

NRC FORM 313  
(10-94)  
10 CFR 30, 32, 33  
34, 35, 36, 39 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120  
EXPIRES 6-30-96

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-8 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

APPLICATION FOR MATERIAL LICENSE

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY  
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS  
U.S. NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555-0001

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:

LICENSING ASSISTANT SECTION  
NUCLEAR MATERIALS SAFETY BRANCH  
U.S. NUCLEAR REGULATORY COMMISSION, REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PA 19406-1415

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

NUCLEAR MATERIALS LICENSING SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION II  
101 MARIETTA STREET, NW, SUITE 2900  
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION III  
801 WARRENVILLE RD.  
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV  
611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TX 76011-8064

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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 JURISDICTIONS.

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

- A. NEW LICENSE
- B. AMENDMENT TO LICENSE NUMBER
- C. RENEWAL OF LICENSE NUMBER 21-13255-01

2. NAME AND MAILING ADDRESS OF APPLICANT (include Zip code)

DMC Physicians Group  
22341 W. Eight Mile Road  
Detroit, MI 48219

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

22341 W. Eight Mile Road  
Detroit, MI 48219

41935 W. Twelve Mile Road  
Novi, MI

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dawn Edwards, Medical Physic  
Consultants, Inc.

TELEPHONE NUMBER  
734-662-3197

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 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 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 \$

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, 36, 39 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 82 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.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Kate Upton, Vice President, Dmc Physician Group, Oakland Network

SIGNATURE

Kate Upton

DATE

8/1/00

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		

APPROVED BY

DATE

RECEIVED

AUG 04 2000

REGION III

PRINTED ON RECYCLED PAPER

306824



**DMC Physician Group**  
Detroit Medical Center / Wayne State University

**Health Care Centers**

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**Detroit**  
22341 W. 8 Mile Rd.  
Detroit, MI 48219  
313-592-3500 Phone

**Livonia**  
17940 Farmington Rd.  
Livonia, MI 48152  
734-523-6800 Phone

**Novi**  
41935 W. 12 Mile Rd.  
Novi, MI 48377  
248-347-8000 Phone

July 14, 2000

UNITED STATES NUCLEAR REGULATORY COMMISSION  
Region III, Materials Licensing Section  
801 Warrenville Road  
Lisle, IL 60532-4351

**Re: Renewal application for license number 21-13255-01.**

Enclosed, please find the Renewal application for our facility.

Please note that we have recently changed our name to DMC Physicians Group to better reflect our association with the DMC medical center.

If you have any questions regarding the application please contact Dawn Edwards, our physics consultant, at 734-662-3197.

Thank you for your cooperation in this matter.

Sincerely,

Administrator



www.dmc.org  
AUG 4 2000

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### RADIOACTIVE MATERIAL AND USE

<b>Byproduct Material</b>	<i>Item 5</i> <b>Amount</b>	<i>Item 6</i> <b>Purpose</b>
Material in 35.100	As Needed	Uptake, dilution, and excretion studies
Material in 35.200 (excluding generators that require depleted uranium shielding)	As Needed	Imaging and localization studies
Material in 35.300	As Needed	Therapeutic administration (excluding Nal-131 for thyroid carcinoma)

### RADIATION SAFETY PROGRAM RESPONSIBILITY

*Item 7.1*

**Authorized Users**

**Materials**

Harold Daitch, M.D.

35.100, 35.200 and 35.300 (excluding Nal-131 for thyroid carcinoma) and 31.11.

Richard Small, M.D.

35.100, 35.200 and 35.300 (excluding Nal-131 for thyroid carcinoma) and 31.11.

Seymour Mirkes, M.D.

35.100, 35.200 and 35.300 (excluding Nal-131 for thyroid carcinoma) and 31.11.

*Item 7.3*

**Radiation Safety Officer**

Harold Daitch, M.D.

## PERSONNEL TRAINING PROGRAM

### *Item 8.1*

All radiation workers and ancillary personnel, such as housekeeping, maintenance and security whose duties will require them to work in the vicinity of radioactive materials will receive instruction. The list of topics covered, the date of the instruction, and the names of those attending will be kept on hand for review. Format will be lectures or handouts or videotaped presentations or demonstrations as directed by the Radiation Safety Officer.

