ROENTGEN ASSOCIATES, P.C.
1020 PROFESSIONAL DRIVE
FLINT, MICHIGAN 48504

Phone 733-2190

P. K. McLeod, M. D.

December 18, 1981

U.S. Nuclear Regulatory Commission
Office of Inspection and Enforcement
799 Roosevelt Road
Glen Ellyn, Illinois 60137

030-17996

GENTLEMEN:

Please amend License number 21-20128-01 to include usage at 1020 Professional Drive, Flint, Michigan 48504 as well as the present 1198 North Belsay Rd. Burton, Michigan 48509 address. Attached is a copy of the additional facility diagram. All other conditions of the license (including equipment) remains the same.

Sincerely,

Peter K. McLeod, M.D.

PKM/cm

4517 $40 7B
Amendment
12/29/81
Brown

12/29/81
Dec. PB13 Rec
Brown
III

12/30/81

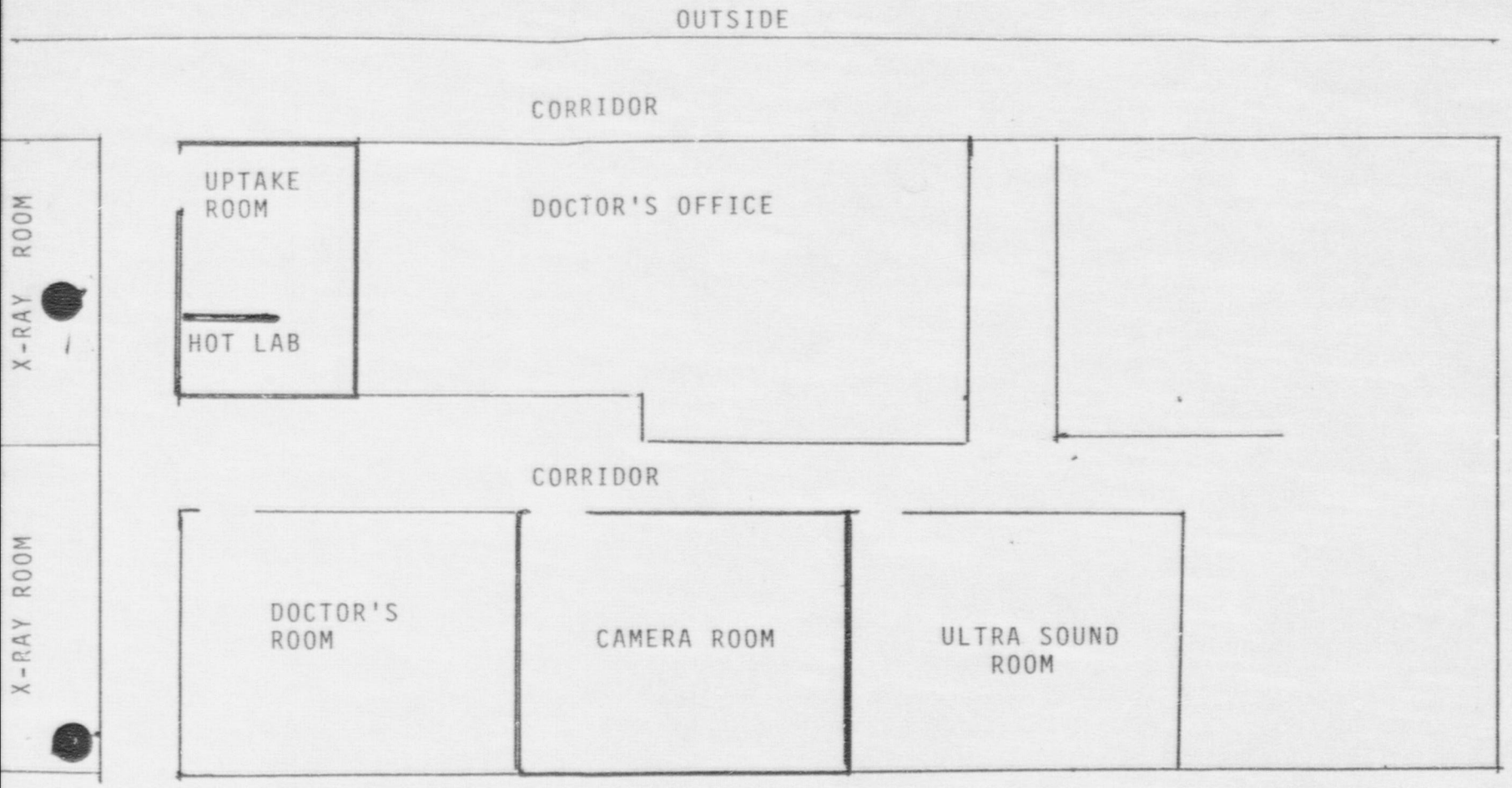
8902230286 880331
REG3 LIC30
21-20128-01 PNU

