

WILLIAM L. PALAZZO, M.D., F.A.C.R.
DEPARTMENT OF NUCLEAR MEDICINE
SADDLE BROOK GENERAL HOSPITAL
P.O. BOX 561
SADDLE BROOK, N. J. 07662
TELEPHONE: 366-8032 9 A.M. to 12 noon
843-8400 9 A.M. to 2 P.M.

MS 12
P8

UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION I OFFICE 631 PARK AVE.
KING OF PRUSSIA, PENNSYLVANIA 19406

OCTOBER 25, 84

ATTN: JOHN E. GLENN, PH.D.
CHIEF OF NUCLEAR MATERIALS SECTION

RE: BYPRODUCT MATERIAL LICENSE 29-18240-01

MAIL CONTROL # 17556

DEAR DR. GLENN;

THIS IS IN REFERENCE TO YOUR LETTER DATED SEPTEMBER 21, 1984, IN RESPONSE TO OUR LICENSE RENEWAL. IN ANSWER TO YOUR QUESTION PLEASE NOTE THE FOLLOWING:

1. PLEASE DELETE XENON 133 FROM OUR LICENSE.
2. PLEASE DO NOT DELETE IN VITRO STUDIES FROM OUR LICENSE.
3. REGARDING ITEM 9 FROM OUR LICENSE. THE RANGE OF OUR SURVEY METER IS FROM 1 MR/HR TO 20 R/HR
[NUCLEAR CORPORATION OF AMERICA; SERIAL#1113
MODEL # CS 40].

THE RANGE OF OUR GM METER IS FROM 0.01MR/HR - 50MR/HR.
[MODEL CDV-700, SERIAL # 62621]

4. REGARDING THE MAKEUP OF THE RADIOISOTOPE COMMITTEE MEETING;
THE MEMBERS ARE AS FOLLOWS.
 - A. THE RADIATION SAFETY OFFICER, WILLIAM L. PALAZZO,
M.D., F.A.C.R.
 - B. REPRESENTING ADMINISTRATION: PAUL CARDILLO
 - C. THE REPRESENTATIVE OF THE HOSPITAL'S NURSING STAFF,
MRS. PATRICIA SIMPSON.

NOTE: SEE MAKEUP OF RADIATION SAFETY COMMITTEE ON
ORIGINAL LICENSE APPLICATION DATED MAY 15, 1984

8512230571 851105
REG1 LIC30
29-18240-01 PDR

5. EQUIVALENT PROCEDURES ATTACHED.
6. EQUIVALENT PROCEDURES ATTACHED.
7. EQUIVALENT PROCEDURES ATTACHED.

17556
"OFFICIAL RECORD COPY"

ML10

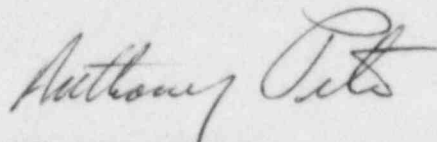
NOV 13 1984

8. RING BADGES ARE WORN BY ALL OCCUPIED PERSONNEL
9. NRC ALARA PROGRAM HAS BEEN REVIEWED AND ACCEPTED BY THE RADIATION SAFETY COMMITTEE. PLEASE FIND THE ALARA PROGRAM SIGNED AND ENCLOSED.
10. AS INDICATED PREVIOUSLY IN ANSWER TO #3 OUR SURVEY METER FROM NUCLEAR CORPORATION OF AMERICA IS CAPABLE OF MEASURING UP TO 20 R/HR.

I HOPE THE ENCLOSED INFORMATION ANSWERS ALL YOUR QUESTIONS REGARDING OUR BYPRODUCT MATERIAL LICENSE #29-18240-01.