### 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.

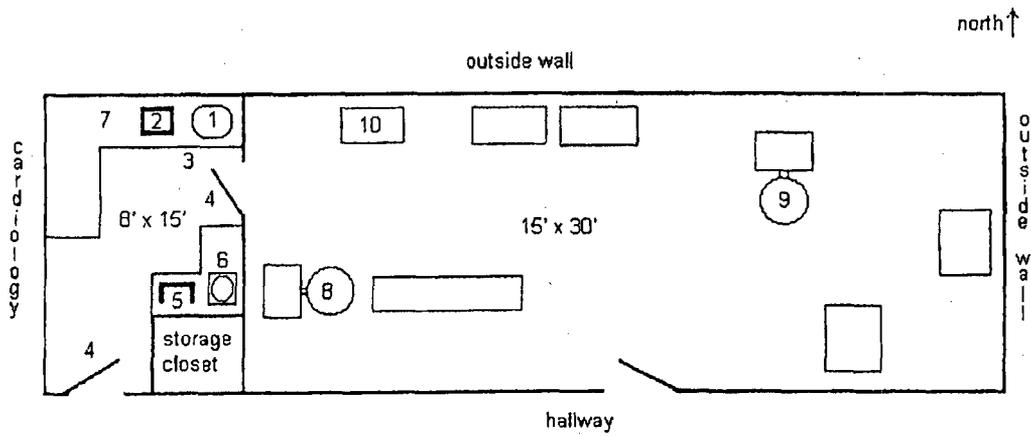
### Instruction Topics

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.
10. Quality Management Program - all policies and procedures. (As Necessary)
11. Radioactive Material Shipment

### FACILITY DIAGRAM

Item 9.1

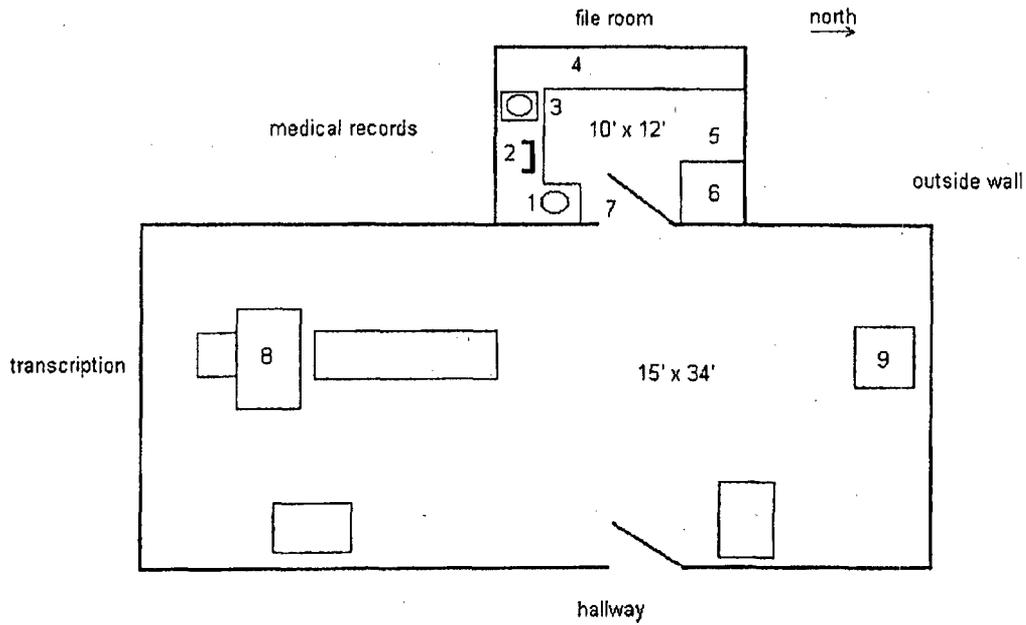
22341 W. Eight Mile Road  
Detroit, Michigan



- |                               |                         |
|-------------------------------|-------------------------|
| 1. sink                       | 6. dose calibrator      |
| 2. sealed source storage      | 7. future generator     |
| 3. waste storage (under sink) | 8. spect camera         |
| 4. lockable doors             | 9. planar camera        |
| 5. lead glass face shield     | 10. uptake probe / well |

Item 9.1 cont.

41935 W. Twelve Mile Road  
Novi, Michigan



- |  |                  |
|--|------------------|
| 1. sink                                    | 6. waste storage |
| 2. lead glass face shield / sealed sources | 7. lockable door |
| 3. dose calibrator                         | 8. spect camera  |
| 4. package receipt area                    | 9. uptake probe  |
| 5. future generator                        |                  |

*Item 9.1 cont.*

Radioactive waste will be stored within a lead brick box or other leaded containers. Generators are not currently used. Before use is implemented, additional lead shielding will be obtained and positioned to ensure that exposure levels in unrestricted areas are at or below the levels allowed in 10 CFR 20. Sufficient shielding will be used to ensure that no member of the public is allowed to receive greater than the allowable limits given in 10 CFR 20.

In accordance with 10CFR20.1406 we will adhere to the following:

1. We will minimize contamination of our facility and the environment by performing daily exposure rate surveys and weekly wipe tests to identify areas of contamination. Contaminated areas will be immediately decontaminated.
2. All radioactive materials used at this facility have half-lives less than 65 days; therefore all radioactive materials will be decayed on site. If we terminate our license, all radioactive waste that has not fully decayed in storage will be transferred to a licensed disposal facility.
3. Upon termination of our license, will be perform a close-out survey of all areas authorized for radioactive use. The close-out survey will consist of surveys with a GM meter to detect ambient exposure rates and wipe tests to determine if removable contamination is present.

