

Servicing Imaging Systems International, Inc.
Dr. Aharon Ben-Haim, Physicist
267 Park Street
Upper Montclair, NJ 07043
Tel: (201) 783-3638
Fax: (201) 783-8479

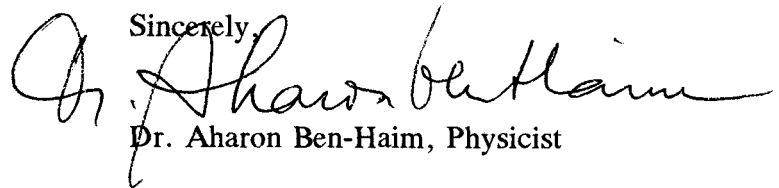
U.S. Nuclear Regulatory Commission Region I
Nuclear Material Section B
631 Park Avenue
King of Prussia, PA 19406

March 20, 1995

Dear Madam/Sir:

We are submitting our application for a license to use radiopharmaceuticals as specified in our application in our laboratory at Linwood Plaza 158, Fort Lee, Suite 318-323. Please contact us if further information is required.

Sincerely,

A handwritten signature in dark ink, appearing to read "A. Ben-Haim", written over the typed name.

Dr. Aharon Ben-Haim, Physicist

MAR 21 1995

121517

(6-93)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

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 (MNBB 7714), 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.

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. **L&L 30214**

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

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.

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
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137-5927

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW
MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, 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

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

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

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



A. NEW LICENSE



B. AMENDMENT TO LICENSE NUMBER _____



C. RENEWAL OF LICENSE NUMBER _____

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

SERVICING IMAGING SYSTEMS INTERNATIONAL
267 Park street
Upper Montclair, NJ 07043

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

New Jersey Medical Group
158 linwood Plaza - Suite 318-323
Fort Lee, NJ 07024

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dr. Aharon Ben-Haim
Physicist

TELEPHONE NUMBER

(201)783-3638

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

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 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.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE

Dr. Aharon Ben-Haim, owner

SIGNATURE

DATE

3/20/95

FOR NRC USE ONLY

TYPE OF FEE

FEE LOG

FEE CATEGORY

AMOUNT RECEIVED

CHECK NUMBER

COMMENTS

APP

ARR1

7C

\$ 1,100

825

REMITTER: SIS INTERNATIONAL, INC.

APPROVED BY

DATE

4/11/95

Item 5 and 6 - Radioactive Material and Purpose

Authorization is requested to utilize the following materials:

	<u>Byproduct Material</u>	<u>Amount</u>	<u>Purpose</u>
5.a	Material in 10 CFR 35.200 Sched. A, Group 2	As needed	6.a Medical use
5.b	Tl-201 (not a byproduct)	As needed	6.b Medical use
5.c	Co-57 sealed sources	20 mCi	6.c Camera flood source Dose calibrator QA

Item 7 - Individuals responsible for Radiation Safety Program Their Training and Experience

Asim G. Dikengil, M.D. is the authorized user. Dr. Dikengil is the authorized user on State of New Jersey Radioactive Materials License NJSL-20475/00/002. See attachment ATT 7.1.2

Dr. Aharon Ben-Haim, a medical physicist for over 30 years, is the owner and the Radiation Safety Officer. See Supplement A.

Item 8 - Training for Individuals working in or frequenting Restricted Areas

We will establish and implement the model training program published in Appendix A of Regulatory Guide 10.8, Revision 2. Prior to commencing operations, radiation safety training will be provided to all staff, as well as specific technical training to technologists and physicians, by the RSO, Dr. Aharon Ben-Haim.

8.1 List of Trainees

Staff Training

to be selected

Technical Training

Dr. Terrance Lee, cardiologist
Gladys Dominique, NT

8.2 Other Training Programs

NA

Item 9 - Facilities and Equipment

9.1 Annotated Drawing

See appended drawing ATT 9.1

9.2 Survey Instrument 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 Calibration

We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to Regulatory Guide 10.8, Revision 2.

9.4 Personnel Monitor Program

We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2.

9.5 Imaging Equipment

NA

9.2 Other Equipment and Facilities

NA

Item 10 - Radiation Safety Program

10.1 Radiation Safety Committee/ Radiation Safety Officer

Because this is a private small entity a Radiation Safety Committee is not required. The owner of the entity is also the Radiation Safety Officer.

10.2 ALARA Program

We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2.

10.3 Leak test

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

10.4 Safe Use of Radiopharmaceuticals

We will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2.

10.5 Spill Procedures

We will establish and implement the model spill procedures published in Appendix J to Regulatory Guide 10.8, Revision 2.

10.6 Ordering and Receiving

We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2.

10.7 Opening Packages

We will establish and implement the model procedure for opening packages, that was published in Appendix L to Regulatory Guide 10.8, Revision 2.

10.8 Unit Dosage Records

We will establish and implement the model procedure for a unit dosage record system that was published in Appendix M.1 to Regulatory Guide 10.8, Revision 2.

10.9 Multidose Vial Records

We will establish and implement the model procedure for a multidose vial record system that was published in Appendix M.2 to Regulatory Guide 10.8, Revision 2.