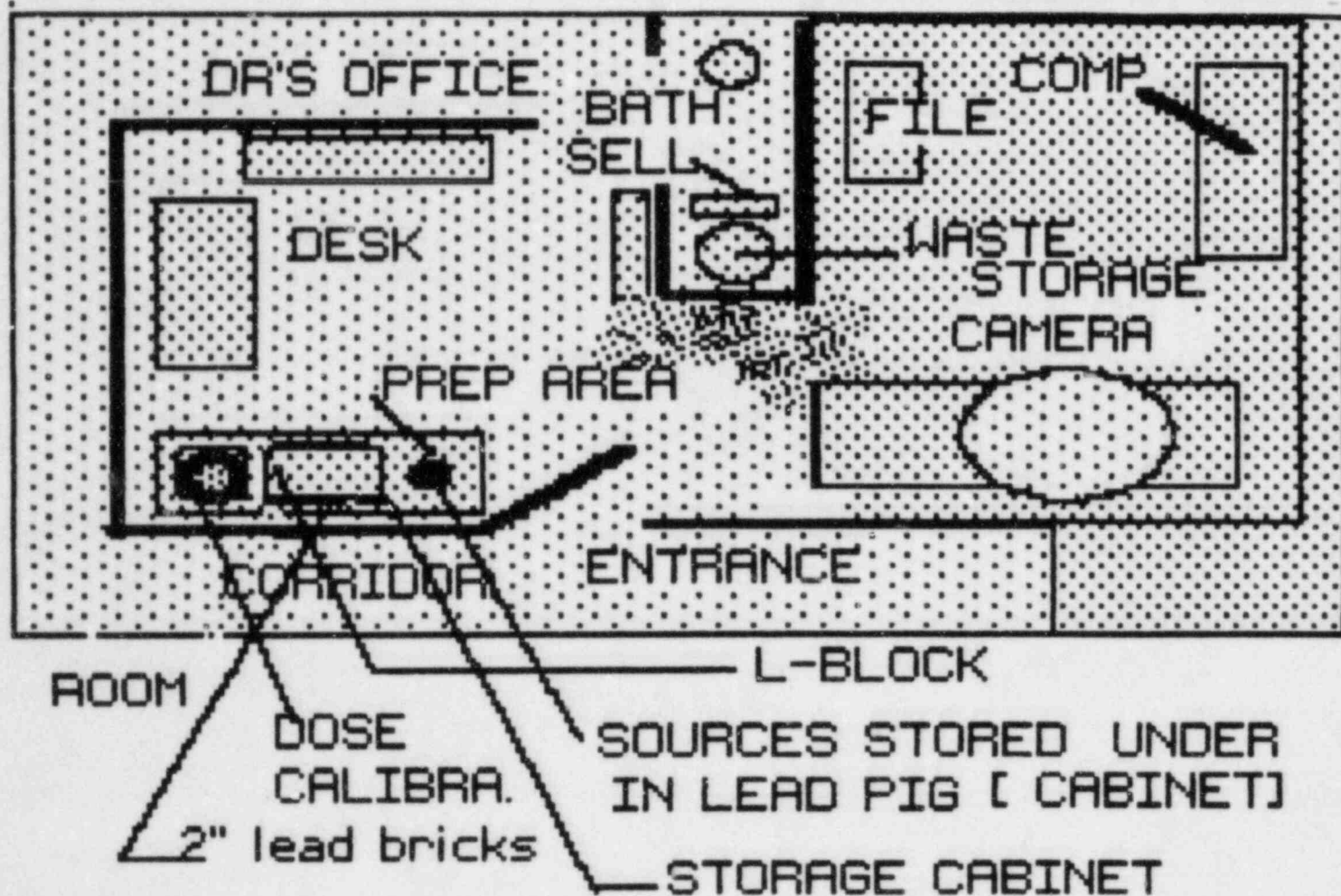
SHOULD YOU HAVE ANY QUESTIONS REGARDING THE ABOVE INFORMATION, PLEASE FEEL FREE TO CONTACT THE HOSPITAL.

