NRC FORM 313
(8-84)
10 CFR 30, 32, 33, 34, 35 and 40

APPLICATION FOR MATERIAL LICENSE

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 5-31-87

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.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL 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 JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
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
MATERIAL RADIATION PROTECTION 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
MATERIAL RADIATION PROTECTION 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)*

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

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

Diabetes and Thyroid Associates, PC
10711 Spotsylvania Avenue
Fredericksburg, VA 22408

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

10711 Spotsylvania Avenue
Fredericksburg, VA 22408

45-25458-01
030-34894

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Mark A. McClanahan, MD

TELEPHONE NUMBER: (540)891-8592

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 | 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, 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
Mark A. McClanahan	Mark A. McClanahan	President	10-28-98

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] < $250K
- [ ] $250K - 500K
- [ ] $500K - 750K
- [ ] $750K - 1M
- [ ] $1M - 3.5M
- [ ] $3.5M - 7M
- [ ] $7M - 10M
- [ ] > $10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)*

- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
			258197 NMSS/RGNI MATERIALS-002	
AMOUNT RECEIVED	CHECK NUMBER			DATE

PRIVACY ACT STATEMENT ON THE REVERSE

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.

5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

American Association of Clinical Endocrinologists

Certifies that

Mark A. McClanahan, M.D., F.A.C.E.

Successfully Completed the
"Radiological Physics: AACE Nuclear Medicine Course"

on
October 17-24, 1998

The American Association of Clinical Endocrinologists (AACE) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

AACE designates this continuing medical education activity for 80 credit hours in Category 1 of the Physician's Recognition Award of the American Medical Association.

AACE *President*
Helena W. Rodbard, M.D., F.A.C.E.

AACE

Chairman, CME Committee
Nelson B. Watts, M.D., F.A.C.E.

American Association of Clinical Endocrinologists

Certifies that

Mark A. McClanahan, M.D., F.A.C.E.

Successfully Completed the
Nuclear Thyroidology Course
Iodine 131 Course

on
October 17-24, 1998

Has completed its 80 hour course on the use of Iodine 131 for the treatment of hyperthyroidism and thyroid carcinoma

AACE President
Helena W. Rodbard, M.D., F.A.C.E.

AACE

Course Director
H. Jack Baskin, M.D., F.A.C.E.

AH. 7.14

EXHIBIT 2

SUPPLEMENT A

SUPPLEMENT — **U.S. NUCLEAR REGULATORY COMMISSION**

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
Mark A. McClanahan, MD	VA

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Endocrinology, Diabetes, and Metabolism		1991
Internal Medicine		1989

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: CLOCK HOURS IN LECTURE OR LABORATORY	TYPE AND LENGTH OF TRAINING: CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	Kansas City, MA 10/98	25.0	
b. RADIATION PROTECTION	Kansas City, MA 10/98	25.0	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Kansas City, MA 10/98	10.0	
d. RADIATION BIOLOGY	Kansas City, MA 10/98	20.0	
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE

EXHIBIT 3

SUPPLEMENT B

SUPPLEMENT — **U. S. NUCLEAR REGULATORY COMMISSION**

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME: Mark A. McClanahan

STREET ADDRESS: 10711 Spotsylvania Avenue

CITY: Fredericksburg | STATE: VA | ZIP CODE: 22408

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
	Thyroid scan	20+	
	Thyroid uptake	20+	
	Lung perfusion scan		
	Xenon ventilation study		
	Aerosol ventilation scan		
	Renal flow scan		
	Brain scan		
	Liver/spleen scan		
	Bone scan		
	Gastroesophageal study		
	LeVeen shunt study		
	Cystogram		
	Dacryocystogram		
	Cardiac perfusion scan.		
	Cardiac stress ventriculogram		
	Cardiac rest ventriculogram		
	Gallium scan		

WH
WAYNESBORO HOSPITAL
An affiliate of Summit Health

May 14, 1998

To Whom it may concern:

I am a radiologist with a subspeciality in Nuclear Medicine. While I was at Mary Washington Hospital, I worked with Dr. Mark McClanahan. During a two year period we treated more than twenty patients with radioactive I131 for hyperthyroidism.