10.10 Molybdenum Concentration Records

NA

10.11 Implant Source Use Records

NA

10.12 Area Survey Procedures

We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2.

10.13 Air Concentration Controls

NA

10.14 Radiopharmaceutical Therapy

NA

10.15 Implant Therapy

NA

10.16 Other Safety Procedures

NA

Item 11 - Waste Management

11.1 Waste Disposal

We will establish and implement the model procedure for waste disposal that was published in Appendix R to Regulatory Guide 10.8, Revision 2.

11.2 Other Waste Disposal

NA

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 RSO Dr. Aharon Ben-Haim, physicist			2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED	
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B		MONTH AND YEAR CERTIFIED C	
University of Technology in Vienna, Austria	Technical Physics Sc. D.		December 1962	
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	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE	
a. RADIATION PHYSICS AND INSTRUMENTATION	Vienna, 1957, 1958 IAEA Vienna 1962	200	100	
b. RADIATION PROTECTION	IAEA Vienna 1962-1967		100	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Vienna, 1953-1959 IAEA Vienna 1962	200	100	
d. RADIATION BIOLOGY	NA			
e. RADIOPHARMACEUTICAL CHEMISTRY	NA			
5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
Tc-99m	10	Beilinson Hospital	5	Medical Research
Ca-47	0.01	IAEA Vienna	1	Dosimetry
Cs-132	0.01	IAEA Vienna	5	Whole Body Counting
K-42	0.01	IAEA Vienna	5	Whole Body Counting
K-42	1	Montevideo, Uruguay	5	Medical Res.

State of New Jersey
 Department of Environmental Protection and Energy
 Bureau of Radiation Protection
 Radioactive Materials Section
 CN 415
 Trenton, New Jersey 08625-0415
 Phone (609)-987-2132

Page 1 of 7

License # : 20475/00

Amendment # : 002

Radioactive Materials Licensee Data

Pursuant to the New Jersey Radiation Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive or use the radioactive material(s) designated below; and to such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the State Department of Environmental Protection and Energy, now or hereafter in effect, and to any conditions specified below.

1. License # : NJSL-20475/00/002 2. Expires : 04/30/95

3. Name : SERVICING IMAGING SYSTEMS
 INTERNATIONAL, INC.

RSO : AHARON BEN-HAIM, SC.D.

ADM : ASIM G. DIKENGIL, M.D.

4. Address : 267 PARK STREET

City : MONTCLAIR TOWN

State : NJ

Zip : 07043-0000

County : ESSEX

Phone : (201)-783-3638

5. Reference :

Radioactive Materials Data

6. Radioactive Materials	7. Chemical and/or Physical Form	8. Maximum Quantity Licensee May Possess at Any One Time (mCi)
A Any naturally occurring and/or accelerator produced material included under Group II, Section 4.7 of NJAC 7:28-4.	Any radiopharmaceutical included under Group II, Section 4.7 of NJAC 7:28-4.	50.0000
B CO-57	Sealed Source	20.0000
C TL-201	Liquid	5.0000

9. Authorized Use:

State of New Jersey
Department of Environmental Protection and Energy
Bureau of Radiation Protection
Radioactive Materials Section
CN 415
Trenton, New Jersey 08625-0415
Phone (609)-987-2132

Page 2 of 7

License # : 20475/00

Amendment # : 002

Radioactive Materials Data

9. Authorized Use:

- A Any diagnostic procedure under Group II of NJAC 7:28-4, Section 4.7
- B For calibrating and checking of instruments.
- C For calibrating and checking of instruments.

State of New Jersey
Department of Environmental Protection and Energy
Bureau of Environmental Radiation
Radioactive Materials Section

Page 3 of 7

CN 415
Trenton, NJ 08625-0415
Phone (609)-987-2132

License # : 20475Amendment # : 2

Radioactive Materials License

10. Radioactive material shall only be used at New Jersey Medical Group, 158 Linwood Plaza, Suite 318-323, Fort Lee, New Jersey.
11. Radioactive material listed in Conditions 6, 7 and 8 that are used for cardiac imaging and function studies shall be used by or under the supervision of the following: Asim G. Dikengil, M.D.
12. Compliance with other U.S. Agencies having jurisdiction and regulations for radiopharmaceuticals must be maintained.
13. The licensee shall retain records of misadministrations in the use of the licensed radioactive materials. Misadministrations being defined as a radiopharmaceutical or radiation from a sealed source which is improperly used as follows:
 - A. Administration of the wrong radiopharmaceutical or sealed source.
 - B. Administration to the wrong patient.
 - C. Administration by a route other than that intended by the prescribing physician.
 - D. Administered diagnostic dose differing by more than 50 percent of the prescribed dose.
 - E. Administered therapeutic dose differing by more than 10 percent of the prescribed dose.

Records of misadministrations are to include the following information: name of the referring physician, description of the event, the effect on the patient and the action taken to prevent recurrence.

