DCD/DCB

DeKalb Memorial Hospital, Inc.

East Seventh Street
Auburn, Indiana 46706
(219) 925-4600

October 23, 1989

30-13805

U.S. NUCLEAR REGULATORY COMMISSION License No. 13-18506-01
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

Gentlemen:

This refers to the letter and accompanying notice dated September 26, 1989. The following is our response to the letter and Mr. W.P. Reichhold's July 26, 1989 safety inspection.

VIOLATION ONE: 10 CFR 35.22 (a) (1) and 10 CFR 35.22 (a) (3). Membership of the Radiation Safety Committee does now include a nursing and management representative. Their attendance at the RSC meeting is noted in the minutes. Alternate members have been identified in case of member's illness or vacation. Memos will be sent to all members one week prior to the meeting, notifying them of the time and place, plus requesting a reply if unable to attend. Full compliance will be achieved by October 25, 1989.

VIOLATION TWO: 10 CFR 35.70 (f)
Bids have been let for a wipe test counter, Model 05-574 to be used to analyze wipe test samples and results recorded in dpm/100 cm 2. A purchase order will be issued within 30 days. The included policy and Swipe/Survey test location/ record form are evidence of our actions taken. The RSO will review each form, sign, and date each record sheet. These records will also be reviewed quarterly at the RSC meetings.

VIOLATION THREE: License Condition No. 14
All authorized users of radioactive materials have been instructed in the need to monitor their hands and clothing prior to leaving the area. Our polices have been admended and we have established and implemented the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2". These rules will be monitored by the RSO and Departmenal Director. These rules will be reviewed annually during refresher inservices. Full compliance will be achieved on October 25, 1989.

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VIOLATION FOUR: License Condition No. 14
"We have established and implemented a model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2." We submit these rules as our corrective actions although no orders of therapeutic iodine has occured since our violation. Full compliance will be achieved as of October 25, 1989.

Respectfully Submitted:

J. M. Corey
President
DeKalb Memorial Hospital
East Seventh Street
Auburn, Indiana 46706

APPENDIX I

RADIATION SAFETY COMMITTEE

1. Raymond W. Gize, M.D., Radiation Safety Officer

Head of Nuclear Medicine Department, DeKalb Memorial Hospital, Auburn, Indiana. Trained at Indiana University Medical School. Experienced with Radioisotopes since 1968. Board certified in General Radiology in 1972. Board certified by American Board of Nuclear Medicine in 1976. Clinical Fellow of the American Cancer Society 1969-1970. Member of RSNA, ACR, AAA and SNM.

2. William H. Hathaway, M.D.

Trained at Indiana University School of Medicine licensed in general practice in 1969. Member of SAMA and NARI. Currently in general practice in Auburn, Indiana and an active member of the medical staff of DeKalb Memorial Hospital.

3. John C. Harvey, M.D.

Trained at Indiana University School of Medicine. Licensed in general practice in 1962. Member of AMA and DeKalb Medical Society. Currently in general practice in Auburn, Indiana. On the active medical staff of DeKalb Memorial Hospital.

4. Marcia Blomeke, R.T., A.R.R.T.

Approved Technologist at DeKalb Memorial Hospital.

5. Deborah Claxton, R.T., A.R.R.T.

Approved Technologist at DeKalb Memorial Hospital.

6. Bruce Roach, R.T., A.R.R.T.

Radiology Director and approved Technologist at DeKalb Memorial Hospital.

7. LoAnne Bassett, R.N.

Nursing representative, Inservice Education Director at DeKalb Memorial Hospital.

8. Paul Bell

Director of Ancillary Services at DeKalb Memorial Hospital and Administrative Representative.

