NRC FORM 313
(9-88)
10 CFR 30, 32, 33, 34, 35 and 40

APPLICATION FOR MATERIAL LICENSE

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 8-30-90

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 21-13255-01

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Woodland Medical Group
22341 W. Eight Mile Rd.
Detroit, MI 48219

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

Woodland Medical Group
22341 W. Eight Mile Rd.
Detroit, MI 48219

and

Woodland Medical Group
41935 W. Twelve Mile Rd.
Novi, Mi 48050

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Duane Zenn (Medical Physics Consultants, Inc.)

TELEPHONE NUMBER: 313-662-3197

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 7c
AMOUNT ENCLOSED $ 580.00

RECEIVED
APR 5
U.S. NRC
REGION III
90 APR -5 A9:26

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE-CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
X Harold J. Daitch MD	HAROLD J. DAITCH MD	RSO.	3/15/90

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS
REN	Apr 7	7C	CK from Woodland Medical Centers, Inc.
AMOUNT RECEIVED	CHECK NUMBER		
$580	046534		

APPROVED BY: ect — DATE: 4/5/90

RECEIVED
MAR 29 1990
REGION III

NRC FORM 313 (9-88)

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 7.5 HRS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE RECORDS AND REPORTS MANAGEMENT BRANCH (P-530), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

CONTROL NO. 89025 MAR 29 1990

Woodland Medical Group
NRC License 21-13255-01 Renewal Request
March 1, 1990

RADIOACTIVE MATERIAL AND USE

Item 5 Byproduct Material	Amount	Item 6 Purpose
Material in 35.100	As Needed	Uptake, dilution, and excretion studies
Material in 35.200	As Needed	Imaging and localization studies
Material in 35.300	As Needed	Radiopharmaceutical therapy
Material in 31.11	As Needed	In Vitro Studies

RADIATION SAFETY PROGRAM RESPONSIBILITY

Item 7.1 Authorized Users	Materials
Harold Daitch, M.D	35.100, 35.200, 35.300, and 31.11
Richard Small, M.D.	35.100, 35.200, 35.300, and 31.11
Seymour Mirkes, M.D.	35.100, 35.200, 35.300, and 31.11

Item 7.3
Radiation Safety Officer

Harold Daitch, M.D.

Woodland Medical Group
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PERSONNEL TRAINING PROGRAM

Item 8.1
Personnel

All radiation workers and ancillary personnel whose duties will require them to work in the vicinity of radioactive materials will receive instruction. Ancillary personnel may include housekeeping, security, nursing, maintenance, and ECG technologists.

Training Frequency

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

2. During annual refresher training.

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

Instruction Topics

1. Applicable regulations and license conditions.

2. Areas where radioactive material is used or stored.

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

4. Appropriate radiation safety procedures.

5. The licensee's in-house work rules.

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

7. Appropriate response to emergencies or unsafe conditions.

8. The worker's right to be informed of occupational radiation exposure and bioassay results.

9. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of the license and license conditions, as required by 10CFR19.

Documentation will be kept on hand for review of the list of topics covered, the date of the instruction, and the names of those attending.