14. The licensee shall not open sealed sources containing radioactive material.

State of New Jersey
Department of Environmental Protection and Energy
Bureau of Environmental Radiation
Radioactive Materials Section
CN 415

Page 4 of 7

Trenton, NJ 08625-0415
Phone (609)-987-2132

License # : 20475

Amendment # : 2

Radioactive Materials License

15. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months.
- A. The test shall be capable of detecting the presence of 0.005 microcuries of removable radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surface of the device in which the sealed source is permanently mounted or stored.
- B. If the test reveals the presence of 0.005 microcuries of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with the Department regulations. Within five days after obtaining results of the test, a report shall be filed with the Department describing the circumstances, the test results and the corrective action taken.
- C. The sealed sources shall be tested for leakage and/or contamination by appropriately trained personnel.
16. Repair, initial leak tests and disposal of sealed sources containing radioactive material shall be performed only by the manufacturer or by other persons specifically licensed by New Jersey or the Federal Government to perform this service.
17. Radioactive material with a physical half life of less than 300 days may be disposed of as non-radioactive waste provided that (a) the radioactive waste is stored behind adequate shielding to meet the requirements of New Jersey Radiation Code 28-6, (b) the radioactive waste is held for ten half-lives of the longest lived radioisotope to be disposed of, (c) the radioactive waste is monitored with a GM meter prior to disposal to insure background levels, (d) all radiation labels are removed or obliterated and (e) a log shall be maintained to include the results of the radiation survey and date of disposal.

State of New Jersey
Department of Environmental Protection and Energy
Bureau of Environmental Radiation
Radioactive Materials Section
CN 415

Page 5 of 7

Trenton, NJ 08625-0415
Phone (609)-987-2132

License # : 20475Amendment # : 2

Radioactive Materials License

18. A survey of the administration area used for stress thallium studies shall be performed and documented on the day the test is done.
19. The licensee shall make the following items available to their staff:
 - A. Copy of the New Jersey Radiation Protection Code.
 - B. Copy of the New Jersey State Radioactive Material License.
20. The licensee shall post the following items in an area frequented by employees engaged in the use of licensed materials:
 - A. Notice to Employees -- RPP-14.
 - B. Emergency procedures involving major, minor spills including the names and phone numbers of people to contact.
 - C. Appropriate signs and labels in areas and/or containers and equipment in which radiation and/or radioactive material are contained. These postings are to conform to Subchapter 10 of the Code.
21. The following tests shall be performed as a minimum:
 - A. Surveys of:
 1. All radioactive materials received.
 2. All radioactive waste decayed to background levels prior to release.
 3. Controlled areas, where licensed materials are used on days they are used.
 4. Uncontrolled areas, where licensed materials are used on days they are used.

Department of Environmental Protection and Energy
Bureau of Environmental Radiation
Radioactive Materials Section
CN 415
Trenton, NJ 08625-0415
Phone (609)-987-2132

Page 6 of 7License #: 20475Amendment #: 2**Radioactive Materials License**

5. Personnel who handle radioactive materials when radioactive materials are used.
- B. Wipe tests of:
1. Controlled areas, weekly, where unsealed sources of licensed materials are used during weeks the material is used.
22. The following records shall be maintained:
- A. Radioactive materials received including but not necessarily limited to date of receipt, radionuclide, activity, mass or volume of material, results of package survey, instrument used for surveys and surveyor's initials.
 - B. Radioactive materials administered to patients including but not necessarily limited to date of administration, radionuclide, calibrated activity administered, quantity, patient name, administrator's signature.
 - C. Radioactive material disposals including but not necessarily limited to:
 1. Disposals to Vendor: nuclide, activity, vendor name, quantity, date of disposal.
 2. Disposal by Decay: Results of survey of the waste, date of survey, date of waste disposal, instrument used, and surveyor's initials.
 3. Disposal to Sanitary Sewer: nuclide, activity, volume of dilution waste per day, date of disposal.
 4. Disposals to Air: nuclide, activity, volume of dilution air, nuclide concentration in air, date of disposal.
 - D. Survey instrument calibration performed annually and after instrument repair.

ATT 7.1.2

Department of Environmental Protection and Energy
Bureau of Environmental Radiation
Radioactive Materials Section
CN 415
Trenton, NJ 08625-0415
Phone (609)-987-2132

Page 7 of 7

License #: 20475

Amendment #: 2

Radioactive Materials License

- E. Sealed source leak tests at intervals not to exceed six months. Results are to be reported in microcuries.
 - F. Surveys performed in controlled and uncontrolled areas including but not necessarily limited to: test results in mR/hr, date performed, instrument used and surveyor's initials.
 - G. Wipe tests performed in controlled areas including but not necessarily limited to: test results in dpm, date performed, instrument used and surveyor's initials.
 - H. Personnel dosimetry records including but not necessarily limited to: name, social security number, and prior employment exposure history.
 - I. Daily personnel monitoring results including but not necessarily limited to: instrument used, date performed and initials.
- 23. While utilizing radioactive material, personnel shall use protective equipment and clothing including but not necessarily limited to: syringe shields, remote handling equipment, adequate shielding, laboratory coats and disposable gloves.
 - 24. Eating, drinking, smoking and applying cosmetics shall not be permitted in controlled areas.
 - 25. Except as specifically provided by this license, the licensee may possess and use radioactive material described in this license only in accordance with statements, representations and procedures contained in application dated October 13, 1994 signed by Dr. Aharon Ben-Haim and letters dated November 18, 1994, December 1, 1994 and January 24, 1995.
 - 26. New Jersey Department of Environmental Protection and Energy
Signature