SINCERELY YOURS,



ANTHONY PETERS
HOSPITAL ADMINISTRATOR

CC: WILLIAM PALAZZO, M.D., F.A.C.R.,
RADIATION SAFETY OFFICER



AUDITORS SIGNATURE _____
 DATE _____

SADDLE BROOK NUCLEAR MEDICINE DEPT

Item 11

10/25/84

SURVEY FORM REFERENCES DIAGRAM MARKED ITEM 11
SADDLE BROOK NUCLEAR MEDICINE DEPARTMENT

SURVEYOR: _____ DATE: _____

SURVEY METER: CDV 700 D.O.C. _____

SERIAL# _____ BCKG _____ MR/HR

COUNTING INSTRUMENT: _____ BCKG _____ CPM

INSTRUMENT SETTINGS:

AREAS	MR/HR	CPM	COMMENTS
ENRANCE	_____	_____	_____
CORRIDOR	_____	_____	_____
PREP AREA	_____	_____	_____
L-BCKG/FLOOR	_____	_____	_____
WASTE STORAGE	_____	_____	_____
WASTE FLOOR	_____	_____	_____
DOSE CAL.	_____	_____	_____
CAMERA	_____	_____	_____
CONSOLE	_____	_____	_____
DESK/FILE	_____	_____	_____
COMPUTER	_____	_____	_____
STAFF HANDS	_____	_____	_____

SURVEYOR'S SIGNATURE

SURVEY FORM REFERENCES DIAGRAM MARKED ITEM 11
SADDLE BROOK NUCLEAR MEDICINE DEPARTMENT

SURVEYOR: _____ DATE: _____

SURVEY METER: CDV 700 D.O.C. _____

SERIAL# _____ BCKG _____ MR/HR

COUNTING INSTRUMENT: _____ BCKG _____ CPM

INSTRUMENT SETTINGS:

AREAS	MR/HR	CPM	COMMENTS
ENRANCE	_____	_____	_____
CORRIDOR	_____	_____	_____
PREP AREA	_____	_____	_____
L-BLOCK/FLOOR	_____	_____	_____
WASTE STORAGE	_____	_____	_____
WASTE FLOOR	_____	_____	_____
DOSE CAL.	_____	_____	_____
CAMERA	_____	_____	_____
CONSOLE	_____	_____	_____
DESK/FILE	_____	_____	_____
COMPUTER	_____	_____	_____
STAFF HANDS	_____	_____	_____

SURVEYOR'S SIGNATURE

REGARDING ITEM 12 AND 13 OF NRC FORM 313M DESCRIPTION OF FACILITY:

PERSONNEL TRAINING PROGRAM

INSTRUCTIONS FOR HOUSEKEEPING OR NURSING OR ANY OTHER NON-OCCUPATIONAL PERSONNEL FREQUENTING THE NUCLEAR MEDICINE DEPARTMENT.

1. MINIMIZE THE TIME YOU MUST SPEND ACHIEVING THE PURPOSE FOR WHICH YOU HAVE COME TO THE DEPARTMENT.
2. DO NOT STAND ANY CLOSER TO PATIENTS THAN NECESSARY.
3. DO NOT ENTER THE HOT LAB WITHOUT TECHNICAL ASSISTANCE.
4. READ ALL DEPARTMENT POLICY AND REQUIREMENTS REGARDING FOOD, ETC., IN THE DEPARTMENT - FOLLOW THE REGULATIONS.
5. FOLLOW TECHNICIANS INSTRUCTIONS REGARDING BEST LOCATION FOR INITIATING OR CARRYING OUT YOUR PURPOSE IN THE DEPARTMENT.
6. DO NOT HANDLE ANY SYRINGES THAT YOU DID NOT BRING TO THE DEPARTMENT.
7. DO NOT DISPOSE OF ANY WASTE FROM THE ROOM INDICATED AS THE "HOT LAB" WITH THE "CAUTION RADIOACTIVE MATERIALS" SIGN.
8. DO NOT DISCARD ANY PACKAGES WITHOUT FIRST CHECKING WITH TECHNICIANS.
9. DO NOT WANDER AIMLESSLY - GO ONLY TO THOSE ROOMS IN WHICH YOU HAVE BEEN TOLD TO GO BY DEPARTMENT PERSONNEL.
10. IF YOU HAVE ANY QUESTIONS ASK FIRST, THEN ACT.