Woodland Medical Group-Novi
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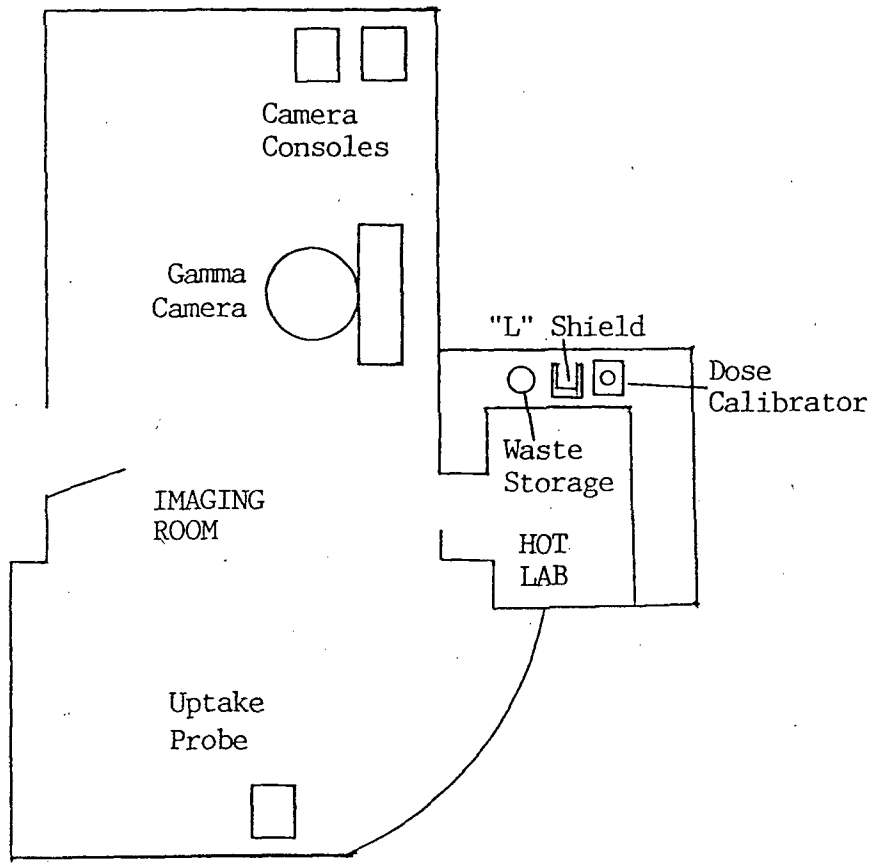
FACILITY DIAGRAM

