NRC Form 374A (8-82)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 1 PAGES

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
35-13539-01

Docket or Reference number
030-02928

Amendment No. 19

This copy is for your files

Grady Memorial Hospital
2220 Iowa
Chickasha, Oklahoma 73018

In accordance with letter dated May 11, 1983, License Number 35-13539-01 is amended as follows:

Condition 12. is amended to read:

12. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Don Delzer, M.D.	ALL
John Gardner, M.D.	Groups I, II and III Xenon 133 In vitro studies
James Milton, M.D.	Groups I, II and III Xenon 133 In vitro studies Iodine 131 as iodide for treatment of thyroid carcinoma, hyperthyroidism and cardiac dysfunction Phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases
Danny Rhodes, M.D.	Groups I, II and III Xenon 133 In vitro studies
Carolyn Crumley, M.D.	Groups I, II and III Xenon 133 In vitro studies

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date AUG 0 9 1983

By R. J. Everett
Material Radiation Protection Section
Region IV
Arlington, Texas 76011

NRC FORM 313A SUPPLEMENT A (8-78) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Bhagwat D. Ahluwalia, Ph.D.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Science in Nuclear Medicine	Nuclear Medicine Science in all its branches	June 1980

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Panjab Univ. & Saha Inst. of Nuclear Rad. Physics: 1961-64 Boston University Ph.D. 1965-71 Univ. of Colorado Med. Cent. 1972	300 150 100	200 300 + 50
b. RADIATION PROTECTION	Boston University: 1965-71 Univ. of Colorado Med. Ct. 1972 Mass. General Hospital 1973	50 50 20	100 + 50 + 20 +
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Panjab Univ. Saha Inst. Boston Univ. Univ. of Colorado Med. Ct.	100 50 20	100 + 50 + 20
d. RADIATION BIOLOGY	Univ. Of Colorado Med. Ct 1972	60	20
e. RADIOPHARMACEUTICAL CHEMISTRY	Univ. of Colorado Med. Ct 1972	50	40

5. EXPERIENCE WITH RADIATION (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Mo-99	1 Ci	Univ. of Colorado Med. Ct	9 months	Medical
I-131	250 mCi	Univ. of Colorado Med. Ct V.A. Med. Center Okla City Mass. General Hospt. Boston	Over 9 years	Medical
N-13, O-15 C-14 etc	20 mCi	Mass. General Hospt.	Over 5 years	Medical Medical
Cr-51	10 mCi			
Tc-99m	300 mCi	V.A. Med. Center Okla City	Over 3 years	Medical

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Broad material license # 35-00520-04

AMERICAN BOARD OF SCIENCE IN NUCLEAR MEDICINE

The American Board of Science in Nuclear Medicine,
organized through the cooperation of
the American College of Nuclear Medicine,
the American College of Nuclear Physicians,
and The Society of Nuclear Medicine,

hereby certifies that

Bhagwat D. Ahluwalia, Ph.D.

has met established standards and qualifications,
and passed examinations conducted under its authority
June 23, 1980
thereby demonstrating to the satisfaction of the Board
the ability to practice Nuclear Medicine Science
in all its branches, with special competence in

Nuclear Medicine Physics and Instrumentation

President | Vice President | Secretary | Treasurer

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association
and the American Society of Therapeutic Radiologists
Hereby certifies that

Bhagwat D. Ahluwalia, Ph.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this third day of June, 1983
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of
Therapeutic Radiological Physics &
Diagnostic Radiological Physics

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

AMERICAN BOARD OF MEDICAL SPECIALTIES

President

Secretary

Continuation of Supplement A
Training and Experience

B. Ahluwalia, Ph.D.

1. Ph.D Radiation Physics, Boston University, Boston, Mass, 1972.

2. Approved user of radioactive materials under byproduct material licenses:

   V.A. Medical Center, Oklahoma City, Oklahoma, License #35-005260-02

   Oklahoma Memorial Hospital, Oklahoma City, Oklahoma, License #35-16329-02.