REGARDING ITEM # 13:

PROCEDURES FOR ORDERING AND RECEIPT OF RADIOACTIVE MATERIALS

A. ORDERING

PERSONNEL ORDERING RADIOACTIVE MATERIALS WILL ORDER ONLY THOSE AND THE AMOUNTS AUTHORIZED BY THEIR LICENSE (S) FROM A MANUFACTURER/DISTRIBUTOR WHO HOLDS A VALID NRC LICENSE. THE PERSON ORDERING WILL HAVE AN ADEQUATE CURRENT KNOWLEDGE OF THE DEPARTMENT INVENTORY AS TO PREVENT EXCEEDING THE POSSESSION LIMITS. ONLY PERSONNEL AUTHORIZED TO PLACE ORDERS BY THE RADIATION SAFETY OFFICER CAN MAKE REQUESTS TO MANUFACTURERS.

B. RECEIPT

1. DURING NORMAL WORKING HOURS CARRIERS WILL BE INSTRUCTED TO DELIVER RADIOACTIVE PACKAGES DIRECTLY TO THE DEPARTMENT DESIGNATED ON THE PACKAGE. IF NO DEPARTMENT IS DESIGNATED, IT WILL BE BROUGHT TO NUCLEAR MEDICINE.
2. DURING OFF-DUTY HOURS SECURITY (OR REASONABLE FACSIMILE) PERSONNEL, WHO HAS BEEN ADEQUATELY BRIEFED ON THE HAZARDS (AS DESCRIBED IN ITEM 12) WILL ACCEPT DELIVERY AND BRING THE PACKAGE IMMEDIATELY TO THE NUCLEAR MEDICINE DEPARTMENT. HE WILL UNLOCK THE DEPARTMENT'S HOT LAB AND PLACE THE PACKAGE INSIDE. IN THE EVENT THIS IS NOT POSSIBLE, HE WILL AT LEAST LOCK THE PACKAGE INSIDE THE NUCLEAR MEDICINE DEPARTMENT PROPER.
3. THE TECHNOLOGIST ARRIVING ON DUTY THEN ASSUMES DELIVERY AS DESCRIBED IN ITEM 14.

SEE INSTRUCTION SHEET FOR SECURITY OR OTHER PERSONNEL RECEIVING PACKAGES ATTACHED.

INSTRUCTION TO SECURITY AND OTHER NON-OCCUPATIONALLY EXPOSED
HANDLING RADIOISOTOPE PACKAGES IN THE HOSPITAL.

IT HAS BEEN DETERMINED THAT PERSONNEL FOLLOWING THESE INSTRUCTIONS WILL RETAIN THEIR NON-OCCUPATIONAL STATUS; HOWEVER, IF IT IS DETERMINED THAT THE VOLUME OF SERVICE NECESSITATES CHANGING YOU TO OCCUPATIONAL STATUS, FILM BADGES WILL BE SUPPLIED, AT LEAST FOR A 3 MONTH TRIAL BASIS TO JUSTIFY EXISTENCE OF THE NECESSITY.

INSTRUCTIONS:

1. COURIER WILL HAVE SECURITY PAGED TO PICK-UP PACKAGES AND DELIVER THEM TO NUCLEAR MEDICINE.
2. IN GENERAL YOU WILL MINIMIZE YOUR EXPOSURE TO RADIO-ISOTOPES BY MAXIMIZING YOUR DISTANCE FROM THEM (USE A REMOTE CARRYING DEVICE AS OPPOSED TO CARRYING BY HAND).
3. THE LEAST TIME YOU SPEND DOING THE JOB CAREFULLY, OF COURSE, THE LESS EXPOSURE YOU WILL HAVE.
4. THE PACKAGES ARE ADEQUATELY SHIELDED SO THAT THEY WILL NOT OVEREXPOSE YOU IF YOU CARRY 10 OF THEM AT A DISTANCE OF 1 YARD FOR 4 HOURS PER MONTH OR CARRY 10 OF THEM IN YOUR HANDS FOR 10 MINUTES PER MONTH.
5. ANY ADDITIONAL LEAD-SHIELDING SURROUNDING THE PACKAGE WILL, OF COURSE, REDUCE THIS EXPOSURE.
6. IF PACKAGE LOOKS PHYSICALLY DAMAGED, DAMP, WET, AND IS SUSPECTED TO BE LEAKING, PUT ON DISPOSABLE RUBBER GLOVES, PLACE PACKAGE IN A PLASTIC BAG, REMOVE RUBBER GLOVES, AND PLACE THEM IN THE BAG, SECURE THE BAG'S TOP, NOTIFY THE RADIATION SAFETY OFFICER LISTED BELOW IMMEDIATELY, AND DO NOT TRANSPORT PACKAGE TO THE NUCLEAR MEDICINE DEPARTMENT.
7. IF A CARRIER DELIVERS A DAMAGED OR LEAKING PACKAGE, INSTRUCT CARRIER TO REMAIN FOR MONITORING AND DECONTAMINATION UPON ARRIVAL OF THE RADIATION SAFETY OFFICER.
8. IF PACKAGE INTEGRITY IS NORMAL, DELIVER TO NUCLEAR MEDICINE DEPARTMENT OR DEPARTMENT OF ADDRESSEE.
9. UNLOCK HOT LAB DOOR, PLACE BOX ON FLOOR INSIDE DOOR, RELOCK DOOR, AND RETURN TO YOUR PREVIOUS ASSIGNMENT.

RADIATION SAFETY OFFICER: WILLIAM PALAZZO, M.D.

INSTRUCTIONS FOR PERSONNEL OPENING AND MONITORING PACKAGES
CONTAINING RADIOACTIVE MATERIALS

1. THE PACKAGE ONCE IT IS RECEIVED BY THE NUCLEAR MEDICINE DEPARTMENT SHOULD BE VISUALLY INSPECTED FOR ANY SIGNS OF DAMAGE (E.G. WETNESS, CRUSHED). IF DAMAGE IS NOTED, IMMEDIATELY NOTIFY THE RADIATION SAFETY OFFICER. IF PACKAGE IS IN ACCEPTABLE CONDITION, LOG APPROPRIATE IDENTIFICATION IN PACKAGE MONITORING LOG BOOK (SEE ATTACHED SAMPLE "PACKAGE MONITORING LOG SHEET").
2. THE PACKAGE SHALL BE MONITORED AS SOON AS PRACTICABLE AFTER RECEIPT, BUT NO LATER THAN THREE HOURS AFTER THE PACKAGE IS RECEIVED DURING NORMAL WORKING HOURS, OR EIGHTEEN HOURS IF RECEIVED AFTER NORMAL WORKING HOURS.
3. THE TECHNICIAN MUST WEAR RUBBER GLOVES PRIOR TO AND DURING THE OPENING OF THE PACKAGE.
4. BEFORE OPENING THE PACKAGE, THE G.M. SURVEY METER SHOULD BE TURNED ON AND SET ON THE 0-500 MREM/HOUR RANGE. ALL SIX SIDES OF THE PACKAGE SHOULD BE MONITORED AT THE SURFACE (IF NECESSARY REDUCE RANGE ON SURVEY METER TO ENABLE A MORE ACCURATE ASSESSMENT OF EXPOSURE RATE). THE MAXIMUM METER READING SHOULD BE LOGGED IN THE PACKAGE MONITORING LOG BOOK. IF ANY READING IS IN EXCESS OF 200 MREM PER HOUR, THE PACKAGE SHOULD IMMEDIATELY BE PLACED IN THE LEAD STORAGE AREA, BEHIND THE LEAD AND THE RADIATION SAFETY OFFICER NOTIFIED.
5. AN AREA OF NOT LESS THAN 100 CM² OF EXTERNAL PACKAGE SURFACE SHALL BE WIPED WITH ABSORBENT PAPER AS SPECIFIED IN 10 CFR 20.205 (B) (1). IF THE WIPE IS FOUND TO REMOVE CONTAMINATION, THE RADIATION SAFETY OFFICER SHOULD BE NOTIFIED. THE RESULTS OF THE WIPE TEST SHALL BE LOGGED IN THE PACKAGE MONITORING LOG BOOK.
6. IF THE PACKAGE IS BELOW 200 MREM/HOUR AND EXTERIOR SURFACE NONCONTAMINATED, THE PACKAGE SHOULD BE OPENED CAREFULLY AND THE PACKING MATERIAL VISUALLY INSPECTED FOR STAINS, WETNESS OR ANY UNUSUAL MARKINGS. EACH SOURCE CONTAINER SHALL BE WIPE TESTED FOR CONTAMINATION BEFORE HANDLING. IF ANY OF THESE CONDITIONS ARE NOT MET, THE PACKAGE SHOULD BE PLACED IN THE LEAD CAVE AND THE RADIATION SAFETY OFFICER NOTIFIED.