Date 1/26/95

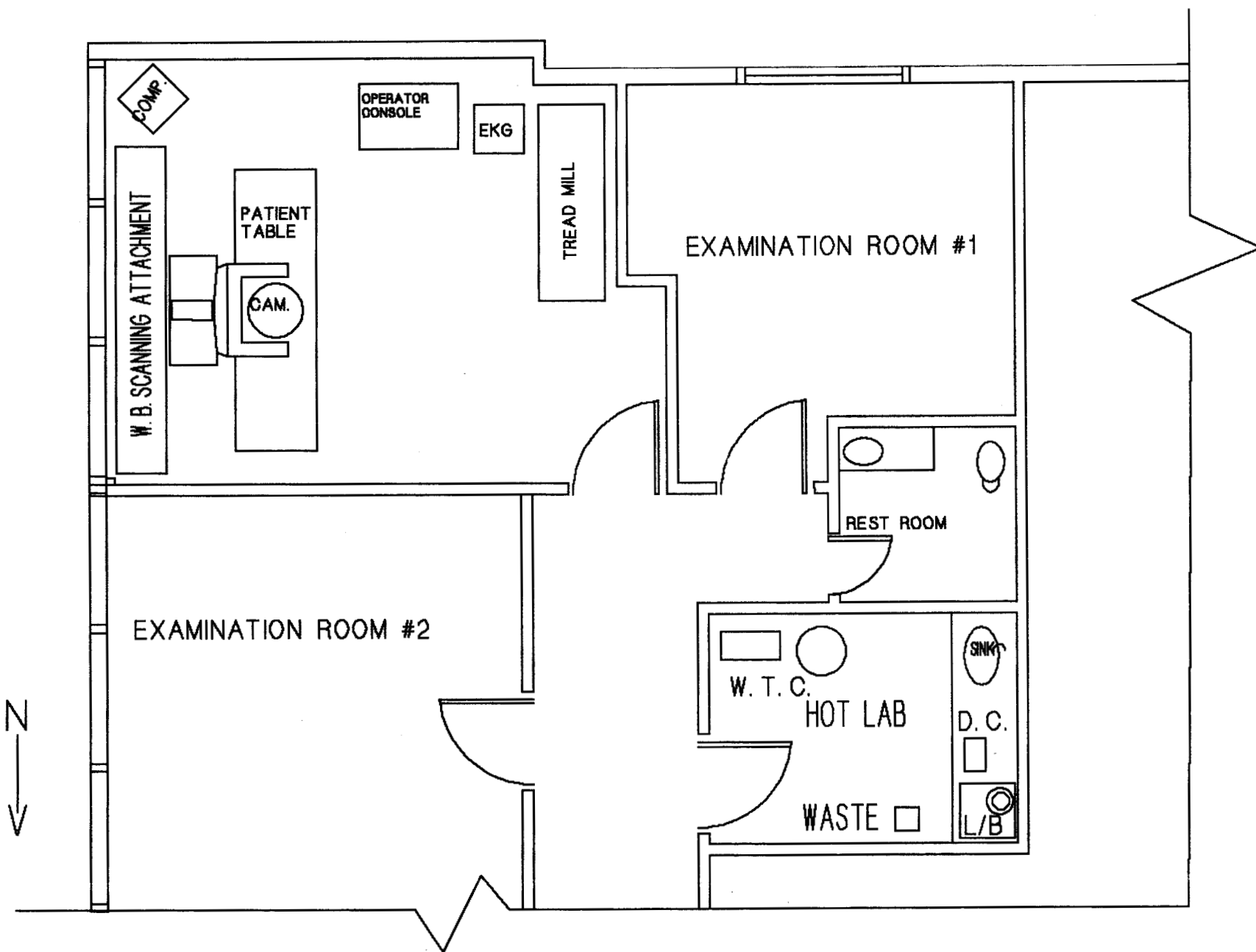
For the State of New Jersey
Department of Environmental Protection and Energy

By John Leaney
(Signature)

3 FT

OFFICIAL RECORD COPY ML 10

121517



ATT 9.1

APPENDIX A

Model Training Program (See §§ 19.12 and 35.21)

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, you may say on your application, "We will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, Revision 2, and have appended a table ATT 8.1 that identifies the groups of workers who will receive training and the method and frequency of training." You may use lectures, video-taped presentations, or demonstrations, for example, as methods of training.

If you prefer, you may develop your own training program for review. If you do so, you should consider for inclusion all the features in the model program and carefully review the requirements of § 19.12. Say on your application, "We have developed a training program for your review that is appended as ATT 8.1." Be sure to include the table that identifies groups of workers, the method of their training, and the frequency of training.

It may not be assumed that safety instruction has been adequately covered by prior occupational training, board certification, etc. Site-specific training should be provided for all workers. Ancillary personnel (e.g., nursing, clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. All training should be tailored to meet the needs of the individuals in attendance. A training program that provides necessary instruction should be written and implemented.

MODEL 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 a 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 or 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 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 pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.
10. Question and answer period.

APPENDIX B

Model Procedure for Calibrating Survey Instruments (See § 35.51.)