If you desire some more information please contact me.

Sincerely,

Frank L.D'Amelio M.D.

FLD:nhm

501 East Main Street
Waynesboro, PA 17268-2394
717-765-4000

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM	20+	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR: Frank D'Amelio, MD

b. NAME OF INSTITUTION: Mary Washington Hospital

c. MAILING ADDRESS: Sam Perry BLVD

d. CITY: Fredericksburg Va

e. MATERIALS LICENSE NUMBER(S): 01

5. PRECEPTOR'S SIGNATURE: Frank L. D'Amelio, M.D

7. PRECEPTOR'S NAME *(Please type or print)*: FRANK L. D'Amelio, M.D

8. DATE: October 27, 1998

Diabetes and Thyroid Associates

January 25, 1999

Dr. David Collins
U.S. NRC, Region II
Material Radiation Protection Section
101 Marietta Street, Suite 2900
Atlanta, GA 30323

Fax 404-562-4955

SUBJECT: APPLICATION FOR MATERIAL LICENSE

Dear Dr. Collins:

As per our phone conversation earlier today, I will be using I^{123} to perform Thyroid uptakes which is licensed through the state of Virginia.

I, therefore, request that you amend my application to include only treatment of hyperthyroid patients with I^{131} and not for the purpose of measuring thyroid uptake.

I thank you for your assistance with this matter. Please call me at anytime if I may clarify any aspect of this application.

Sincerely,

Mark A. McClanahan, MD F.A.C.E.

10711 Spotsylvania Avenue, Fredericksburg, VA 22408

NRC Form 313
Applicant: Diabetes and Thyroid Associates, PC
10711 Spotsylvania Avenue
Fredericksburg, VA 22408
(540)891-8592

Item 5/6:

Byproduct Material	Amount	Purpose
Materials in 35.300	As needed, not to exceed 1Ci	hyperthyroidism treatment

Item 7: Individual responsible for Radiation safety program, and training, experience: Mark A. McClanahan, MD, FACE, see ATT 7.14 (exhibit 2).

The authorized user involved in medical use have the following special responsibilities:

1. Examination of patients and medical records to determine if a radiation procedure is appropriate.
2. Prescription of the radiopharmaceutical dosage or dose and how it is to be administered.
3. Actual use of, or direction of technologists or other paramedical personnel in the use of, byproduct material, and
4. Interpretation of results of diagnostic procedures and evaluation of results of therapy procedures.

Item 7.1 Authorized Users for Medical Use and Their Training
The proposed authorized user and his training are listed in ATT 7.1.

Item 7.2 Authorized Users for Nonmedical Use
NA

Item 7.3 Radiation Safety Officer
Mark A. McClanahan, MD will serve as the Radiation Safety Officer. His training is listed previously in ATT 7.1

Item 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS
We Have established a training program and have appended here with a table (ATT 8.1) that identifies the groups of workers who will receive training and the method and frequency of training.

Item 9: Facilities and Equipment.

9.1. An annotated drawing of the room and adjacent areas where byproduct material will be routinely used is appended as ATT 9.1a. A table of the equipment to be used is appended as ATT 9.1b. A description of the areas of use, including construction materials and features is appended as ATT 9.1c.

9.2. Survey Meter Calibration
We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2.

9.3. Dose Calibrator
We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to Regulatory Guide 10.8, Revision2.

9.4. Personnel Monitor Program
We have established a personnel external exposure monitoring program here attached as ATT 9.4 for your review.

9.5. Imaging Equipment
NA

9.6. Other Equipment and Facilities
NA

Item 10: Radiation Safety Program.

10.1 Radiation Safety Committee/Radiation Safety Officer
As we are a medical office we will not have a Radiation Safety Committee and Dr. McClanahan will serve as the RSO. We will issue a Radiation Safety Officer "charter" and Delegation of authority that are appended as ATT 10.1 and ATT 10.1a.