Control No. 05731

DEC 21 1981

2

Roentgen Associates, P.C.
1020 Professional Dr.
Flint, Michigan 48504



1. Hot lab
2. Uptake room
3. Camera room

} Walls 3/16" lead lined

Control No. 05731

over →

Control No. 05731

1. Radiopharmaceutical receipt and unpackaging
2. Sink
3. "dose" Calibrator (shielded)
4. Lead-glass face shield + additional shielding ("dose" preparation and compounding)
5. Lead brick shielded storage area (Generator and other radioactive storage)
6. Thyroid uptake system
7. Gamma Camera

WHEELOCK MEMORIAL HOSPITAL
7280 STATE ROAD
GOODRICH, MICHIGAN 48438
TELEPHONE: 313-636-2221

March 12, 1981

Dear Sirs:

I am the Chief Executive Officer of Wheelock Memorial Hospital. I am writing this letter to confirm that Peter K. McLeod, M.D., has admitting privileges for his nuclear medicine patients at this hospital.

The hospital agrees to accept such patients.

Sincerely,

Norma J. Murphy
Chief Executive Officer

NJM/br

SUPPLEMENTAL SHEETS

Item 7. MEDICAL ISOTOPES COMMITTEE

N.A.

Item 8. TRAINING AND EXPERIENCE

Dr. Peter K. McLeod was previously licensed under license No. 21-15723-01. Dr. McLeod is licensed to practice medicine in the State of Michigan.

Item 9. INSTRUMENTATION

See attached APPENDIX C

Item 10. CALIBRATION OF INSTRUMENTS

See attached APPENDIX D

Item 11. FACILITIES AND EQUIPMENT

A. Facilities:

(see attached diagram)

B. Equipment:

For Health Physics and Clinical Instrumentation see Item 9.

For reducing internal exposures, disposable gloves, absorbent pads, etc. will be used.

For reducing external exposures, remote handling devices, shielding (lead bricks, lead glass "face" shield, syringe holders, lead "pigs") will be used. Syringe shields will be used when the use does not interfer with patient care (e.g. in the case of difficult injections).

Item 12. PERSONNEL TRAINING PROGRAM

All personnel will receive proper instruction in the items specified in 19.12 of 10CFR Part 19, including items a through j page 10.8-6 of REGULATORY GUIDE 10.8.

Instruction will be given upon hire with an annual review.

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Eberline

      Manufacturer's model number: E-520 with Hp-190 G.M. probe

      Number of instruments available: 1

      Minimum range: 0 mr/hr to .2 mr/hr

      Maximum range: 0 mr/hr to 2000 mr/hr

   b. Manufacturer's name: _____

      Manufacturer's model number: _____

      Number of instruments available: _____

      Minimum range _____ mr/hr to _____ mr/hr

      Maximum range _____ mr/hr to _____ mr/hr

2. Dose calibrator

   Manufacturer's name: Capintec

   Manufacturer's model number: CRC-5

   Number of instruments available: 1

3. Diagnostic instruments

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	G.E.	Maxi II
Thyroid Uptake System	Picker	MagnaScanner + Uptake Option

4. Other

APPENDIX D

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.