3. Radiation Safety Officer

   V.A. Medical Center, Oklahoma City, Oklahoma

   Consultant Radiation Safety Specialist

      Oral Roberts University, Tulsa, Okla, NRC 35-18282-01, Since 1980

      V.A. Medical Center, Muskogee, Okla, NRC 35-13184-01, Since 1980

      Glow Lite Corp., Pauls Valley, Oklahoma, NRC 35-19956 02E

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APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Atomic Products Corporation, Center Moriches, N.Y. 11934

   Manufacturer's model number: 069-701 with G.M. Probe and Cs-137 check source (10 micro Ci)

   Number of instruments available: ONE

   Minimum range: 0.0 mR/hr to 0.5 mR/hr

   Maximum range: 0.0 mR/hr to 50 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: Atomic Products Corporation, Center Moriches, N.Y.

   Manufacturer's model number: CAL/RAD II 086-061, 086201 Moly brakthrough shield

   Number of instruments available: ONE

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Technicare, Johnson & Johnson	Segmia 438 15" field of view 37 PM Tubes
Area Monitor	Atomic Product Corporation	Primealert 35 085-437

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

ITEM NO: 10

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items

* 1. Survey instruments will be calibrated at least annually and following repair.

* 2. Calibration will be performed at two points on each scale. 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% of the calculated or known values for each point checked. Readings within ± 20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

* 3. Survey instruments will be calibrated

___ a. By the manufacturer

* b. At the licensee's facility

Calibration source:
Manufacturer's Name Radium Chemical
Model No. 25 mgm Ra-226
Activity in millicuries 24.3 mCi
Accuracy ± 5%
Traceability to primary standard NBS

c. By a consultant or outside firm
(I) Name: B. Ahluwalia, Ph.D.

(II) Location: Department of Radiological Sciences
Radiological Physicist,
University of Oklahoma
Health Sciences Center
Oklahoma City, OK 73190

(III) Procedures and sources
* have been approved by NRC and are on file in License No. 35-00526-04
* are attached.

A. Calibration of Survey Meter

1. The sources shall be approximate point sources with activity traceable within 5% accuracy to the U. S. National Bureau of Standards (NBS) calibration. One sealed 25 mgm Radium (Ra-226) tube will be used for calibration.

2. The calibration shall be performed at least annually and after servicing.

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ITEM NO: 10 (Continued)

3. Each scale of the instrument shall be calibrated approximately 1/3 and 2/3 of full scale. The inverse square law will be used with the above mentioned sources to calculate the exposure rate at different distances. Measurement will be made at suitable height from the ground in an open area to minimize the effect of scattered radiation.

4. A calibration graph will be prepared for each instrument if necessary.

5. Consistency checks using either a built-in Radium check source or a low level Cs-137 standard seal source will be read before and after each survey.

6. Battery check will be read before each survey.

7. Record of calibrations and maintenance services will be kept.

8. For low energy calibration Co-57 standard source of 5 mCi will used. Procedures as detailed above will be used.

Section 2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR*

All radiopharmaceuticals must be assayed for activity to an accuracy of 10 percent. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

A. Test for the following:

1. Instrument constancy (daily)
2. Instrument accuracy (at installation and annually thereafter)
3. Instrument linearity (at installation and quarterly thereafter)
4. Geometrical variation (at installation)

B. After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above (dependent upon the nature of the repairs).

C. Test for Instrument Constancy

Instrument constancy means that there is reproducibility, within a stated acceptable degree of precision, in measuring a constant activity over time. Assay at least one relatively long-lived reference source such as Cs-137, Co-57,** or Ra-226** using a reproducible geometry before each day's use of the instrument. Preferably, at least two reference sources (for example, 3-5 mCi of Co-57 and 100-200 μCi of Cs-137 or 1-2 mg Ra-226 (with appropriate decay corrections) will be alternated each day of use to test the instrument's performance over a range of photon energies and source activities.

1. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).
2. Measure background level at same instrument setting, or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.
3. Calculate net activity of each source subtracting out background level.
4. For each source, plot net activity versus the day of the year on semilog graph paper.
5. Log the background levels.
6. Indicate the predicted activity of each source based on decay calculations and the $\pm$5 percent limits on the graph.
7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.
8. Variations greater than $\pm$5 percent from the predicted activity indicate the need for instrument repair or adjustment.
9. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

D. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

E. Test of Instrument Linearity

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will use a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (e.g., the first elution from a new generator).

1. Assay the Tc-99m vial in the dose calibrator, and subtract background level to obtain net activity in millicuries.
2. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.
3. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table

---

*See ANSI N42.13-1978, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides" (American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018).

**Co-57 and Ra-226 are not subject to NRC licensing; the respective State agency should be consulted to determine its requirements for possessing this material.

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Assay Time (hr)*	*Correction Factor*
0	31.633
6	15.853
24	1.995
30	1
48	0.126

Example: If the net activity measured at 30 hours was 15.625 mCi, the calculated activities for 6 and 48 hours would be 15.625 mCi x 15.853 = 247.7 mCi and 15.625 mCi x 0.126 = 1.97 mCi, respectively.

4. On log-log coordinate paper, plot the measured net activity (for each time interval) versus the calculated activity (for the same time interval).

5. The activities plotted should be within ±5 percent of the calculated activity if the instrument is linear and functioning properly. Errors greater than ±5 percent indicate the need for repair or adjustment of the instrument.

6. If instrument linearity cannot be corrected, it will be necessary in routine assays to use either (a) an aliquot of the eluate that can be accurately measured or (b) the graph constructed in step 4 to relate measured activities to calculated activities.

F. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than ±2 percent. (Even though correction factors may be provided by the manufacturer, the accuracy of these should be checked.) When available from the manufacturer, certified data on geometrical variations may be used in lieu of these measurements.

To measure variation with volume of liquid, a 30-cc vial containing 2 mCi of Co-57 or other appropriate radionuclide in a volume of 1 ml will be used.

1. Assay vial at the appropriate instrument setting, and subtract background level to obtain net activity.

2. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step 1. (Follow good radiation safety practices to avoid contamination and to minimize radiation exposure.)

3. Select one volume as a standard (such as the volume of reference standard used in performing the test for instrument accuracy), and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor (CF).

Example: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes and 10 ml is the reference volume selected.

$$4 \text{ ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

4. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

5. The true activity of a sample is calculated as follows:

True Activity = Measured Activity x Correction Factor

where the correction factor used is for the same volume and geometrical configuration as the sample measured.

6. Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30-cc vial, and a correction factor may be calculated.

7. It should be noted that differences of 200 percent in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125, which should be assayed in a dose calibrator only if the reliability of such an assay can be established. Glass tubes and syringes may also vary enough in thickness to cause significant errors in assaying I-125. Hence, adequate correction factors must be established.

An alternative to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction if significant).

G. Test for Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides, including Cs-137, Co-57, and Ba-133, using appropriate reference standards whose activities have been calibrated by comparisons with standard sources that have been assayed by NBS and documented.

* Assay times should be measured in whole hours and correction factors should be used to the third decimal place as indicated. The more recent half-life of $T_{1/2}$ = 6.02 hours has been used in calculating these correction factors.

The activity levels of the reference sources used should approximate those levels normally encountered in clinical use (e.g., Co-57, 3-5 millicuries) giving adequate attention to source configuration. Identify in your application the three sources that you will use. State nuclide, activity, and calibration accuracy. The lower-energy reference standards (Tc-99m, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

1. Assay the reference standard in the dose calibrator at the appropriate setting, and subtract the background level to obtain the net activity.

2. Repeat step 1 for a total of 3 determinations, and average results.

3. The average activity determined in step 2 should agree with the certified activity of the reference source within ± 5 percent after decay corrections.

4. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.

5. Keep a log of these calibration checks.

6. Calibration checks that do not agree within ± 5 percent indicate that the instrument should be repaired or adjusted. If this is not possible, a calibration factor should be calculated for use during routine assays of radionuclides.

7. At the same time the instrument is being initially calibrated at the licensee's facility with the reference standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.), and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source) without requiring more reference standards. Keep a log of these initial and subsequent readings.

Alternate Method for Dose Calibrator Linearity:

Commerciallt available Attenuators such as "LINEATOR" or "CALICHECK" will be used to establish the linearity of the dose calibrator. Procedures prescribed by the manufacturer will be followed.

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CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

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

or About 150 mCi of Tc-99m will be used to check linearity by the decay method, or with the use of commercially ~~available attenuators such as "LINEATOR or CALICHECH".~~ Commercially prescribed procedures for the use of these attenuators will be followed to establish linearity.

X Other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	5	5%
Ba-133	0.1-0.5	0.4	5%
Cs-137	0.1-0.2	0.3	5%
Ra-226 Will not be used	1-2	--	--

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.

*For licensees who are not authorized for Mo-99/Tc-99m generators, activity must be equivalent to the highest activity used.

ITEM NO: 11

COMMUNITY HOSPITAL
WEST SECOND and LINCOLN
ELK CITY, OKLAHOMA 73644

NUCLEAR MEDICINE SERVICE
FACILITY AND EQUIPMENT

The Nuclear Medicine Services of the Department of Radiology will be located in the multimodality room located east of the existing "Mammography" suite.This multimodality room will also have ultrasound imaging equipment in the north-east corner. It is contemplated at this time that only ultrasound patients will be scheduled in this suite when no nulear imaging patient is present. When the nuclear or the ultrasound imaging patient load increases a perment partition will be considered. This area is quite close to diagnostic radiology facility of the hospital. The ovelall area of this multi modality room is about 375 sq. feet. The patient waiting area will be shared with other radiology patients prior to injection or imaging.

The hospital plans to routinely receive a Moly-Tech generator from Mallinckrodt/ New England Nuclear / Amersham . Routine procedures of moly brakthrough, etc.will be performed on each elution. Records of dose for each patient and elution will be kept. All patients will be injected in the imaging room. Flood pahntom, standard sources, moly-tech generator and eluted activity will be stored in the room designated as hot laboratory. There will be room monotor in this area. All the activity and standard sources will be shielded with 2" lead bricks. Technitium radioactive waste will be stored under the sink and properly shielded. Old generators will be held for decay under the sink or shipped to the supplier.

The floor plan will meet the requirements of exposure levels for the restricted and unrestricted areas specified in 10CFR 20.101 and 20.105.

Receipt and storage of radioactive materials:

1. All radioactive materials will be received and loged in the log book kept in the imaging area.
2. All radioactive material will be stored in the original containers and stored in the designated area. adequate shielding will be provided in the storage area to reduce the exposure levels to less than or about 2 mr/hour at 15 cm from the sources.
3. Imaging and storage area will be locked when the authorised personnel are not present. Only authorised persons will be permitted for patient injection and use of radiopharmaceuticals.
4. The sink in the imaging area will be designated for radioactive emergencies use.