7. ONCE THE EXTERIOR AND PACKING MATERIAL OF THE PACKAGE HAS BEEN FOUND TO BE IN ORDER, THE VIAL IN THE LEADED CONTAINER SHOULD BE INSPECTED TO ASSURE THE VIAL HAS NOT BEEN BROKEWN IN SHIPPING. THE SHIELDING CONTAINER SHOULD BE CAREFULLY OPENED AND VISUAL INSPECTION OF THE VIAL IN THE CONTAINER SHOULD BE MADE TO ASSURE THE VIAL INTACTNESS. ONCE THE VIAL HAS BEEN FOUND TO BE INTACT, THE CONTAINER AND THE VIAL SHOULD BE STORED IN ITS PROPER PLACE, I.E., THE REFRIGERATOR OR LEAD STORAGE CAVE.
8. VERIFY THAT THE PACKAGE CONTENTS MATCH THE WRITTEN REQUEST FOR THE RADIOACTIVE DRUG, AND THE PACKING SLIP SUPPLIED BY THE MANUFACTURER. "LOG" RESULT OF THIS CHECK.
9. BEFORE DISCARDING, THE EMPTY PACKAGE AND PACKING MATERIAL SHALL BE MONITORED WITH THE G.M. SURVEY METER TO ASSURE THEY ARE NOT CONTAMINATED. THE RADIATION LABELS SHALL BE REMOVED BEFORE DISCARDING IN THE REGULAR TRASH.

ITEM 14
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LABORATORY RULES FOR THE USE OF
RADIOACTIVE MATERIAL

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. MONITOR HANDS, FEET, AND CLOTHING FOR CONTAMINATION AFTER EACH GENERATOR ELUTION AND RADIOPHARMACEUTICAL KIT PREPARATION, AND AFTER EACH DOSE PREPARATION/ADMINISTRATION OR BEFORE LEAVING THE AREA WITH THE GM SURVEY METER. LOG THE METER READINGS.
4. USE SYRINGE SHIELDS FOR PREPARATION OF PATIENT DOSES AND ADMINISTRATION TO PATIENTS EXCEPT IN CIRCUMSTANCES, SUCH AS PEDIATRIC CASES, WHERE THEIR USE WOULD COMPROMISE THE PATIENT'S WELL-BEING.
5. DO NOT EAT, DRINK, SMOKE OR APPLY COSMETICS IN ANY AREA WHERE RADIOACTIVE MATERIAL IS STORED OR USED.
6. ASSAY EACH PATIENT DOSE IN THE DOSE CALIBRATOR PRIOR TO ADMINISTRATION. DO NOT USE ANY DOSES THAT DIFFER FROM THE PRESCRIBED DOSE BY MORE THAN 10%.
7. WEAR PERSONNEL MONITORING DEVICES (FILM BADGE OR TLD) AT ALL TIMES WHILE IN AREA WHERE RADIOACTIVE MATERIALS ARE USED OR STORED. THESE SHOULD BE WORN AT CHEST OR WAIST LEVEL.
8. WEAR TLD FINGER BADGES DURING ELUTION OF GENERATOR AND PREPARATION, ASSAY, AND INJECTION OF RADIOPHARMACEUTICALS.
9. DISPOSE OF RADIOACTIVE WASTE ONLY IN SPECIALLY DESIGNATED RECEPTACLES. SURVEY RECEPTACLES DAILY TO ASSURE EXPOSURE LEVELS ARE LESS THAN 2.0 mR/HR. IN RESTRICTED AREAS AND LESS THAN 0.2mR/HR. IN NON-RESTRICTED AREAS.
10. NEVER PIPETTE BY MOUTH.
11. SURVEY GENERATOR, KIT PREPARATION, AND DOSE PREPARATION AREAS AFTER EACH PROCEDURE OR AT THE END OF THE DAY WITH GM SURVEY METERS, AND LOG READINGS. IF NECESSARY, REPOSITION SOURCES AND/OR SHIELDING TO MAINTAIN EXPOSURE LEVELS LESS THAN 2.0 mR/HR. ALSO PERFORM A WIPE TEST FOR EACH AREA LISTED ABOVE AND LOG RESULTS. DECONTAMINATION PROCEDURES ARE WARRANTED IF REMOVABLE CONTAMINATION FOUND ON ANY WIPE YIELDS A LARGER THAN BACKGROUND READING ON THE GM SURVEY METER WITH THE WINDOW OPEN.