Item 9.1

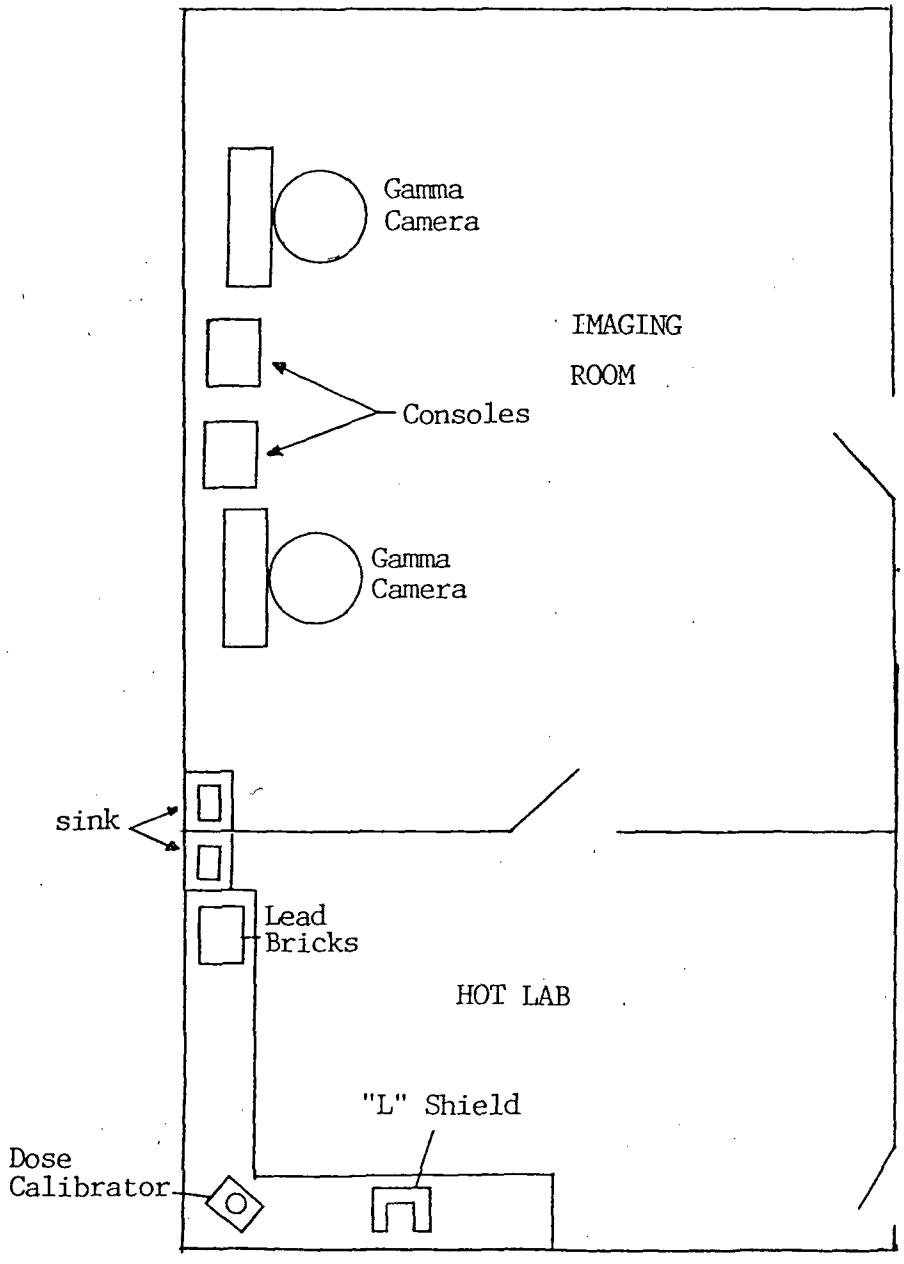


All unrestricted areas surveyed were less than 2.0 mR/h.

Woodland Medical Group-Detroit
NRC License 21-13255-01 Renewal Request
March 1, 1990

FACILITY DIAGRAM

Item 9.1



All unrestricted areas surveyed were less than 2.0 mR/h.

CONTROL NO. 89025

Woodland Medical Group - Detroit
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EQUIPMENT LIST

Item 9.1 (cont.)

Imaging Equipment

Searle Lem Gamma Camera

Siemens ZLC-370 Gamma Camera

Dose Calibrator

Capintec CRC-10R

Survey Meters

Bicron 2000 GM Survey Meter

Eberline Model E-520 GM Survey Meter

Other

Picker Uptake Probe

Woodland Medical Group - Novi
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EQUIPMENT LIST

Item 9.1 (cont.)

Imaging Equipment

General Electric Maxi-Camera-37

Dose Calibrator

Capintec CRC-4

Survey Meters

Eberline Model E-120 GM Survey Meter

Other

Nucleus Multichannel Analyzer

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CALIBRATION OF SURVEY INSTRUMENTS

Item 9.2
All survey instruments will be calibrated and checked in accordance with 10CFR35.51. Survey instruments will be calibrated by:

1. The manufacturer.

2. Medical Physics Consultants (NRC License No. 21-20153-01).

3. Any authorized user licensed to perform survey meter calibrations as a service.

CONTROL NO. 89025

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CALIBRATION OF DOSE CALIBRATOR

Item 9.3

Test	Frequency	Tolerance
Constancy	Daily prior to patient dose assays	+/- 10%
Linearity	Installation, following repair, and quarterly	+/- 10%
Accuracy	Installation, following repair, and annually	+/- 10%
Geometry Dependence	Installation and following repair	+/- 10%

CONSTANCY testing will be performed using a long-lived reference source (e.g., Cesium-137) with activity greater than 50 microcuries. Zero or record the background reading on the appropriate setting. Assay the source for both the reference source setting and the most commonly used radiopharmaceutical settings. Record the readings and compare to the calculated values. The Radiation Safety Officer will be notified and the unit will be repaired or replaced if the constancy error exceeds 10 percent.

LINEARITY testing will be performed using a Technetium-99m source having activity at least as great as the maximum activity administered to patients. Testing will be conducted with the decay or the leaded-sleeve method over the entire range of administered activity.

Decay method: Assay the source at approximately 0, 6, 24, 30, 48, etc hours over the entire range of use(between the highest activity administered to patients and 10 uCi). Record the net activities, time, and date. Using a measured activity for reference which is closest to that which is commonly administered to patients, calculate the expected readings and compare to the measured readings. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the linearity error exceeds 10 percent over the range of use.