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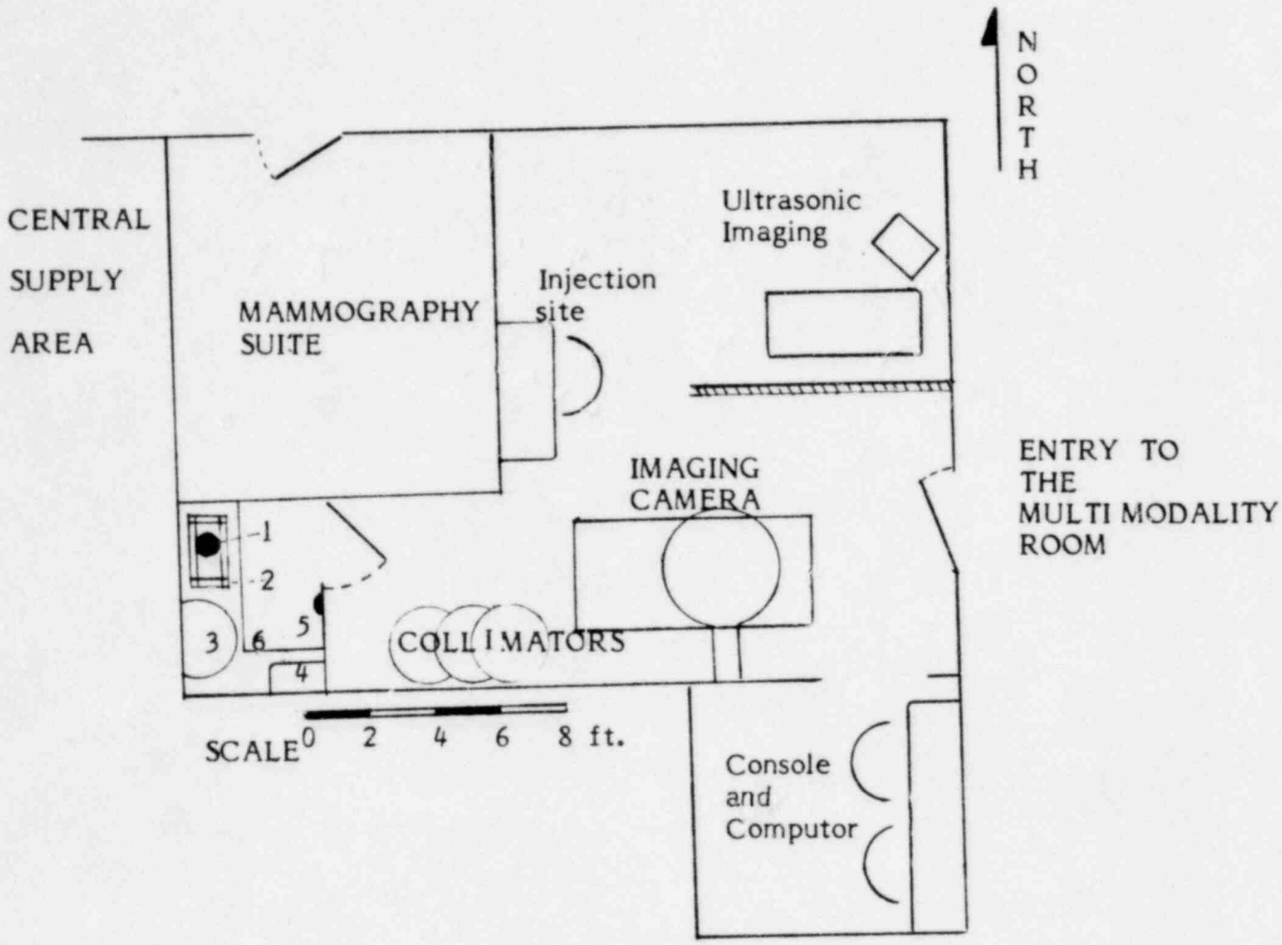
COMMUNITY HOSPITAL
ELK CITY, OKLAHOMA 73644

NUCLEAR MEDICINE SERVICE
ROOM DESIGN AND EQUIPMENT LOCATION



LEGEND

1 Moly-Technitium Generator
2 Lead Shield
3 Sink
4 Dose Calibrator
5 Area Monitor
6 Area for stage for decay
Under the table

PERSONNEL TRAINING PROGRAM

A. Specific Training Program:

All employees who work with or in the vicinity of radioactive materials will receive proper instructions as specified in Section 19.12 of 10 CFR Part 19. All new such employees will be briefed by the Radiation Safety Officer or his designate regarding procedures of safe use of radiation.