12. CONFINE RADIOACTIVE SOLUTIONS IN COVERED CONTAINERS PLAINLY IDENTIFIED AND LABELLED WITH NAME OF COMPOUND, RADIONUCLIDE, DATE, ACTIVITY, AND RADIATION LEVEL IF APPLICABLE.
13. ALWAYS TRANSPORT RADIOACTIVE MATERIAL IN SHIELDED CONTAINERS.
14. ALWAYS USE DISPOSABLE COVERINGS (WITH PLASTIC BACKING) WHERE RADIOACTIVE MATERIALS IN SOLUTION ARE PREPARED.
15. ALWAYS USE REMOTE HANDLING TONGS WHEN HANDLING OR ASSAYING UNSHIELDED SOURCES, ESPECIALLY IF IN QUANTITIES GREATER OR EQUAL TO PATIENT DOSES. THIS IS EXTREMELY IMPORTANT FOR THE ELUTION OF A GENERATOR.

EMERGENCY PROCEDURES

MINOR SPILLS:

1. NOTIFY: NOTIFY PERSONS IN THE AREA THAT A SPILL HAS OCCURRED.
2. PREVENT THE SPREAD: COVER THE SPILL WITH ABSORBENT PAPER.
3. REPORT: REPORT INCIDENT TO THE RADIATION SAFETY OFFICER.
4. CLEAN UP: USE DISPOSABLE GLOVES AND REMOTE HANDLING TONGS. CAREFULLY FOLD THE ABSORBENT PAPER AND PAD. INSERT INTO A PLASTIC BAG AND DISPOSE OF IN THE RADIOACTIVE WASTE CONTAINER. INCLUDE ALL OTHER CONTAMINATED MATERIALS SUCH AS DISPOSABLE GLOVES.
5. SURVEY: WITH A G.M. SURVEY METER, CHECK THE AREA AROUND THE SPILL, YOUR HANDS AND CLOTHING FOR CONTAMINATION. PERFORM A WIPE TEST TO ASSURE THE ABSENCE OF REMOVABLE CONTAMINATION BEFORE RESUMING NORMAL OPERATIONS. LOG SURVEY AND WIPE TEST RESULTS AND OTHER RELATED INFORMATION ON THE INCIDENT FOR LABORATORY RECORDS.

MAJOR SPILLS:

1. CLEAR THE AREA: NOTIFY ALL PERSONS NOT INVOLVED IN THE SPILL TO VACATE THE ROOM.
2. PREVENT THE SPREAD: COVER THE SPILL WITH ABSORBENT PADS, BUT DO NOT ATTEMPT TO CLEAN IT UP. CONFINE THE MOVEMENT OF ALL PERSONNEL POTENTIALLY CONTAMINATED TO PREVENT THE SPREAD.
3. SHIELD THE SOURCE: IF POSSIBLE, THE SPILL SHOULD BE SHIELDED, BUT ONLY IF IT CAN BE DONE WITHOUT FURTHER CONTAMINATION OR WITHOUT SIGNIFICANTLY INCREASING YOUR RADIATION EXPOSURE.
4. CLOSE THE ROOM: LEAVE THE ROOM AND LOCK THE DOOR(S) TO PREVENT ENTRY.
5. CALL FOR HELP: NOTIFY THE RADIATION SAFETY OFFICER IMMEDIATELY.