10.2. ALARA
We will establish and implement the ALARA program that is appended with the current regulatory dose limits for radiation workers as ATT 10.2.

10.3. Leak Test
We will establish and implement a procedure for leak-testing sealed sources that is appended for your review as ATT 10.3.

10.4. Safe Use of Radiopharmaceuticals
We will implement the safety rules appended for review as ATT 10.4.

10.5. Spill Procedure
We will establish and implement spill procedures appended here as ATT 10.5 for your review.

10.6. Ordering and Receiving
We will establish and implement the procedure for ordering and receiving radioactive material that is here appended as ATT 10.6 for your review.

10.7. Opening packages
We will developed a package opening procedure for your review that is appended as ATT 10.7.

10.8. Unit Dosage Records
We will establish and implement a procedure for a unit dosage record that is appended as ATT 10.8 for your review.

10.9. Multidose Vial Records
NA

10.10 Molybdenum Concentration Records
NA

10.11 Implant Source Use Records
NA

10.12 Area Survey Procedures
We will establish and implement a procedure for area surveys that is appended as ATT 10.12 for your review.

10.13 Air Concentration Control
NA

10.13.1 Worker Dose from Nobel Gases
NA
10.13.2 Worker Dose from Aerosols
NA
10.13.3 Public dose from Airborne Effluent
NA
10.13.4 Spilled Gas Clearance Time
NA

10.14. Radiopharmacological Therapy
NA

10.15. Implant Therapy
NA

10.16. Other Safety Procedures
NA

Item 11: WASTE DISPOSAL

11.1 Waste Disposal
We will establish and implement the a procedures for waste disposal which is appended as ATT 11.1 for your review.

11.2. Other Waste Disposal
NA

Item 12: FEE CATEGORY
Fee enclosed

Item 13: CERTIFICATION
See NRC Form 313

Item 14: QUALITY MANAGEMENT PROGRAM

We have developed a Quality Management Program (QMP) for your review that is appended as ATT 14.1.

§35.930 Training for radiopharmaceutical therapy

Except as provided in §35.970, the licensee shall require the authorized user of radiopharmaceuticals in §35.300 to be a **PHYSICIAN [y]** who:

[ ] a. - is certified by: [_____ Date]

[ ] the American Board of Nuclear Medicine;
[ ] the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;
[ ] Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
[ ] The American Osteopathic Board of Radiology after 1984; OR

[y]b. - Has had classroom and laboratory training in basic radioisotope handling therapeutic techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows:

[y] 1. 80 hours of classroom and laboratory training that includes: **Oct 17-24, 1998**

[ ] i radiation physics and instrumentation;
[ ] ii radiation protection;
[ ] iii mathematics pertaining to the use and measurement of radioactivity; and
[ ] iv radiation biology; AND

[] 2. supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

[y] i. use of I-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals;

and [ ] ii use of i-131 for treatment of thyroid carcinoma in 3 individuals.

§35.932 Training for treatment of Hyperthyroidism

Except as provided in §35.970, the licensee shall require the authorized user of only I-131 for the treatment of hyperthyroidism to be a **[y] physician** with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of I-131, and supervised clinical experience as follows:

[y] a. 80 hours of classroom and laboratory training that includes: **October 17-24, 1998**

[y] i radiation physics and instrumentation;
[y] ii radiation protection;
[y] iii mathematics pertaining to the use and measurement of radioactivity; AND

[y] b. supervised clinical experience under the supervision of an authorized user that includes the use of I-131 for the diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals.