Sleeve method: The sleeves will be calibrated at the time of an intial reading of a decay-method linearity test. The testing procedure will be performed according to the manufacturer's instructions. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the linearity error exceeds 10 percent over the range of use.

Item 9.3 (cont.)

ACCURACY testing will be performed using cesium-137 and cobalt-57 or barium-133 reference sources having NBS-traceable activities greater than 50 microcuries. The net measured activities will be compared to the calculated activities based on radioactive decay. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced if the accuracy error exceeds 10 percent.

GEOMETRY DEPENDENCE testing will be performed using a solution of technetium-99m having an activity concentration of 1-10 mCi/ml. If generators and/or radiopharmaceutical kits are normally used, both of the following tests will be performed:

Unit dose users will assay 0.5 cc of the solution in a 3 cc plastic syringe. The solution in the syringe will then be diluted with water and assayed at incremental volumes of 1.0, 1.5, and 2.0 cc. Record all readings. Select a standard volume closest to that normally used for injections and divide the activity by the other measured activities. If any error exceeds 10 percent, correction factors will be applied to the appropriate volumes and a correction factor chart will be applied to the dose calibrator. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the geometry error exceeds 10 percent.

Generator/kit users will assay 1.0 cc of the solution in a 30 cc glass vial. The solution in the vial will then be diluted with water and assayed at incremental volumes of 3, 5, 7, 9, 11, 13, 15, 17, and 19 cc. The assays should take place within 10 minutes. Record all readings. Select a standard volume closest to that normally used for mixing kits and divide the activity by the other measured activities. If any error exceeds 10 percent, correction factors will be applied to the appropriate volumes and a correction factor chart will be applied to the dose calibrator. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the geometry error exceeds 10 percent.

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PERSONNEL MONITORING PROGRAM

Item 9.4

1. The RSO or delegate will promptly review all film or TLD exposure reports to look for workers or groups of workers whose reported exposures are unusual.

2. All individuals who are occupationally exposed to radiation on a regular basis and may receive greater than one-tenth the quarterly permissible limits will be issued a film or TLD whole body monitor.

3. All individuals who handle radioactive material on a regular basis will be issued a film or TLD finger monitor.

4. All individuals who are occupationally exposed to significant radiation levels on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for those patients.

5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

6. All film and TLD badges will be changed on a monthly basis.

MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

Item 10.2

This license is for an out-patient diagnostic clinic and, therefore, is not required to have a Radiation Safety Committee. The statements following which refer to the Radiation Safety Committee will actually mean Radiation Safety Officer for this license. All pertinent responsibilities of the Radiation Safety Committee will be met by the Radiation Safety Officer with the assistance of the radiological physics consultants.

1. Management Commitment

   a. We, the management of this medical facility, are committed to the program described herein for keeping individual and collective doses 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 intructions to foster the ALARA concept within our facility. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

   c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if 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 when reasonable. If 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

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 methods of use for which application has been made 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 exposures ALARA.

(3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority

(1) The RSC will delegate authority to the RSO for the enforcement of the ALARA concept.

(2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its actions in the minutes of the quarterly meeting.

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 in which the investigational levels in Table I 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.

Table I: Investigational Levels

Body Part Exposed	Level I (mrems per calendar quarter)	Level II (mrems per calendar quarter)
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 the whole body	750	2250

(3) The RSC will evaluate our institution's overall efforts for maintaining doses 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

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. Review of specific methods of use may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.

(3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

b. Education Responsibilities for the 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 formulating the procedures that they will be required to followed.

(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 implement changes in the program to maintain doses ALARA.

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for new uses.

(2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA.

b. Authorized User's Responsibility to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

b. Workers will be instructed in recourses available if they feel that ALARA in not being promoted on the job.

6. Establishment of Investigational levels in Order to Monitor Individual Occupational External Radiation Doses

This facility hereby establishes investigational levels for occupational external radiation doses which, when exceeded will initiate review or investigation by the RSC and/or RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO 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 1:

a. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no futher action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

b. Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose 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, review each such dose in comparison with those of others performing similiar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's NRC Form-5 or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

d. Reestablishment of investigational Levels to levels above those listed in Table 1.