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

- X 1. Survey instruments will be calibrated at least annually and following repair.
- X 2. Calibration will be performed at two points on each scale used for radiation protection purposes, i.e., at least up to 1 R/hr.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ± 10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

- X 3. Survey instruments will be calibrated

- _____ a. By the manufacturer
- _____ b. At the licensee's facility

- (1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
or _____
Exposure rate at a specified distance _____
Accuracy _____
Traceability to primary standard _____

- _____ (2) The calibration procedures in Section I of Appendix D will be used
OR
_____ (3) The step-by-step procedures, including radiation safety procedures, are attached.

- X c. By a consultant or outside firm

- (1) Name Bio-Med Associates, Inc.

- (2) Location 753 Boulevard, Kenilworth, N.J. 07033

- ### (3) Procedures and sources

X have been approved by NRC and are on file in License No. 29-14967-01

_____ have been approved by an Agreement State; a copy of the Agreement State license, the procedures, and a description of the sources are attached, and the consultant's report will contain the information on

_____ the attached "Certificate of Instrument Calibration."

_____ the consultant's reporting form as attached.

_____ are described in the attachment, and the consultant's report will contain the information on

_____ the attached "Certificate of Instrument Calibration."

_____ the consultant's reporting form as attached.

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

(Licensee's Name)

(Date)

1. Management Commitment

- a. We, the management of this (medical facility, hospital, etc.), are committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC)¹ and a Radiation Safety Officer (RSO).
- b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.
- c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.
- d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

¹Private practice physician licenses do not include an RSC.

2. Radiation Safety Committee (RSC)²

a. Review of Proposed Users and Uses

- (1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
- (2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.
- (3) The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

- (1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.
- (2) The RSC will support the RSO in those instances where it is necessary for the RSO to assert his/her authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

²The RSO on private practice physician licenses will assume the responsibilities of the RSC under Section 2.

c. Review of ALARA Program

- (1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- (2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 0-1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).³
- (3) The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

- (1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.
- (2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of Section 6 of this program.
- (3) Quarterly review of records of radiation level surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for ALARA Program

- (1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

³The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify further investigations.

- (2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

- (1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
- (2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

4. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

- (1) The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.
- (2) The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of Authorized User to Persons Under His/Her Supervision

- (1) The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.
- (2) The authorized user will ensure that persons under his/her supervision who are

subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Persons Who Receive Occupational Radiation Exposure

- a. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.
- b. The worker will know what recourses are available if he/she feels that ALARA is not being promoted on the job.

6. Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures

This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed in Table O-1 below. These levels apply to the exposure of individual workers.

Table O-1

	<i>Investigational Levels (mrems per calendar quarter)</i>	
	<i>Level I</i>	<i>Level II</i>
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

* Not normally applicable to nuclear medicine operations except those using significant quantities of beta-emitting isotopes.

The Radiation Safety Officer will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring not less than once in any calendar quarter as required by § 20.401 of 10 CFR Part 20. The following actions will be taken at the Investigational Levels as stated in Table O-1:

- a. Quarterly exposure 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 O-1 values for the Investigational Level I.

- b. Personnel exposures 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 and will report the results of the 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 action 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.

- c. Exposure equal to or greater than 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 warranted, will 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 RSC 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 at the time of the next inspection.

- d. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table O-1.

In cases where a worker's or a group of workers' exposures 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 RSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds

the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. Signature of Certifying Official⁴

I hereby certify that this institution (or private practice) has implemented the ALARA Program set forth above.

⁴The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator) or, in the case of a private practice, the licensed physician.

X *W. L. Palazzo*
Signature

X W. L. Palazzo MD
Name (print or type)

X Nuclear Physician
Title

Institution (or Private Practice) Name and Address:

Saddle Brook General Hosp
300 Market St
Saddle Brook NJ 07662