Other topics such as safety methods, radiopharmaceutical development, etc., will be covered.

B. General Training Program:

All employees including technical, clerical, nursing, housekeeping and security personnel will receive proper instruction in the terms specified in 19.12 of 10 CFR Part 19. The instructions will be provided by the Radiation Safety Officer. The instructions will include:

1. Areas where radioactive materials are used and stored.
2. Potential hazards associated with radioactive materials.
3. Radiologic safety procedures appropriate to their respective duties.
4. Pertinent NRC regulations.
5. Pertinent terms of the license.
6. Rules and regulations of the licensee.
7. Employee's obligation to report unsafe conditions.
8. Appropriate response to emergencies and unsafe conditions.
9. Employee's right to be informed of their radiation exposure and bioassay results.
10. Locations where the licensee has posted or made available notices, copies of pertinent regulations and copies of pertinent licensees and conditions.

Besides the annual education, appropriate employees will be instructed in case there is significant change in duties, regulations, or the change in the terms of the license.

ITEM NO: 13

PROCEDURES FOR ORDERING AND
RECEIVING OF RADIOACTIVE MATERIALS

1. The procedures related to ordering and receiving will be those outlined in appendix E of the regulatory guide 10.8.

2. Receipt of Radioactive Materilas during Off-hours and holidays:

   The department of radiology has a night and week end technologist. This technologist will be responsible for proper receipt, inspection, proper survey, wipe testing and record keeping.

3. All radioactive materila receipts will be verified , any error in receipt will be communicated to the shipper.

4. All personnel involved in the receipt of the radioactive materials will be provided proper training and instruction s as outlined in section 12.

APPENDIX E

PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY OF RADIOACTIVE MATERIAL

1. The Supervisory Nuclear Medicine Technologist will place all orders for radioactive materials and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. A system for ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of the following:

   a. Ordering of routinely used materials

      (1) Written records that identify the isotope, compound, activity levels, and supplier, etc., will be used.

      (2) The written records will be referenced when opening or storing radioactive shipment.

   b. Ordering of specially used materials (e.g., therapeutic uses)

      (1) A written request* will be obtained from the physician who will perform the procedure.

      (2) Persons ordering the materials will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.

      (3) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.

   c. It is essential that written records* be maintained for all ordering and receipt procedures.

3. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

4. During off-duty hours, security personnel or other designated individuals will accept delivery of radioactive packages in accordance with the procedures outlined in the sample memorandum below.

* In the case of special orders, the physician's written request and appropriate shipping/receipt records will be referenced and the dose assayed prior to its administration.

SAMPLE** MEMORANDUM

MEMORANDUM FOR: Security Personnel

FROM: John Jones, Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIO[illegible]MATERIAL

Any packages containing radioactive material that arrive [illegible]m. and [illegible]a.m. or on Sundays shall be signed for by the Security guard on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package on top of the counter immediately to the right of the door, and relock the door.

If the package is wet or appears to be damaged, immediately contact the hospital Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER: _____

OFFICE PHONE: _____

HOME PHONE: _____

** Submit a copy of your own institution's memorandum.

APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205(a)(1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels 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). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 μCi/100 cm^2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).

2. For all packages, the following additional procedures for opening packages will be carried out:

   a. Put on gloves to prevent hand contamination.

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

   c. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If >10 mR/hr, stop procedure and notify Radiation Safety Officer.

   d. Measure surface exposure rate and record. If >200 mR/hr, stop procedure and notify Radiation Safety Officer.

   e. Open the package with the following precautionary steps:

      (1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.

      (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition,* packing slip, and label on bottle.

      (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).

      (4) Check also that shipment does not exceed possession limits.

   f. Wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., μCi/100 cm^2, etc.). Check wipes with a thin-end-window G-M survey meter, and take precautions against the spread of contamination as necessary.

   g. Monitor the packing material and packages for contamination before discarding.