§35.934, §35.970, §35.972, §35.13 on other side

Licensee: Diabetes and Thyroid Associates License No. 45-25458-01

Name: Mark McClanahan, M.D. Docket No. 030- 34894

Individual qualified **YES**

viewer: David J. Collins Date January 25, 1999

§35.934 Training for treatment of thyroid carcinoma,

Except as provided in §35.970, the licensee shall require the authorized user of only I-131 for the treatment of thyroid carcinoma to be a [ ] **PHYSICIAN** with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of I-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

[ ] a. 80 hours of classroom and laboratory training that includes:

[ ] i radiation physics and instrumentation;

[ ] ii radiation protection;

[ ] iii mathematics pertaining to the use and measurement of radioactivity; AND

[ ] b. supervised clinical experience under the supervision of an authorized user that includes the use of I-131 for the treatment of thyroid carcinoma in 3 individuals

§35.970 Training for experienced authorized users

Physicians, dentists or podiatrists identified as authorized users for the medical, dental or podiatric use of byproduct material on a Commission or Agreement State license issued before April 1, 1987 who perform only those methods for which they were authorized on that date need not comply with the training requirements of SubPart J

§35.972 Recentness of Training Training or certification completion date [_**1998**__]

The training and experience specified in this Subpart must have been obtained within the 7 years preceding the date of application Or
the individual must have had related continuing education and experience since the required training and experience was completed.

§35.13(b)(3)&(4)identified as an authorized user on an NRC or and Agreement State license, or on permit of a Broad Scope license.

License No. _____

Licensee Name _____

Provide copy of document cited

ATT 8.1
Personnel Training Program

Personnel will be instructed:

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

2. During annual refresher training.

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

Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions.

2. Areas where radioactive material is used and stored.

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

4. Appropriate radiation safety procedures.

5. 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. Worker's rights 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 pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

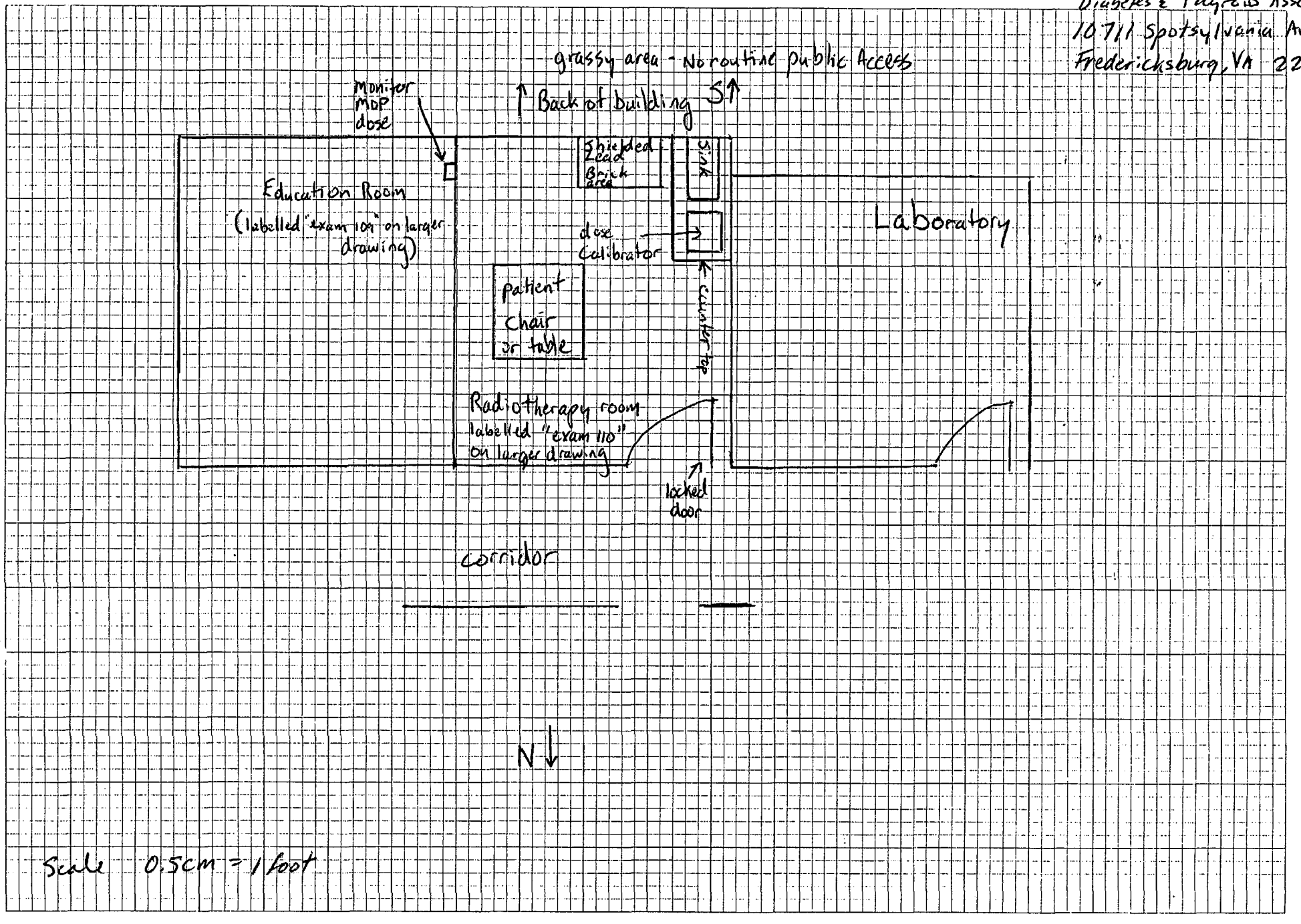
10. Question and answer period.