You or your contractor may use the following guidance to calibrate survey instruments. If you, or the contractor, follow all the guidance, you may say on your application, "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."

If your procedure does not follow the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.51. Say on your application, "We have developed a survey instrument calibration procedure for your review that is appended as ATT 9.2," and append your survey instrument calibration procedure.

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually and after servicing. (Battery changes are not considered "servicing.")

MODEL PROCEDURE

1. The source must be approximately a point source.
2. Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.
3. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.
4. The source should be of sufficient strength to give an exposure rate of about 30 mR/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of Cs-137 or 21 millicuries of Co-60.
5. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.
6. A record must be made of each survey meter calibration.
7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.

8. Three kinds of scales are frequently used on survey meters:
 - a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately $1/3$ and $2/3$ of full scale.
 - b. Meters that have a multidecade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately $1/3$ and $2/3$ of the decade.
 - c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be at approximately $1/3$ and $2/3$ of the decade.
9. Readings above 1,000 mR/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.
10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.
11. The report of a survey meter calibration should indicate the procedure used and the data obtained. The description of the calibration will include:
 - a. The owner or user of the instrument;
 - b. A description of the instrument that includes manufacturer, model number, serial number, and type of detector;
 - c. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;
 - d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
 - e. The reading indicated with the instrument in the "battery check" mode (if available on the instrument);
 - f. The angle between the radiation flux field and the detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel with or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument);
 - g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;

- h. The apparent exposure rate from the check source; and
 - i. The name of the person who performed the calibration and the date on which the calibration was performed.
12. The following information will be attached to the instrument as a calibration sticker or tag:
- a. The source that was used to calibrate the instrument;
 - b. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);
 - c. For each scale or decade, one of the following as appropriate:
 - (1) The average correction factor,
 - (2) A graph or graphs from which the correction factor for each scale or decade may be deduced, or
 - (3) An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative;
 - d. The angle between the radiation flux and the detector during the calibration; and
 - e. The apparent exposure rate from the check source.

Note: One-word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker.

See Exhibit 7 for a form you may want to use.

APPENDIX C

Model Procedure for Calibrating Dose Calibrator (See § 35.50.)

You or your contractor may use the following model procedure for checking and testing the dose calibrator. If you, or the contractor, follow the model procedure, you may say on your application, "We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to Regulatory Guide 10.8, Revision 2."

If you develop your own dose calibrator calibration procedure for review, you should carefully review § 35.50 and all the features in the model procedure. Say on your application, "We have developed a dose calibrator calibration procedure for your review that is appended as ATT 9.3," and append your dose calibrator calibration procedure.

MODEL PROCEDURE

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. (These recommended tolerances are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances.)
 - a. Constancy at least once each day prior to assay of patient dosages (± 5 percent).
 - b. Linearity at installation and at least quarterly thereafter (± 5 percent).
 - c. Geometry dependence at installation (± 5 percent).
 - d. Accuracy at installation and at least annually thereafter (± 5 percent).
2. After repair, adjustment, or relocation of the dose calibrator, repeat the above tests as appropriate.
3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, Co-57,* or Ra-226* using a reproducible geometry each day before using the calibrator. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:
 - a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).
 - b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.

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

- c. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.
 - d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
 - e. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The regulation requires repair or replacement if the error exceeds 10 percent.
4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.
 5. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

Decay Method

- a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity on the Dose Calibrator Linearity Test Form (see Exhibit 8). This first assay should be done in the morning at a regular time, for example, 8 a.m.
- b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 10 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.
- c. Convert the time and date information you recorded to hours elapsed since the first assay.
- d. On a sheet of semilog graph paper or on a copy of the sample form in Exhibit 8, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Then plot the data.
- e. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. $(A - \text{observed} - A - \text{line}) / (A - \text{line}) = \text{deviation}$.
- f. If the worst deviation is more than ± 0.05 , the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary

to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

- g. Put a sticker on the dose calibrator that says when the next linearity test is due.

Shield Method

If you decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate them.

- a. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps b through d below must be completed within 6 minutes.
- b. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
- c. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
- d. Continue for all sleeves.
- e. Complete the decay method linearity test steps b through g above.
- f. From the graph made in step d of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step b.
- g. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step c.
- h. Continue for all sleeves.
- i. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

- a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.
- b. Steps c through e below must be completed within 6 minutes.
- c. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
- d. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

- e. Continue for all sleeves.
 - f. On a sheet of semilog graph paper or on a copy of the sample form in Exhibit 8, label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.
 - g. Plot the data using the equivalent decay time associated with each sleeve.
 - h. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. $(A - \text{observed} - A - \text{line}) / A - \text{line} = \text{deviation}$.
 - i. If the worst deviation is more than +0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."
 - j. Put a sticker on the dose calibrator that says when the next linearity test is due.
6. Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.
- a. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.
 - b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated on the Dose Calibrator Geometry and Accuracy Form (see Exhibit 9).
 - c. Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
 - d. Repeat the process until you have assayed a 2.0-cc volume.
 - e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the

data and draw horizontal 5 percent error lines above and below the chosen "standard volume."