## EQUIPMENT LIST

### *Item 9.1 (cont.)*

#### **Imaging Equipment**

Tomographic Gamma Camera

#### **Dose Calibrator**

Capintec or equivalent

#### **Survey Meters**

GM Survey Meter

Low Range (0-0.5 mR/hr)

High Range (>1000 mR/hr)

#### **Other**

Lead Glass Face Shields

Leaded Syringe Shields

Remote Handling Tools

Lead Bricks

Radiac Wash

### **CALIBRATION OF SURVEY INSTRUMENTS**

*Item 9.2*

All survey instruments will be calibrated and checked in accordance with 10 CFR 35.51. Survey instruments will be calibrated by :

1. The manufacturer;
2. Medical Physics Consultants: (NRC License # 21-20153-01)
3. Any authorized user licensed to perform survey meter calibrations as a service.

### CALIBRATION OF DOSE CALIBRATOR

Item 9.3

Page 1 of 2

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 30 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 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 activity.

*Item 9.3 (cont.)*

Page 2 of 2

**Sleeve method:** The sleeves will be calibrated at the time of an initial reading of a decay-method linearity test. Either the "Calicheck" or "Lineator" product will be used and the testing procedure will be performed according to the manufacturer's instructions. 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.

**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 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 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 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.

### 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 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.
7. We will use a NVLAP accredited dosimetry processor.

**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 following statements which refer to the Radiation Safety Committee will actually mean Radiation Safety Officer for this license. The Radiation Safety Officer will meet all pertinent responsibilities of the Radiation Safety Committee 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 instructions 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.

*Item 10.2 (cont.)*

**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) Management will delegate authority to the RSO for the enforcement of the ALARA concept.
- (2) Management will support the RSO when it is necessary for the RSO to assert authority.

**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.

Item 10.2 (cont.)

**Table I: Investigational Levels**

Body Part Exposed	Level I (mrems per calendar quarter)	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	1250	3750
3. Skin of the whole body	1250	3750
4. Eye (lens)	375	1125

(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 or cause to be performed 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 or cause to be reviewed 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 or cause to be reviewed 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 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 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 or cause to be established 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**

(1) 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 is 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 further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

Item 10.2

**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 similar 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. Re-establishment of Investigational Levels to levels above those listed in Table 1.**

In cases where a worker or group of worker's doses need to exceed an investigational level, a new, higher investigational level maybe 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.



Signature

HAROLD J. DATCH, M.D.

Name (Print or Type)

CHIEF, DEPT OF DIAGNOSTIC IMAGING

Title

**PROCEDURE FOR LEAK-TESTING SEALED SOURCES**

*Item 10.3*

1. Medical Physics Consultants, Inc. (NRC License No. 21-20153-01), or anyone licensed by the NRC to perform leak testing as a service. Sources will be leak tested on a bi-annual basis that is not to exceed 6 months.

## 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. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for contamination.
11. With a radiation detection survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.
12. 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.

*Item 10.4 cont.*

13. 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 30 uCi. Check the patient's name and I.D. number and the prescribed radionuclide, chemical form, and dosage before administering.
14. Always keep radioactive materials in shielded locations or containers.
15. When practical, use a cart or wheelchair to move flood sources, syringes, waste, and other radioactive material.
16. Do not pipette by mouth.

## 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 and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to ensure that the Report and Survey are completed properly.

#### **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 and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to see that the report and the survey are completed properly.

### 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. **For routinely used materials**
    - (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. **For occasionally used materials (e.g., therapeutic dosages)**
    - (1) The authorized user who will perform the procedure will make a written request that indicates the 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 Nuclear Medicine department.
4. If off duty deliveries are necessary, the carrier has been given a key to the Nuclear Medicine Hot Lab. The carrier will then place the package within the Nuclear Medicine Hot Lab and re-lock the door.

Sample Memorandum

MEMO TO: Radiopharmaceutical Carrier  
FROM: Radiation Safety Officer  
SUBJECT: Delivery of Packages Containing Radioactive Material

You have been given a key to the Nuclear Medicine Hot Lab for delivery of packages. When delivering packages containing radioactivity, packages should be taken directly to the Nuclear Medicine Hot Lab. The Hot Lab door should be unlocked, the packaged placed in the designated receipt area and the door immediately re-locked.

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

If you have any questions concerning this memorandum, please call our Radiation Safety Officer at 248-347-8220.