ATT 8.1 Table of Worker Groups and the Training They Will Receive

GROUP OF WORKERS	TYPE OF TRAINING	FREQUENCY
Physicians	Conferences,Chapter Meetings,Video Tape, In-service lectures or the like	Annually
Technologists	In-Service Lecture, Conferences, Chapter Meetings, Video Tape or the like	Upon employment and annually
Nurses	In-service Lectures, Video, etc.	Upon employment and annually
Clerical	In-service Lectures, Video, etc.	Upon employment and annually
Housekeeping	In-service Lectures, Video,etc.	Upon employment and annually

ATT 9.10

Diabetes & Thyroid Associ
10711 Spotsylvania Aven
Fredericksburg, VA 2240



ATT 9.1b Table of Equipment

EQUIPMENT	MANUFACTURER	MODEL NUMBER
Survey Meter (range 0-2000mR/hr)	Bicron	2000
Survey Meter Detector	Capintec	End-window GM probe
Dose Calibrator	Capintec	CRC-15R
Thryoid probe	Capintec	Captus2000
Well counter	Capintec	Captus 2000
Lead Bricks		
tongs		
lead bricks or square leaded box		

ATT 9.1c

The locked radiotherapy room has spill-resistant vinyl wall covering and a Amtico International-manufactured floor covering, Stratica®. This is a chlorine-free, PVC alternative with excellent chemical resistance and low volatile organic emission. The counter top is constructed of high impact, spill resistant laminated vinyl. There is a shower within the building easily accessible from this room.

ATT 9.4

Personnel External Exposure Monitoring Program

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low.

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly basis.

3. All individual who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.

4. All individuals who are occupationally exposed to radiation on an occasional basis, will be issued a whole body monitor when caring for such patients.

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

ATT 10.1

Radiation Safety Officer Charter and Delegation of Authority

Charge. The Radiation Safety Officer (RSO) shall:

1. Ensure that licensed material will be used safely. This includes the review of, as necessary, the training programs, equipment, facility, supplies and procedures;

2. Ensure that licensed material is used in compliance with NRC regulations and our liscense.

3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program;

4. Establish a table of investigational levels for individual occupational radiation exposures; and

5. Identify program problems and solutions.

Responsibilities. The RSO shall:

1. Be familiar with all pertinent NRC regulations, the license application, the license, and amendments;

2. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures.

3. Prepare a summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive.

4. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g. nursing, housekeeping) are appropriately instructed as required in section 19.12 of 10 CFR Part 19;

5. Review at least annually and to produce a summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with NRC regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports, results of NRC inspections, written safety procedures, and the adequacy of the management control system.