- f. If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.
 - g. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.
 - h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
 - i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.
 - j. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume."
 - k. If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.
7. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Bureau of Standards (NBS) or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) should be used. The regulations require that one must have a principal photon energy between 100 keV and 500 keV. The regulations also require that, if a Ra-226 source is used, it must be at least 10 microcuries; other sources must be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.
- a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement on the

Dose Calibrator Geometry and Accuracy Form (see Exhibit 9). Repeat for a total of three determinations.

- b. Average the three determinations. The average value should be within 5 percent of the certified activity of the reference source, mathematically corrected for decay.
 - c. Repeat the procedure for other calibrated reference sources.
 - d. If the average value does not agree, within 5 percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent.
 - e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.
 - f. Put a sticker on the dose calibrator that says when the next accuracy test is due.
8. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

See Exhibits 8 and 9 for some forms you may want to use.

APPENDIX D

Model Personnel External Exposure Monitoring Program (See § 20.101.)

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may say on your application, "We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own program for review. If you do, you should consider for inclusion all the features in the model program and carefully review the requirements of § 20.101. Say on your application, "We have developed an external exposure monitoring program for your review that is appended as ATT 9.4," and append your monitoring program.

MODEL 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. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film or thermoluminescence dosimeter (TLD).
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 individuals 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, such as nurses caring for radiopharmaceutical therapy or implant patients, 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 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.

APPENDIX G

Model Program for Maintaining Occupational Radiation Exposure at Medical Institutions ALARA (See § 35.20.)

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own ALARA program for NRC review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.20. Say on your application, "We have developed an ALARA program for your review that is appended as ATT 10.2," and append your program.

ALARA PROGRAM

(Licensee's Name)

(Date)

1. Management Commitment

- a. We, the management of this (medical facility, hospital, etc.), 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 institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).
- b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.
- c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.
- d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable

level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee

a. Review of Proposed Users and Uses

- (1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
- (2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure 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

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

- (1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.
- (2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

c. Review of ALARA Program

- (1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- (2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 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 (see Section 6 below for a discussion of investigational levels).*

*The NRC has emphasized that the investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify investigations.

Table 1
Investigational Levels

	Investigational Levels (mrems per calendar quarter)	
	Level I	Level II
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250
*Not normally applicable to medical use operations except those using significant quantities of beta-emitting isotopes.		

- (3) The RSC will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer

a. Annual and Quarterly Review

- (1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. 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 doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.
- (3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

b. Education Responsibilities for ALARA Program

- (1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

- (2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to 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 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. 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 institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 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.

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 Form NRC-5 or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

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

In cases where a worker'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.

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

AHARON BEN-HAIM

Name (print or type)

OWNER / RSD

Title

*The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

APPENDIX H

Model Procedure for Leak-Testing Sealed Sources (See § 35.59.)

You or your contractor may use the following model procedure to leak-test sealed sources. If you, or the contractor, follow the model procedure you may say on your application, "We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix H to Regulatory Guide 10.8, Revision 2."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.59. Say on your application, "We have developed a leak-test procedure for your review that is appended as ATT 10.3," and append your leak-test procedure.

MODEL PROCEDURE

1. Make a list of all sources to be tested. This should include at least 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, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
 - a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
 - b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.
 - c. For teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care to touch neither field light and mirror nor crosshairs. Also wipe the primary and secondary collimators and trimmers.
 - d. If you are testing radium sources at the same time you are testing NRC-licensed sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the adsorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.

4. The samples will be analyzed as follows:
- a. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a ratemeter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.
 - b. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay 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, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must 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 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under an NRC or Agreement State license, the NRC must be notified. (See paragraph 21.21(b) of 10 CFR Part 21 and paragraph 35.59(e)(2) of 10 CFR Part 35.)
 - g. Sign and date the list of sources, data, and calculations.

APPENDIX I

Model Rules for Safe Use of Radiopharmaceuticals (See § 35.21.)

You may use the following model rules as they appear here, saying on your application, "We will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own rules for safe use of radiopharmaceuticals for review. If you do so, you should consider for inclusion all the items in the model rules and carefully review the requirements of Part 35. Say on your application, "We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as ATT 10.4," and append your model rules for the safe use of radiopharmaceuticals.

MODEL 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 with a crystal probe or camera.
4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
7. 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.
8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.
9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
10. Never pipette by mouth.

11. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.
12. 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.
13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.
14. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it is more than 10 percent off from the prescribed dosage, except for prescribed dosages of less than 10 microcuries. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.
15. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
16. Because even sources with small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

APPENDIX J

Model Spill Procedures (See § 35.21.)

You may use the following model spill procedures as they appear here, saying on your application, "We will establish and implement the model spill procedures published in Appendix J to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own spill procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. Say on your application, "We have developed spill procedures for your review that are appended as ATT 10.5," and append your spill procedures.

MODEL PROCEDURES

Minor Spills of Liquids and Solids

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 a 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 (see Exhibit 10) and the Radioactive Spill Contamination Survey (see Exhibit 11).

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 a 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 (see Exhibit 10) and the Radioactive Spill Contamination Survey (see Exhibit 11).

The following is not part of the model spill procedure:

Major Spills and Minor Spills

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides the best spill procedure may be restricted access pending complete decay.