In cases where a worker or group of workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented. The RSC will review the justification for and must approve or disapprove all revisions of investigational levels

7. Signature of Certifying Official

I hereby certify that this institution has implemented the ALARA Program set forth above.

Harold J. Deitch MD

Signature

HAROLD J. Deitch MD.

Name (Print or Type)

RSO,

Title

Woodland Medical Group
NRC License 21-13255-01 Renewal Request
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PROCEDURE FOR LEAK-TESTING SEALED SOURCES

Item 10.3

We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix H to Regulatory Guide 10.8, Revision 2.

RULES FOR THE SAFE USE OF RADIOPHARMACEUTICALS

Item 10.4

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Either after each procedure or before leaving the area, monitor your hands and clothing for contamination in a low background area.

4. Use syringe shields for routine preparation of patient dosages and administration to patients, except in those circumstances in which their use is contraindicated. In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose.

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

6. Do not store food, drink, or personal effects in areas where radioactive material is used or stored.

7. Wear personnel monitoring devices (as prescribed by the RSO) at all times while in areas where radioactive materials are used or stored. Store personnel monitoring devices at the facility in a designated low-background area.

8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.

9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

10. Never pipette by mouth.

11. Confine radioactive solutions in shielded containers that are clearly labeled with the isotope, compound name, and the date and time of receipt or preparation. Syringes and/or syringe shields shall be labeled with the radiopharmaceutical name or abbreviation contained within, type of study, or patient's name.

12. Assay each patient dose in the dose calibrator before administration. Do not use a dose if it differs from the prescribed dose by more than ten percent, except prescriptions of less than 10 uCi. Check the patient's name and I.D. number and the prescribed radionuclide, chemical form, and dosage before administering.

13. Always keep radioactive materials in shielded locations or containers.

14. When practical, use a cart or wheelchair to move flood sources, syringes, waste, and other radioactive material.

EMERGENCY PROCEDURES

Item 10.5

Minor Spills

1. NOTIFY: Notify persons nearby that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use disposable gloves and remote handling tools. Carefully fold the absorbent paper with the clean side out and insert in a plastic bag for transfer to a radioactive waste container. Also place the contaminated gloves and any other contaminated disposable material in the bag.

4. SURVEY: Survey the area with a low-range, GM survey meter. Check the area around the spill, hands, clothing, and shoes for contamination.

5. REPORT: Report the incident to the RSO who will supervise the cleanup of the spill and complete the Radioactive Spill Report.

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 paper, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: This should be done only if it can be done without further contamination or a significant increase in radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. NOTIFY: Notify the RSO immediately.

6. PERSONNEL DECONTAMINATION: Decontaminate personnel by removing contaminated clothing and flushing the contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination released by the perspiration.

7. REPORT: The RSO will supervise the cleanup of the spill and complete the Radioactive Spill Report.

PACKAGE ORDER AND RECEIPT PROCEDURES

Item 10.6

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

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

   a. <u>For routinely used materials</u>

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

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

   b. <u>For occasionally used materials (e.g., theraputic dosages)</u>

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

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

3. For deliveries during normal working hours, packages are received at the Receiving Dock. The personnel at the Receiving Dock are instructed to bring the packages to the Nuclear Medicine Department immediately. The memorandum provided to the Receiving Dock is enclosed.

4. If off duty deliveries are necessary, the packages are received by the Security Guard on duty. The package is then taken immediately to the Hot Lab and is left in the locked room. The memorandum provided to the Security personnel is enclosed.

5. The package order and receipt procedures for the Brachytherapy sources in the Radiation Oncology Department are enclosed.

PROCEDURE FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

Item 10.7

1. Put on gloves to prevent hand contamination.

2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop and notify the RSO.

3. Measure the exposure rate from the package at 1 meter and at the package surface. If the rate is higher than expected, stop and notify the RSO. The surface dose rate should not exceed 200 millirem per hour. Packages with the "White I" labels should be less than 0.5 millirem per hour at the package surface.