6. Recommend remedial action to correct any deficiencies in the radiation safety program;

7. Ensure that the byproduct material license is amended if required prior to any changes in facilities, equipment, policies, procedures, or personnel.

ATT 10.1a

Memo To: All D.A.T.A.Employees
From: Dr. Mark A. McClanahan
Date:

Subject: Delegation of Authority

I have been appointed Radiation Safety Officer and am responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program, identifying radiation safety problems, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions and ensuring compliance with regulations. I am hereby delegated the authority necessary to meet those responsibilities.

ATT 10.2

ALARA PROGRAM

Diabetes and Thyroid Associates, PC
10-26-98

1. Management Commitment

a. We, the management of this medical office, 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 officer for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our office. This officer will be the 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 practical 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. Review of the ALARA Program

(1) The RSO will continually review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSO will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 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.

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 . This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the staff or outside consultants. Reviews 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 dose are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report.

(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 in ALARA levels during the previous quarter and will prepare a summary report.

b. Education Responsibilities for ALARA Program

(1) The RSO will utilize briefings, educational sessions, and written memoranda, as appropriate, 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 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 dose ALARA.

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult with the RSO 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. Trial runs may be helpful.

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 medical office hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSO. The investigational levels we have adopted are listed in the following table. These levels apply to the exposure of individual workers.

Table of Investigational Levels for Occupational Radiation Exposure

	Investigational Levels (per calendar quarter)		
Total Effective Dose Equivalent (TEDE)	Level I (mrem) **125**	Level II (mrem) **375**	Annual Limit (mrem) **5000**
Sum of Deep Dose Equivalent (DDE) and Committed Dose Equivalent (CDE) for any Individual Organ	**1250**	**3750**	**50000**
Lens of the Eye or Eye Dose Equivalent	**375**	**1125**	**15000**
Whole Skin or any Extremity Shallow Dose Equivalent	**1250**	**3750**	**50000**

The RSO will review and initial the results of personnel monitoring, using NRC Form 5 "Current Occupational External Radiation Exposures" or an equivalent such as the dosimeter processor's report, not less than once in any calendar quarter and will report the results to the staff. The following actions will be taken at the investigational levels as stated in the table of Investigational Levels.

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 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 shortly 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 RSO. The RSO 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.

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

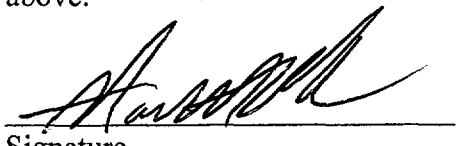
The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and actions taken, if any, will be presented to the staff.

d. Re-establishment of Investigational Levels to levels above those listed in the table.

In cases where a worker's or a 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.

7. Signature of Certifying Official*

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



Signature

Mark A. McClanahan
Name

President
Title

*The person who is authorized to make commitments for the administration of the medical office.

ATT 10.3

Procedure for Leak-Testing Sealed Sources

Procedure

1. Make a list of all sources to be tested. This should include the isotope, the activity on a specified date and the physical form.

2. If you will be testing sources stronger than a few millicuries, set out a survey meter so you can monitor your exposure rate.

3. Prepare a separate wipe sample for each source. A cotton swab, alcohol prep pad, or tissue paper is suitable. Number each wipe corresponding to the source for which it will be used. For small sealed sources, wipe the entire accessible surface area. Pay particular attention to seams and joints.

4. The samples will be analyzed as follows:

    a. A thin-end-window GM survey meter will be used. This instrument must be sufficiently sensitive to detect 0.005microcurie.

    b. The detection efficiency of the survey meter will be estimated by assaying a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, a certified check source of a different isotope with a similar spectrum will be used.

    c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.

    d. Record the wipe sample counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.

    e. Continue the same analysis procedure for all wipe samples.

    f. If the wipe sample activity is 0.005 microcuries or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. The NRC will be notified if that is the case.

    g. Sign and date the list of sources, data, and calculations.