Table J-1, which may be used as general guidance to determine whether a major spill procedure or a minor spill procedure should be implemented, was developed based on a comparison of information from the following sources:

1. "Standards for Protection Against Radiation," Proposed Rule, Part 20, published January 9, 1986, Appendix B, Table 1, Column 3 (Derived Air Concentration Values), 51 FR 1092.
2. "Gamma Radiation Levels for One Curie of Some Radionuclides," Radio-logical Health Handbook, January 1970 edition, Department of Health, Education, and Welfare, Washington, DC, p. 131.
3. National Council on Radiation Protection and Measurements, "Safe Handling of Radioactive Materials," NCRP Report No. 30, paragraph 2.3 and Table 2, 1964.
4. "Upgraded Emergency Preparedness for Certain Fuel Cycle and Materials Licensees," Advance Notice of Proposed Rulemaking on Parts 30, 40, and 70, 46 FR 29712, Table 1, June 3, 1981.

Table J-1 may need to be modified before being used for guidance in a specific area of use.

TABLE J-1

Relative Hazards of Common Radionuclides

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major, below are considered minor.

Radionuclide	Millicuries	Radionuclide	Millicuries
P-32	10	Tc-99m	100
Cr-51	100	In-111	10
Co-57	100	I-123	10
Co-58	10	I-125	1
Fe-59	10	I-131	1
Co-60	1	Yb-169	10
Ga-67	100	Hg-197	100
Se-75	10	Au-198	10
Sr-85	10	Tl-201	100

Spill Kit

You may also want to consider assembling a spill kit that contains:

- 6 pairs disposable gloves, 1 pair housekeeping gloves
- 2 disposable lab coats
- 2 paper hats
- 2 pairs shoe covers
- 1 roll absorbent paper with plastic backing
- 6 plastic trash bags with twist ties
- "Radioactive Material" labeling tape
- 1 china pencil or marking pen
- 3 prestrung "Radioactive Material" labeling tags
- Supplies for 10 contamination wipe samples
- Instructions for "Emergency Procedures"
- Clipboard with one copy of Radioactive Spill Report Form
- Pencil

Forms

You may want to use Exhibit 10, Radioactive Spill Report, and Exhibit 11, Radioactive Spill Contamination Survey Forms.

APPENDIX K

Model Guidance for Ordering and Receiving Radioactive Material (See §§ 30.51 and 20.205.)

You may use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may say on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of §§ 30.51 and 20.205. Say on your application, "We have developed a procedure for ordering and receiving radioactive material for your review that is appended as ATT 10.6," and append your procedure for ordering and receiving radioactive material.

MODEL GUIDANCE

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, and 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, the RSO will tell carriers to deliver radioactive packages directly to a specified area.
4. For deliveries during off-duty hours, the RSO will tell security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

Sample Memorandum

MEMO TO: Chief of Security
FROM: Radiation Safety Officer
SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of packages containing radioactive material that arrive during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Room _____. Unlock the door, place the package on top of the counter, and relock the door.

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

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, _____, at extension ____.

Name

Home Telephone

Radiation Safety Officer: _____

Chief of Nuclear Medicine: _____

Chief Nuclear Medicine Technologist: _____

Nuclear Medicine Technologist on call _____

(call page operator at extension ____)

Nuclear Medicine Physician on call _____

(call page operator at extension ____)

APPENDIX L

Model Procedure for Safely Opening Packages Containing Radioactive Material (See §§ 35.23, 30.51, 20.203(f)(4), and 20.205.)

You may use the following model procedure for opening packages. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2."

If you develop your own package opening procedure for review, you should consider for inclusion all the features in the model. Say on your application, "We have developed a package opening procedure for your review that is appended as ATT 10.7," and append your package opening procedure.

MODEL PROCEDURE

1. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in paragraph 20.205(b) of 10 CFR Part 20 (e.g., more than 20 curies of Mo-99, Tc-99m, uncompressed Xe-133, or more than 3 curies of Xe-133, I-131, Cs-137, Ir-192, I-125, or more than 0.001 curie of Ra-226). Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). The NRC Regional Office must be notified if removable contamination exceeds 0.01 microcurie (22,000 dpm)/100 cm².
2. For packages received under the specific license, the following procedure for opening each package will be followed:
 - a. Put on 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).
 - c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface (see § 71.4 of 10 CFR Part 71); the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour at the package surface. (See § 172.403 of 49 CFR Part 172.))
 - 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 the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. [The licensee should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.] Take precautions against the 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.
 - (1) If contaminated, treat this material as radioactive waste.
 - (2) If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
 - h. Make a record of the receipt.
3. For packages received under the general license in § 31.11, the following procedure for opening each package will be followed:
 - a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.
 - b. Check to ensure that the material received is the material that was ordered.

See Exhibit 12 for a sample record form you may want to use.

APPENDIX M

Records of Byproduct Material Use

General

Many suppliers include pressure-sensitive stickers or forms that have much of the information required by the regulations. You may use these in your records and need not duplicate the information on them. Be sure to write down whatever additional information is required but is not cued or printed on them. Information does not have to be recorded in the order given in these procedures. Also, you do not have to replicate entries. For example, if you prepare a multidose vial for use one day, you do not have to record the date each time you draw a dosage from it; if you take 30 Ir-192 seeds that are each 0.5 millicuries, you do not have to list each seed individually.