4. Follow the steps listed below when opening the package.

   a. Remove the packing slip.
   b. Open the outer package following the supplier's instructions, if available.
   c. Open the inner package and verify that the contents agree with the packing slip.
   d. Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
   e. If anything unusual is noticed, stop and notify the RSO.

5. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe with a thin-end window GM meter or a well counter to determine if there is any removable activity. If there is any contamination, notify the RSO.

6. Verify that the material received is the material ordered.

7. Monitor the packing material and the empty packages for contamination with a GM survey meter before discarding. If contaminated, treat as radioactive waste. If not contaminated, deface all radiation labels before discarding.

8. Record the receipt and all readings taken.

9. For packages received under a general license in 31.11, follow the steps listed below for each package.

   a. Visually inspect the package for damage. If damage is noted, stop and notify the RSO.
   b. Verify that material received is the material ordered.

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BYPRODUCT MATERIAL USE

Item 10.8
Unit Dose Records shall contain:

1. Technical Data

   a. Radionuclide
   b. Chemical form or abbreviation
   c. Date of receipt
   d. Activity as recorded on the packing slip
   e. Supplier
   f. Lot or control number

2. Administrative Data

   a. Time and date of administration
   b. Measured activity
   c. Patient name and ID number
   d. Method of disposal
   e. Initials of person recording the information

Item 10.9
Multidose Vial Records shall contain:

1. Technical Data

   a. Radionuclide
   b. Chemical form or abbreviation
   c. Date of preparation
   d. Date, time, and activity of initial assay
   e. Supplier of kit manufacturer

2. Administrative Data

   a. Date and time dosage was drawn
   b. Precribed dosage
   c. Calculated inverse concentration (cc/mCi) at drawing time
   d. Calculated volume needed for prescribed dose
   e. Measured activity
   f. Patient name and ID number
   g. Method of disposal and date
   h. Initials of person recording information

Item 10.10
Molybdenum Concentration Records shall contain:

1. a. Date the generator was received
   b. Date and time of elution
   c. Measured Mo-99 activity in microcuries
   d. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer
   e. Measured Tc-99m activity in millicuries
   f. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and documentation that the ratio is less than specified in 10 CFR 35.204 (a)
   g. Initials of the person who made the record

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AREA SURVEY PROCEDURES

Item 10.12

Surveys for contamination and ambient exposure rates will be performed in accordance with 10 CFR 35.70.

1. All areas where radiopharmaceuticals are eluted, prepared, and administered will be surveyed daily for ambient radiation exposure rates and weekly for removable contamination. Special care will be taken to remove all paraphernalia from patients rooms where diagnostic administrations are occasionally made; and these rooms will not be surveyed.

2. All areas where radioactive materials are stored will be surveyed weekly for ambient radiation exposure rates and for removable contamination.

3. Laboratory areas where each process involves less than 200 uCi of byproduct materials will be survey monthly for ambient radiation exposure rates and removable contamination.

4. Surveys for ambient exposure rates will be performed with a radiation detection survey instrument able to detect as low as 0.1 mR/h.

5. Surveys for removable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 2000 dpm.

6. The trigger level for exposure rate surveys will be rates above the normal background reading for that area.

7. The trigger level for removable contamination surveys will be the detection of values equal to or less than the recommended levels in Table N-1 of the Regulatory Guide 10.8. For example, the action level for Tc-99m contamination will be 2000 dpm or lower.

8. Survey results greater than the trigger levels will result in decontamination or shielding procedures necessary to reduce the exposure or contamination levels to background on repeat surveys.

9. A record shall be kept of all survey results. The record will include:

    a. Location, date, and type of equipment used.
    b. Initials of the person conducting the survey.
    c. Drawing of the area surveyed.
    d. Trigger levels keyed to the location on the drawing.
    e. Results keyed to the location on the drawing.
    f. Corrective actions taken in case of contamination or excessive exposure rates and reduced contamination levels after corrective action.