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 Medical Physics Consultants

(2) Location Suite B 3200 West Liberty Ann Arbor, MI 48104

(3) Procedures and sources

X have been approved by NRC and are on file in License No. 21-16327-01

_____ 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.

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

X — First elution from new Mo-99/Tc-99m generator

or

X — Other* (specify) highest activity used

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Activity (mCi)	Accuracy
Co-57	1-5	± 5%
Ba-133		
Cs-137	.1-.2	± 5%

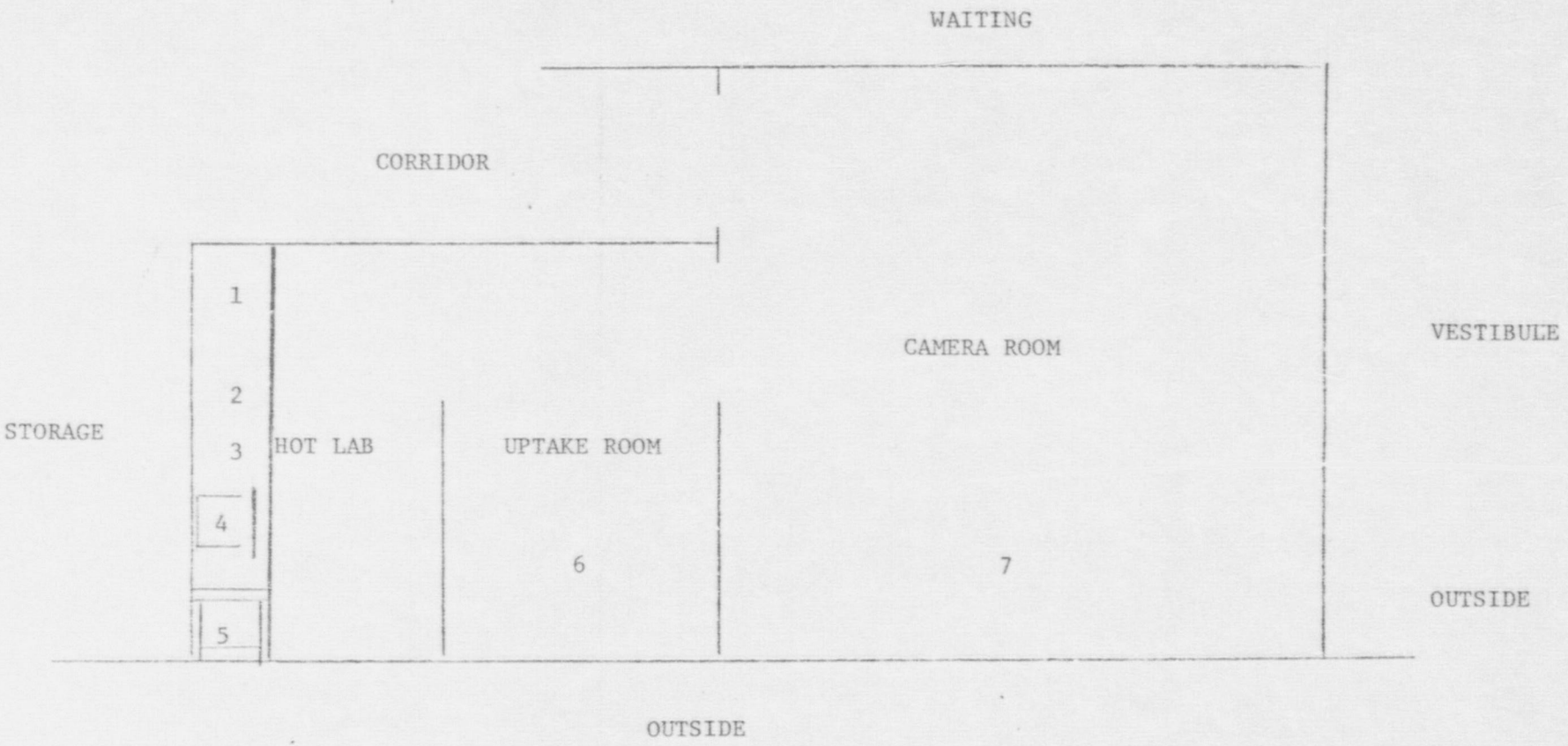
C. X — The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator

or

____ Equivalent procedures are attached.

*Must be equivalent to the highest activity used.