1.3 Administrative Information

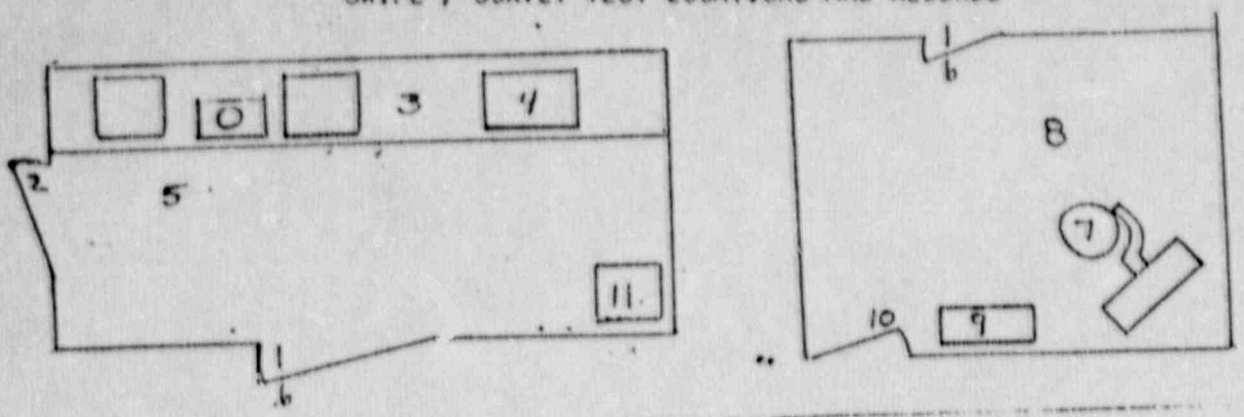
1. The Committee shall meet as often as necessary to conduct its business but not less than once in each quarter.

2. Membership must include one authorized user for each type of use authorized by the license the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Management may appoint alternate members to participate in meetings in the case of absence of principle members and should consider appointing as adjunct members representatives from maintenance, housekeeping, or any other departments deemed necessary. (Adjunct members should abstain from balloting on Radiation Safety Technical questions such as Items 2 through 5 in the "responsibilities" section above.)

3. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.

4. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as X-Ray Radiation Safety, Quality assurance oversight, and research project review and approval.

SWIPE / SURVEY TEST LOCATIONS AND RECORDS



1. MAIN DOOR TO HOT LAB
2. HOT LAB/EKG DOOR
3. HOT LAB COUNTER
4. HOT LAB SINK
5. HOT LAB DOOR
6. HOT LAB/SCAN ROOM DOOR
7. CAMERA HEAD
8. SCAN ROOM FLOOR
9. SCAN ROOM DESK
10. MAIN DOOR TO SCAN ROOM
11. GENERATOR STORAGE CABINET
12. PROTECTIVE CLOTHING, SKINN

BLACK INK=SWIPE TESTS

RED INK=SURVEY METER

DATE	1	2	3	4	5	6	7	8	9	10	11	12	IN
SURVEY	.03	.03	.03	.03	.03	.03	.03	.03	.03	.03	.03	.03	
SWIPE	2000	2000	2000	2000	2000	200	200	200	200	200	200	2000	

SURVEYS: G M METER, MODEL 6A, RECORDED IN mR/hr

SWIPES: WIPE TEST COUNTER, MODEL 05-574, RECORDED IN dpm/100cm2

RSO: _____

DATE: _____

6.2 Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures

Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Committee and/or the Radiation Safety Officer. These levels apply to the exposure of the individual workers.

	mrems per calender quarter LEVEL I	LEVEL II
Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
Hands an forearms; feet and ankles	1875	5625
Skin or Whole body	750	2250

1. Quarterly exposures of individuals to less than Investigational Level I. Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table I values for the Investigational Level I.

2. Personnel exposure equal to or greater than Investigational Level I, but less than Investigational Level II. The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. He will report the results of his reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no active related specifically to the exposure is required unless deemed appropriate by the Committee. The committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

3. Exposure equal to or greater then Investigational Level II. The RSO will investigate in a timely manner the cause (s) of all personnel exposures equaling or exceeding Investigational Level II and, if warrented, take action. A report of the Investigation, actions taken, if any, and a copy of the individual's form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the Committee minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review or the time of the next inspection.

4. Re-establishment of an individual occupational worker s Investigational Level II Above That Listed in Table I.

In cases where a worker's or a group of worker's exposure need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The Radiation Safety Committee will review the justification for, and will approve, all revisions of Investigational Levels II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed above will be followed.

RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrives between 4:30 p.m. and 7 a.m. or on weekends shall be signed for by the mainteance man on duty and taken immediately to the Nuclear Medicine Department. Obtain the key from the switchboard operator, unlock the door, place the package on top of the counter immediately in front of you, and relock the door.

If the package is wet or appears to be damaged, IMMEDIATELY contact Bruce Roach, R.T.R. (If not available call the technician who is on call for X-Ray). Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vechicle is contaminated.

BRUCH ROACH 637-3455

RSO: R.W. GIZE, M.D.

BUSINESS PHONE: 219-925-4600

HOME PHONE: 219-749-5013

3.5 RULES FOR SAFE USE OF RADIOPHARMACEUTICALS

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 ues of other protective methods such as remote delivery of the dose (e.g., through use of 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. Radiopharmaceuticals multi dose 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 preceeding information and total prepared activity, specific activity as mCi/cc at a specific 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 patients 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 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 contract, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

Appendix A

10.0 TRAINING PROGRAM

10.1 Personnel will be instructed:

1. Before assuming duties with, or in the vacinity of, radioactive materials;

2. During annual refresher training; and

3. Whenever there is a significant change in duties, regulations, of the terms of the license.

10.2 Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions;

2. Areas where radioactive material is used or stored;

3. Potential hazards associated with radioactive material in each area where employees will work;

4. Appropriate radiation safety procedures;

5. Licensee's in-house work rules;

6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer;

7. Appropriate response to emergencies or unsafe conditions;

8. Worker's right to be informed of occupational radiation exposure and bioassay results;

9. Locations where the license has been posted or made available, notice, copies of pertinent regulations, and copies of pertinent regulations, and copies of pertinent licensees and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

10. Question and answer period.

See Appendix 16 for list of personnel who will receive training and the method and frequency of training.

Appendix 16

Group identification abd training methods and frequency

1. Nursing Service

Training: Lecture for attendees, taped lecture for personnel unable to attend.

Frequency: Yearly or as necessary.

2. Housekeeping.

Training: Lecture during departmental meeting.

Frequency: Yearly or as necessary.

3. Maintenance

Training: Lecture during departmental meeting.

Frequency: Yearly or as necessary.

4. Radiology

Training: Lecture during departmental meeting.

Frequency: Yearly or as necessary.

5. New Employees

Training: Lecture or video tape.

Frequency: As necessary.

APPENDIX 17

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. Unrestriced areas, Personal Clothing	200	2,000
2. Restricted Areas, Protective Clothing used only in restricted		

GUIDANCE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIALS

5.1 1. The radiation safety officer (RSO) or a designer must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

a. For routinely used materials.

(1) Written records that identify the authorized user or department, isotope, chemical form, activity, and supplier will be made.

(2) The above records will be checked to confirm that material received was ordered through proper channels.

b. For occasionally used materials (e.g., therapeutic dosages).

(1) The authorized user who will perform the procedure will make a written request that indicates the istope, radiopharmaceutical, activity, and supplier.

(2) The person who receivee the material with check the physician's written request to confirm that the material received is what was ordered.

3. For deliveries during normal working hours, the RSO will tell carriers to deliver radioactive packages directly to a specified area.

4. For deliveries during off-duty hours, the RSO will tell maintenance personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the memorandum that follows.

MEMORANDUM

Date: October 5, 1989
To: Director of Maintenance
From: Radiation Safety Officer
Subject: Receipt of Packages containing Radioactive Material

The maintenance person on duty shall accept delivery of packages containing radioactive material that arrives during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Hot Lab. Unlock the door, place the package on top of the counter, and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the Hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our Radiation Safety Officer, Dr. R.W. Gize, at extension 1021.

	Name	Home Telephone
Radiation Safety Officer:	R.W. Gize	749-5013
Director of Radiology:	Bruce Roach	637-3455
Nuclear Medicine Tschologists:	Marcia Blomeke	925-5340
	Deb Claxton	357-5002