      (1) If contaminated, treat as radioactive waste.

      (2) If not contaminated, obliterate radiation labels before discarding in regular trash.

3. Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Record" (see next page) or a form containing the same information.

---

*In the case of special orders (e.g., therapy doses), also compare with physician's written request.

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P.O. No.: _____ Survey Date _____ Time _____

   Surveyor _____

2. CONDITION OF PACKAGE:

   _____ O.K. _____ Punctured _____ Status _____ Wet

   _____ Crushed _____ Other

3. RADIATION UNITS OF LABEL: _____ Units (mR/hr)

4. MEASURED RADIATION LEVELS:

   a. Package surface _____ mR/hr

   b. 3 feet or 1 meter from surface _____ mR/hr

5. DO PACKING SLIP AND VIAL CONTENTS AGREE?

   a. Radionuclide _____ yes _____ no, difference _____

   b. Amount _____ yes _____ no, difference _____

   c. Chem Form _____ yes _____ no, difference _____

6. WIPE RESULTS FROM:

   a. Outer _____ CPM = _____ DPM

      eff = ( )

   b. Final source container _____ CPM = _____ DPM

      eff = ( )

8. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____ mR/hr, CPM

9. DISPOSITION OF PACKAGE AFTER INSPECTION _____

10. IF NRC/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE, AND PERSONS NOTIFIED.

_____

Signature Date

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APPENDIX G

GENERAL RULES FOR SAFE 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 and clothing for contamination after each procedure or before leaving the area.

4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well-being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

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

   b. Do not store food, drink, or personal effects with radioactive material.

6. a. 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 percent.

   b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.

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 and properly shielded receptacles.

10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Always transport radioactive material in shielded containers.

APPENDIX H

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. 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. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

4. SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.

5. REPORT: Report incident to the Radiation Safety Officer.

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.

6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

Dr. Don Delzer, M.D.
RADIATION SAFETY OFFICER: _____*
OFFICE PHONE: ~~225-2511~~ ~~Area Code 405~~
HOME PHONE: ~~(405) 224-~~ 1522

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

See below :

_____

_____

_____

* The appropriate information for your facility should be supplied in these blanks when posting these procedures or submitting them with the application.

Emergency Telephone Numbers:

Radiation Safety Officer: Dr. Don Delzer M.D. :	(405) 224-1522
Alternate names:	
Dr. John Gardner, M.D.	(405)224-7815
Dr. James Melton, M.D.	(405) 222-2511
Mr. John ~~Starback~~ Starback	(405)225-9145
Dr. B. Wally Ahluwalia, Ph.D.	(405)721-0168
	(405)271-6121

APPENDIX I

AREA SURVEY PROCEDURES

1. All elution, preparation, and injection areas will be surveyed daily with an appropriately low-range survey meter and decontaminated if necessary.*

2. Laboratory areas where only small quantities of radioactive material are used (less than 200 μCi) will be surveyed monthly.

3. Waste storage areas and all other laboratory areas will be surveyed weekly.

4. The weekly and monthly surveys will consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 cm^2 for the contaminant involved. Wipes of elution and preparation areas or other "high background" areas will be removed to a low background area for measurement.

5. A permanent record will be kept of all survey results, including negative results. The record will include:

   a. Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies.

   b. Name of person conducting the survey.

   c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

   d. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

   e. Detected contamination levels, keyed to locations on drawing.

   f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

6. Area will be cleaned if the contamination level exceeds 200 dpm/100 cm^2.

* For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey results will be recorded.

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).

_____ Other (specify): _____

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.

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

Community Hospital, Elk City, OKlahoma

(Licensee's Name)

April 29, 1985

(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.

[1] Private 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.

[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

Talton L. Francis

Name (print or type)

Administrator

Title

Community Hospital, Elk City, Oklahoma 73644

Institution (or Private Practice) Name and Address

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

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