	Name	Home Telephone
Radiation Safety Officer:	<u>Harold Daitch, M.D.</u>	(b)(6)
Nuclear Medicine Technologist:	<u>LIZ TAYLOR</u>	(b)(6)

Ex. 6

## 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. Wipe the external surface of the source container and analyze the sample for activity in (dpm's). If the value is above the trigger level specified in 10 CFR 71.87(i), notify the RSO.
5. 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.
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.

**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, administration or disposal
  - d. Activity as recorded on the packing slip and it's associated time
  - e. Supplier
  - f. Lot or control number
  
2. Administrative Data
  - a. Time and date of administration or disposal
  - b. Measured activity and date and time of measurement
  - c. Patient name and ID number
  - d. Method and date of disposal
  - e. Initials of person recording the information
  - f. Prescribed Dosage

*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 and measured
  - b. Prescribed dosage
  - c. Calculated volume needed for prescribed dose
  - d. Measured activity and associated time
  - e. Patient name and ID number
  - f. Method of disposal and date
  - h. Initials of person recording information

We will not possess any volatile radiopharmaceuticals or radioactive gases in multidose vials; therefore, we will not need a fume hood.

*Item 10.10*

**Molybdenum Concentration Records shall contain:**

- 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 or equal to 0.07  $\mu\text{Ci}$  Mo-99 per mCi of Tc-99m
- g. Initial of the person who made the record

## AREA SURVEY PROCEDURES

Item 10.12

Page 1 of 2

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 at the end of each day of use for ambient radiation exposure rates and weekly for removable contamination. Special care will be taken to remove all paraphernalia from patient's 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 by-product materials will be surveyed 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/hr.
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 twice 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.

*Item 10.12*

9. A record shall be kept of all survey results. The record will include:
- Location, date, and type of equipment used.
  - Initials of the person conducting the survey.
  - Drawing of the area surveyed.
  - Trigger levels keyed to the location on the drawing.
  - Results keyed to the location on the drawing.
  - 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.

11. The method for determining the efficiency factor of each counting instrument used to detect contamination for wipe testing is as follows:

A= Calculated source activity of sample isotope in dpm

B= Measured source counts of sample isotope in cpm

C= Measured background counts in cpm

D= B-C (Net Counts in cpm)

Efficiency Factor =  $\frac{\text{Calculated activity in dpm (A)}}{\text{Net counts in cpm (D)}}$

Wipe sample in dpm = Net counts of wipe sample x Efficiency factor

12. The RSO will be notified of all wipe test and ambient survey results that are above the established trigger level.

### PROCEDURES FOR AIR CONCENTRATION CONTROL OF XENON-133

#### *Item 10.13.1*

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 the trap effluent is monitored by a radiation detector designed to monitor effluent gas, the manufacturer's instructions will be followed for monitoring the trap effluent and a record of the checks will be kept.
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 negative pressure.

### EMERGENCY PROCEDURES FOR ACCIDENTAL RELEASE OF XENON-133

1. Notify persons in the room that a spill (release) has occurred.
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 derived air concentration in restricted and unrestricted areas. For Xe-133, Occupational value =  $1 \times 10^{-4}$  uCi/ml (restricted) and  $5 \times 10^{-7}$  uCi/ml (unrestricted).
- V = the volume of the room (ml).

#### **WORKER DOSE FROM AEROSOLS**

*Item 10.13.2*

We will collect spent aerosol in a single-use shielded trap device, therefore no effluent monitoring is needed.

#### **PUBLIC DOSE FROM AIRBORNE EFFLUENT**

*Item 10.13.3*

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

## 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. 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 numerated 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. Each container will be tagged to include:
  - a. the date sealed or set into storage
  - b. the longest-lived isotope in the container
  - c. the initials of the person setting the waste for decay.
3. Material will be decayed for at least 10 half-lives.
4. 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 background levels will be disposed of after all radioactive labels have been defaced.
  - f. The date on which the container was placed in storage will be recorded.
  - g. The date of disposal will be recorded.
  - h. The type of material will be recorded.

(FOR LFMS USE)  
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

Program Code: 02120  
Status Code: 2  
Fee Category: 7C  
Exp. Date: 20000831  
Fee Comments:  
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: WOODLAND MEDICAL GROUP  
Received Date: 20000804  
Docket No.: 3002149  
Control No.: 306824  
License No.: 21-13255-01  
Action Type: Renewal

2. FEE ATTACHED

Amount: \_\_\_\_\_  
Check No.: Ø

3. COMMENTS

Signed D. A. Hersey  
Date 8-21-2000

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 09 is entered / /)

1. Fee Category and Amount: \_\_\_\_\_

2. Correct Fee Paid. Application may be processed for:  
Amendment \_\_\_\_\_  
Renewal \_\_\_\_\_  
License \_\_\_\_\_

3. OTHER \_\_\_\_\_

Signed \_\_\_\_\_  
Date \_\_\_\_\_