ATT 10.4

Rules for Safe Use of Radiopharmaceuticals

Safety Rules

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 for contamination in a low-background area.

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

5. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.

6. Wear a finger exposure monitor during the manipulation of or administrations capsules containing radiopharmaceuticals.

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

8. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.

9. With a radiation detection survey meter, survey the storage and administration areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

10. Prior to administration, assay each patient dosage in the dose calibrator. Do not use a dosage if it is more than 10 percent in variance with the prescribed dosage. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering any radiopharmaceutical.

11. Always keep waste and other radioactive materials in shielded containers.

12. Because even sources with small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move waste or other radioactive material.

ATT 10.5

Spill Procedures

Minor Spills Capsules and liquids (urine)

1. Notify persons in the area that a spill has occurred.

2. Prevent the spread of contamination by covering the spill with absorbent paper.

3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to the radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.

4. Survey the area with a low range radiation detector survey meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.

5. Report the incident to the Radiation Safety Officer (RSO.)

6. The RSO will follow up on the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey.

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.

2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.

3. Shield the source if possible. This should be done only if it can be done without further contamination or significant increase in radiation exposure.

4. Close the room and lock or otherwise secure the area to prevent entry.

5. Notify the RSO immediately.

6. Decontaminate personnel by removing contaminated clothing and flushing 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 that was released by the perspiration.

7. The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey.

ATT 10.6

Procedure for Ordering and Receiving Radioactive Material

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 radioactive materials used in our facility will only be of "routine" nature (i.e. no "occasional use" radioactive material will be used. The system must contain the following information:

   (a) Written records that identify the authorized user, isotope, chemical form, activity, and supplier will be made.

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

3. For deliveries during normal working hours, the RSO will tell carriers to deliver radioactive packages to a specified area.

4. For deliveries during off-duty hours, the RSO will provide a key to the carrier allowing access to the specified area in accordance with procedures outlined in the memorandum below.

MEMO TO: Syncor Carrier
FROM: Dr. Mark A. McClanahan
SUBJECT: Receipt of Packages Containing Radioactive Material

I hereby authorize you to deliver packages to our office during business and non-business hours. If a delivery is made prior to the opening of our office and arrival of my personnel, please enter through the locked side entrance. A key and access code for the security system will be provided to you. Packages should be placed on a wheelchair and immediately taken to our hotlab, Room 110. Unlock the door, place the package on top of the counter, and relock the door.

If a package appears to be damaged, immediately contact Dr. McClanahan as instructed below. Please use the phone in room 110 and remain there until it can be determined that neither you nor your delivery vehicle is contaminated.

If you have questions concerning this memorandum, please call Dr. McClanahan at (540)891-8592 or at (540)899-1201, beeper 641 or at home at (540)720-2539.

ATT 10.7

Opening Packages Containing Radiation

The following procedure will be used for all radioactive packages received displaying a Radioactive White I, Yellow II or Yellow III label which is less than Type A quantities (see listing below):

a. Wear gloves to prevent hand contamination.

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

c. Wipe test the external surface of the package for removable contamination. If activity exceeds 10^{-5} uCi/cm^2 (370 mBq/cm^2) or 2200 dpm/100cm^2, stop and immediately notify the RSO.

d. Open the package with the following precautionary steps:

(1) Remove the packing slip.
(2) Open the outer package following the supplier's instructions, if provided.
(3) Open the inner package and verify that the contents agree with the packing slip.
(4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
(5) If anything is other than expected, stop and notify the RSO.

e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove to a low-background area. Assay the wipe to determine if there is any removable radioactivity by using rhe GM survey meter. If contamination is found:

(1) Notify the RSO.
(2) Take precautions against potential spread of contamination.

f. Check the user request to ensure that the material received is the material that was ordered.
g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.
h. Make a record of the receipt (will be retained for 3 years.)