10. The RSO or their designate will review the survey results on a quarterly basis for conformance to certain action levels.

PROCEDURES FOR AIR CONCENTRATION CONTROL OF XENON-133

Item 10.13

Spent gas will be collected in a shielded trap. We will follow the procedures listed below for monitoring the trap effluent.

1. The trap effluent will be collected from the exhaust of the trapping system upon initial use of each trap and once each month in which the system is used.

2. The trap effluent from one patient study will be collected in a plastic bag.

3. The activity in the bag will be monitored by holding the bag against a camera which has been adjusted to detect Xe-133 and comparing its counts per minutes (cpm) to background cpm.

4. A record will be kept of the date, background cpm, and bag cpm.

5. An action level will be established based on the background cpm or a multiple of background. Significant increases in the bag cpm above normal, indicate that the trap is breaking down and will be replaced.

6. If a xenalert system is available, the manufacturer's instructions will be followed for monitoring the trap effluent.

7. Manufacturer's directions will be followed for replacing the trap.

8. All rooms in which radioactive Xenon-133 gas studies are performed will be maintained at ten percent negative pressure.

WORKER DOSE FROM AEROSOLS

Item 10.13.2

1. "We will collect spent aerosol in a shielded trap and, for reusable traps, monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

PUBLIC DOSE FROM AIRBORNE EFFLUENT

Item 10.13.3

1. "We will not directly vent spent aerosols and gases to the atmosphere and, therefore, no effluent estimation is necessary."

EMERGENCY PROCEDURES FOR ACCIDENTAL RELEASE OF XENON-133

Item 10.13.4

1. Notify persons in the room that a spill (release) has occured.

2. All persons should vacate the room at once.

3. Notify the RSO immediately.

4. Prevent entry into the room until the calculated evacuation time has occurred. The evacuation time is calculated as follows:

   Evacuation time (t) = (-V/Q) ln(CV/A) where:

   A = the highest activity of gas in a single container, (uCi).
   S = measured airflow supply from each vent in the room, (ml/min).
   Q = the total room air exhaust determined by measuring in (ml/min) the airflow to each exhaust vent in the room.
   C = the maximum permissible air concentration in restricted and unrestricted areas. For Xe-133, MPC = 1x10E-5 uCi/ml (restricted) and 3x10E-7 uCi/ml (unrestricted).
   V = the volume of the room (ml).

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WASTE DISPOSAL

Item 11.1

Liquids and Gases

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere.

1. Disposal to the sanitary sewer system will be made in accordance with 10 CFR 20.303. A record will be kept of the following: date, radionuclide, estimated activity released, and place where material was released.

2. Permissible concentrations in effluents will be kept within the limits enumerated in Table II of Appendix B of 10 CFR 20. A record will be kept of the date, radionuclide, estimated activity released, estimated concentration, and vent site at which the material was released.

Decay in Storage

1. Only material with a physical half-life of less than 65 days may be decayed in storage at the facility.

2. Material will be decayed for at least 10 half-lives.

3. Prior to disposal as in-house waste, each container will be monitored as follows:

   a. Low-range GM survey meter will be checked for proper operation.
   b. Waste will be monitored in a low level area.
   c. Any shielding around the container will be removed.
   d. All surfaces of each individual container will be monitored.
   e. Only those containers which cannot be distinguished from backgroud levels will be disposed of after all radioactive labels have been defaced.

4. Mo-99/Tc-99m generators will be held for at least 60 days before being dismantled. When dismantling generators, a low-range GM survey meter will be kept at the work area. The oldest generator will be dismantled first, working forward chronologically. Each individual column will be held in contact with a low-level survey instrument in a low background (less than 0.05 mR/h) area. The generator date and disposal date will be logged in the disposal records. Radiation labels will be removed or defaced on the generator shield. Generators may also be returned to the manufacturer for disposal.

Unit Dose Waste

If a unit dose pharmacy is used, the materials supplied by them (e.g., syringes, needles, etc.) may be returned to the unit dose pharmacy in the original shipping container. Pertinent DOT regulations will be followed as specified by the unit dose pharmacy.