Roentgen Associates, P.C.
1198 North Belsay Rd.
Burton, MI 48508



1. Radiopharmaceutical receipt and unpackaging
2. Sink
3. "dose" Calibrator (shielded)
4. Lead-glass face shield + additional shielding ("dose" preparation and compounding)
5. Lead brick shielded storage area (Generator and other radioactive storage)
6. Thyroid uptake system
7. Gamma Camera

Item 13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

Byproduct material will be ordered by authorized personnel in accordance with licensed possession limits and conditions. Byproduct material received during off-duty hours will be delivered to a locked Nuclear Medicine room that has been identified for radiopharmaceutical receipt.

Delivery persons will be given the following instructions:

Take package(s) to designated Nuclear Medicine Room
Do not open or tamper with package(s) in any way
Place in designated area
Lock door upon leaving

Personnel will be instructed to detain the carrier representative when a damaged or contaminated shipment is suspected.

ITEM 14

RECEIVING, OPENING, AND LOGGING PACKAGES CONTAINING RADIOACTIVE MATERIALS

James E. Carey

Packages containing radioactive materials shall be received by authorized personnel and delivered to the nuclear medicine laboratory. They shall be placed in an area designated for processing and secured against unauthorized removal.

Packages shall be processed as soon as practicable after receipt.

Disposable gloves shall be worn while processing packages and remote handling devices shall be used when practicable. Absorbent pads shall be used to cover the processing area.

Note: Regulations for processing packages containing radioactive materials are found in the Code of Federal Regulations (Title 10, Part 20, Section 20.205). These regulations require each licensee to establish and maintain procedures for safely opening packages containing radioactive materials. They specify which packages shall be monitored for external surface contamination and/or external exposure rates. Many of the packages received for use in the typical nuclear medicine laboratory are exempted from these monitoring requirements. Personnel of each nuclear medicine laboratory should read these regulations carefully to ensure compliance. The following procedure is proposed as a "safe" approach to processing the majority of packages that will be received in the typical nuclear medicine laboratory.

Procedure

1. Monitor the exposure rates at the package surface and at 3 ft from the package surface. If the exposure rate at the package surface exceeds 200 mR/hr or if the exposure rate at three feet exceeds 10 mR/hr, do not open it. Place the package behind the protective lead barrier and notify the Radiation Protection Officer.
2. Open the outer package and remove the packing slip. Open the inner package and verify that the contents agree in activity, chemical form, and calibration date with the packing slip.
3. Check for possible breakage of seals or containers, loss of liquid, or change in color of liquid-absorbing material.
4. If the package appears intact, remove the radioactive material from the outer package and place it behind the protective lead barrier. If the shipment appears damaged or discrepant in any way, do not remove the radioactive material. Place the package behind the protective lead barrier and notify the Radiation Protection Officer.
5. With the radioactive material removed, monitor (G.M. survey meter) the package's outer surface and inner contents for contamination. If contamination is noted, place the package behind the protective lead barrier and notify the Radiation Protection Officer.
6. On form "log 1" record the date, radionuclide, chemical form, activity, supplier, exposure rate at package surface and at 3 ft and any contamination that is noted (see Figure 1).
7. Store the radioactive material at the assigned shielded location.
8. On form "log 2" (Figures 2 and 3), record use and ultimate disposal of remaining radioactive material (also see the section on Radioactive Waste Disposal).

Note: Title 10, Part 20, Section 20.205 requires that exposure rates be measured, and, if they exceed 200 mR/hr at the package surface or 10 mR/hr at 3 ft, that the licensee shall notify the final delivering carrier and the Nuclear Regulatory Commission immediately. It also requires that removable package surface contamination be measured and that the licensee shall notify the final delivering carrier and the Nuclear Regulatory Commission immediately if it exceeds 0.01 μCi/100 cm² of package surface. In the procedure outlined above, if package surface contamination is noted using the G.M. survey meter, the package surface should be "smeared" for removable contamination and the activity per 100 cm² quantified. Required action should then be taken.

