiopharmaceuticals are being used.
- 8. Daily, weekly, and monthly surveys shall be performed starting immediately. All records shall be maintained on file. Please be advised we are in the process of amending our license. This amendment action will reflect a more realistic Radiation Safety Program compatible with our institution.

In addition to correcting the noted violations, we, the hospital management have acquired the services of a health phsics consulting group; presently, Nuclear Medicine Associates of Cleveland, Ohio. We feel adequate management and control of licensed activities can and will be monitored more closely. An amendment application is presently being prepared in order to update changes pending within our Nuclear Medicine Department.

W. L. Axelson, Chief

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Thank you for your consideration in these matters. If you need further information, please feel free to contact either myself or our health physics consultants, Nuclear Medicine Associates, 9700 Garfield Boulevard, Cleveland, Ohio, 44125 (216) 641-5799.

Sincerely,

Neil Gilman Administrator

NG: jmb

Attachment

PERSONNEL TRAINING PROGRAM

In accordance with Section 19.12 of 10 CFR, Part 19, the following is a description of the training required for all personnel who work with or in the vicinity of radioactive materials:

- 1. The nuclear medicine department will be staffed by individuals who will be classified as occupational employees. These individuals will perform their duties from the radiation safety viewpoint under the direction of the physician(s) named on the license application.
- 2. Every effort will be made to hire nuclear medicine technology registered or registry eligible personnel to work with radioactive material. Orientation of such personnel for a day or two by the physician(s) named on the license and/or by the supervising technologist will include the following:
 - Indicate areas where radioactive materials are used or stored.
 - b. Potential hazards associated with radioactive materials.
 - Radiological safety procedures appropriate to their respective duties.
 - d. Pertinent NRC regulations.
 - e. The rules and regulations of the license.
 - f. The pertinent terms of the license.
 - g. Their obligation to report unsafe conditions.
 - h. Appropriate response to emergencies or unsafe conditions.
 - i. Their right to be informed of their radiation exposure and bioassay results.
 - j. Location where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions), as required by 10 CFR, Part 19.

If evaluation of the radiation handling techniques of a new technologist is found to be inadequate, arrangements will be made to send the employee for a 40 hour formal course from our consulting physicists, Nuclear Medicine Associates, Cleveland, Ohio. This course combines didactic and clinical training which will include points "b" through "i" listed above, as well as quality control and patient procedures.

- 3. Our consulting physicists, mentioned in this addendum, will visit our facility quarterly to review all procedures, equipment and records. Personnel will receive refresher training relative to duties, regulations, or terms of the license during these visits or by the physician(s) named on this license application, or by supplementary training at least annually or more frequently, as needed.
- 4. Access into areas where radioactive material is stored or used will be restricted for nonoccupational personnel. When it is necessary for nonoccupational personnel to enter these areas, as in the case of certain patients who need special care, personnel so involved will be present under the direction of the nuclear medicine technologist, who will ensure that the exposure of these persons is held to the minimum required for the performance of the nuclear medicine procedure. Further, all nonoccupational personnel will receive instruction as to the location and potential hazards associated with radioactive material during their orientation process and annually thereafter in the form of verbal instructions and/or interdepartment memos.