M.1 Records of Unit Dosage Use (§§ 30.51, 35.21, 35.53)

You may use the following model procedure to keep a record of unit dosage use. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for a unit dosage record system that was published in Appendix M.1 to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own unit dosage record system for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of §§ 30.51, 35.21, and 35.53. Say on your application, "We have developed a procedure for a unit dosage record system for your review that is appended as ATT 10.8," and append your unit dosage record procedure.

MODEL PROCEDURE

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Supplier;
5. Lot number or control number, if assigned;
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
7. Date of administration or disposal;
8. If administered,
 - a. Prescribed dosage (unless already recorded in clinical procedure manual),

- b. Measured activity in millicuries or microcuries and date and time of measurement,
 - c. Patient name and identification number if one has been assigned;
9. If discarded, the date and method of disposal; and
 10. Initials of the individual who made the record.

See Exhibit 13 for a Unit Dosage Receipt and Use Log Form you may want to use.

M.2 Records of Multidose Vial Use (§§ 30.51, 35.21, 35.53)

You may use the following model procedure to keep a record of multidose vial use. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for a multidose vial record system that was published in Appendix M.2 to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own multidose vial record system for review. If you do so, you should consider for inclusion all the features in the model system and carefully review the requirements of §§ 30.51, 35.21, and 35.53. Say on your application, "We have developed a procedure for a multidose vial record system for your review that is appended as ATT 10.9," and append your multidose vial record procedure.

MODEL PROCEDURE

For each multidose vial that you receive from a supplier or that you prepare, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt or preparation;
4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml);
5. Supplier or kit manufacturer;
6. If administered,
 - a. Prescribed dosage (unless already recorded in clinical procedure manual),
 - b. Date and time dosage was drawn and measured,
 - c. Calculated volume that is needed for the prescribed dosage,
 - d. Measured activity in millicuries or microcuries,
 - e. Patient name and identification number if one has been assigned;
7. If discarded, the method of disposal and date; and
8. Initials of the individual who made the record.

APPENDIX N

Model Procedure for Area Surveys (See § 35.70.)

You may use the following model procedure to perform area surveys. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of § 35.70. Say on your application, "We have developed survey procedures for your review that are appended as ATT 10.12," and append your survey procedures.

MODEL PROCEDURE

Ambient Dose Rate Surveys

1. Survey Areas

- a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
- b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.
- c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.
- d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurement survey meter.

2. Immediately notify the RSO if you find unexpectedly high or low levels.

Removable Contamination Surveys

1. Survey Areas

- a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
- b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.

- c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.
2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm² of removable contamination (200 dpm/100 cm² for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm) to disintegrations per minute or dpm.
3. Immediately notify the RSO if you find unexpectedly high levels.

Records

1. Keep a record of dose rate and contamination survey results. It must include the following information:
 - a. The date, area surveyed, and equipment used.
 - b. The name or initials of the person who made the survey.
 - c. A drawing of the areas surveyed with contamination and dose rate action levels as established by the RSO. (Recommended removable surface contamination action levels are published in Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions." See Regulatory Guide 8.23 or Table N-1 below for guidance in establishing your action levels.)
 - d. Measured dose rates in mR/hr or contamination levels in dpm/100 cm², as appropriate.
 - e. Actions taken in the case of excessive dose rates or contamination and followup survey information.
2. The RSO will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

The following information is not part of the model procedure.

See Exhibit 16 for a sample record form.

Table N-1

**Recommended Action Levels in dpm/100 cm² for Surface
Contamination by Radiopharmaceuticals**

	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
1. Unrestricted areas, personal clothing	200	2,000
2. Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

APPENDIX R

Model Procedure for Waste Disposal (See §§ 20.301, 20.303, 20.306, and 35.92.)

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review the requirements of §§ 20.301, 20.303, 20.306, and 35.92. Say on your application, "We have developed a procedure for waste disposal for your review that is appended as ATT 11.1," and attach your procedure.

Overview

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. With the exception of the patient excreta (see paragraph 20.303(d)) and generally licensed in vitro kit exemptions (see paragraph 31.11(f)), nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See paragraphs 30.51(a) and 20.401(c)(3).)

General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
2. Remind employees that nonradioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.
3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in § 20.303. Material must be readily soluble or dispersible in the water. There are daily and monthly limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations; see paragraph 20.303(d).) Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.
2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR Part 20. These limits apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.
3. Liquid scintillation-counting media containing 0.05 millicurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (§ 20.306). Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste, e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.
2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.
3. Decay the material for at least 10 half-lives.
4. Prior to disposal as in-house waste, monitor each container as follows:
 - a. Check your radiation detection survey meter for proper operation;
 - b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;
 - c. Remove any shielding from around the container;
 - d. Monitor all surfaces of each individual container;

- e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.
 - f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.
5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Log the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from in vitro kits that are generally licensed pursuant to § 31.11 is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).
2. Assemble the package in accordance with the manufacturer's instructions.
3. Perform the dose rate and removable contamination measurements required by paragraph 173.475(i) of 49 CFR Part 173.
4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.