Contaminated containers, liners, shields, etc. should be discarded in the assigned "hot" waste containers. Noncontaminated items may be discarded in the regular waste containers after removing or defacing any label indicating the presence of radioactive material.

Packages containing $Na^{131}I$ or ^{133}Xe should be processed in a fume hood.

Control No. 04598

LOG 1 RADIONUCLIDES RECEIVED – _____ (month)

Date received	Radio-nuclide	Chemical form	Activity (mCi)	Supplier	mR/hr surface	mR/hr at 3 ft	Contamination Yes	Contamination No	Checked by

TOTAL ACTIVITY RECEIVED = (mCi)

FIGURE 1.

LOG 2A MULTIPLE DOSE DISPOSITION RECORD – PREPARED RADIOPHARMACEUTICALS (SUPPLIER & KITS)

Kit _____

_____ mCi TOTAL

SUPPLIER ASSAY (OR LABEL)

mCi Total _____

TOTAL
ACTIVITY
RECEIVED = (mCi)

FIGURE 1.

LOG 2A MULTIPLE DOSE DISPOSITION RECORD – PREPARED RADIOPHARMACEUTICALS (SUPPLIER & KITS)

Kit _____

_____ mCi TOTAL

_____ Date

@ _____ AM PM

_____ ml TOTAL

_____ mCi/ml

SUPPLIER ASSAY (OR LABEL)	
mCi Total	_____
Date	_____
ml Total	_____
mCi/ml	
Lot number	_____

Date & time	Patient name & number	mCi to adminis.	÷mCi/ml X decay factor =	ml adminis.	Initial

Disposal
Date disposed _____
mCi disposed _____
Method _____ Initial _____

FIGURE 2.

LOG 2B MULTIPLE DOSE DISPOSITION RECORD – Mo-99/Tc-99m GENERATOR & GENERATOR ELUATE

ASSAY ($Na^{99m}TcO_4^-$)

_____ mCi Total

_____ Date

@_____ AM PM

_____ ml Total

_____ mCi/ml

^{99}Mo Check

_____ $uCi^{99}Mo/mCi^{99m}$

Al^{+++}

_____ ug/ml

SUPPLIER ASSAY (OR LABEL)

mCi Total (Mo-99) _____
Date _____
Lot number _____

Date & time	Patient name & number	mCi to adminis.	÷mCi/ml X decay factor =	ml adminis.	Initial

Disposal ($Na^{99m}TcO_4^-$)
Date disposed _____
mCi Disposed _____
Method _____ Initial _____

Disposal (generator)
Date disposed _____
mCi Disposed _____
Method _____ Initial _____

FIGURE 3.

ADDI

APPENDIX J

WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with § 20.303 of 10 CFR Part 20.

1. Liquid waste will be disposed of (check as appropriate)

X In the sanitary sewer system in accordance with § 20.303 of 10 CFR Part 20.

____ By commercial waste disposal service (see also Item 4 below).

X Other (specify): Held for decay as in 3.

2. Mo-99/Tc-99m generators will be (check as appropriate)

X Returned to the manufacturer for disposal.

or

X Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.**

____ Disposed of by commercial waste disposal service (see also Item 4 below).

____ Other (specify): _____

3. Other solid waste will be (check as appropriate)

X Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

____ Disposed of by commercial waste disposal service (see also Item 4 below).

____ Other (specify): _____

4. The commercial waste disposal service used will be

_____
(Name) (City, State)

NRC/Agreement State License No. _____

* Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

** These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

Control No. 04598

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

~~Roentgen Associates, P.C.~~
(Licensee's Name)

2/11/81
(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.

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.

[1] Private practice physician licenses do not include an RSC.

[2] The 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.

(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

[3] The 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.

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 0-1 below. These levels apply to the exposure of individual workers.

Table 0-1

	Investigational Levels (mrems per calendar quarter)	
	Level I	*Level II*
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 0-1

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 0-1 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 0-1.

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 Official[4]

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

Signature

Peter K.McLeod, M.D.

Name (print or type)

Radiologist

Title

Institution (or Private Practice) Name and Address:

Roentgen Associates, P.C.
1020 Professional Drive
Flint, MI 48504

[4]The 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.