NRC FORM 313
(10-87)
10 CFR 30, 32, 33, 34
(6-91) 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 6-30-92

APPLICATION FOR MATERIAL LICENSE

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

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

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

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

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

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

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

IF YOU ARE LOCATED IN:

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

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

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

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

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

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

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

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

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 20-19761-02

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

Dana Farber Cancer Institute
44 Binney Street
Boston, MA 02115

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

44 Binney St., Boston, MA 02115
35 Binney St., Boston, MA 02115
462 Brookline Ave., Boston, MA (Michael A. Redstone Animal Facility)

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Ronald Amoling

TELEPHONE NUMBER: 617-735-7516

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

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

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (*See 10 CFR 170 and Section 170.31*)
FEE CATEGORY: 7B
AMOUNT ENCLOSED: $ 700.00

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

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

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

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
William M. Corbett	William M. Corbett, Jr.	Associate Director for Research	4/21/89

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY

AMOUNT RECEIVED	CHECK NUMBER	DATE

ITEM 3

RADIOACTIVE MATERIALS -

- SEE ATT 5

ITEM 6

PURPOSES FOR WHICH LICENSED MATERIALS WILL BE USED -

- SEE ATT 6

ITEM 7

INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

7.1 Authorized Users for Medical Use -

- See section 4.2 of Radiation Safety Manual

7.2 Authorized Users for Non-Medical Use -

- See ATT 7.2

7.3 Radiation Safety Officer -

- See ATT 7.3

ITEM 8

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS -

8.1 TRAINING PROGRAM -

- See ATT 8.1

8.2 OTHER TRAINING PROGRAM -

- See ATT 8.2

ITEM 9

FACILITIES AND EQUIPMENT

9.1 Annotated Drawing

- See ATT 9.1.1, 9.1.2, 9.1.3

9.2 Survey Instrument Calibration

- See ATT 9.2.1, 9.2.2, 9.2.3, 9.2.4

9.3 Dose Calibrator Calibration

- See ATT 9.3.1, 9.3.2, 9.3.3

9.4 Personnel Monitor Program

- See ATT 9.4.1

9.5 Imaging Equipment

- N/A, we are not a mobile nuclear medicine facility

9.6 Other Equipment and Facilities

- See ATT 9.6.1

ITEM 10

10.1 Radiation Safety Committee/Radiation Safety Officer
- see sections 1 and 2 of the Radiation Safety Manual (RSM)

10.2 ALARA Program
- We will implement Model ALARA program as published in Appendix G of Regulatory Guide 10.8, Revision 2.

10.3 Leak Test
- See ATT 10.3

10.4 Safe Use of Radiopharmaceuticals
- See ATT 10.4

10.5 Spill Procedures
- See section 9.2 of Radiation Safety Manual

10.6 Ordering and Receiving
- See section 5 of Radiation Safety Manual
- Off hours reception - See ATT 10.6

10.7 Opening Packages
- See Appendix II of Radiation Safety Manual

10.8 Unit Dosage Records
- We will implement Unit Dose Records procedures as published in Appendix M.1 of Regulatory Guide 10.8, Revision 2.

10.9 Multidose Vial Records
- We will implement Multi Dose Records procedures as published in Appendix M.2 of Regulatory Guide 10.8, Revision 2.

10.10 Molybdenum Concentration Records
- N/A, no generators used.

10.11 Implant Source Records
- We will establish and implement the model procedures for keeping and inventory of implant sources that was published in Appendix M.4 to Regulatory Guide 10.8, Revision 2.

10.12 Area Survey Procedures
- Performed by HUHS as described in ATT 10.12.1 and 10.12.2.
- Nuclear Medicine Department and Radioactive Waste storage areas surveyed weekly.
- Other areas employing byproduct materials surveyed monthly.

10.13 Air Concentration Control
- See ATT 10.13.1

10.14 Radiopharmaceutical Therapy

- We will implement Radiopharmaceutical Therapy safety procedures published in Appendix P of Regulatory Guide 10.8 Revision 2.

10.15 Implant Therapy

- We will establish and implement the model procedure for radiation safety during implant therapy published in Appendix Q to Regulatory Guide 10.8, Revision 2.

ITEM 11

WASTE MANAGEMENT -

- See ATT 11

ATT 3.

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM AMOUNT POSSESSED AT ANY TIME
Any byproduct material Atomic Nos. 3 through 83 except as below:	Any	300 millicuries of each radionuclide; not to exceed a total of 10 curies except as noted below:
Hydrogen 3	Any	25 curies
Carbon 14	Any	1 curie
Phosphorous 32	Any	2 curies
Iodine 125	Any	2 curies
Iodine 131	Any	2 curies
Gold 198	Any	2 curies
Xenon 133	Gas or gas in solution.	5 curies
Osmium 191	Any	5 curies
Iridium 191m	Any	5 curies
Iridium 192	Any	2 curies
Molybdenum 99	Any	5 curies
Technitium 99m	Any	5 curies
Mercury 195	Any	2 curies
Gold 195m	Any	2 curies

PURPOSES FOR WHICH THE LICENSED MATERIAL WILL BE USED

Medical research, diagnosis, and therapy; research and development as defined in 10 CFR 30.4(q) including medical research in humans; animal studies.

AUTHORIZED USERS FOR NON-MEDICAL USE -

All users of byproduct material for non-medical use must be approved by the Radiation Safety Committee and must meet the training criteria outlined in ATT 8.

ATT 7.3

RADIATION SAFETY OFFICER -

- The RSO is Ronald K. Amoling II, as listed on current License No. 20-19761-02.

- See letter dated April 8, 1987

TRAINING FOR INDIVIDUALS WORKING WITH RADIOACTIVE MATERIALS

1. Permits for Human Use are issued only to those who meet the training requirements specified Section 4.2 of the Radiation Safety Manual.

2. All users of greater than exempt quantities are required to receive instruction in radiation safety. The minimum requirement is the six hour lecture course given four times a year by the Harvard University Department of Environmental Health and Safety, or an equivalent course given elsewhere. This course includes lectures on the principles of radiation protection, including types of radiation, permissible levels, regulations, public health aspects, definition of units, interaction with matter, biological effects, significance of exposures from internal and external sources, and simple dose calculations. Also lectures on the practice of radiation protection are given including review of 10 CFR 19&20, bibliography of available books, licensing procedures, package receipt procedures, handling procedures, monitoring, contamination and decontamination, disposal, personnel dosimetry, labelling, use and disposal of animals.

3. Permit Holders are required to complete the study program in the safe use of radioisotopes given by the Harvard University Department of Environmental Health and Safety, or an equivalent course given elsewhere. Attendance is required at the three two-hour sessions described above and at a laboratory session on instrumentation which includes pulse height analyzers, standardization and calibration, and scintillation counters. The course also includes readings and problem sets for the text "Radiation Protection: A Guide for Scientists and Physicians" by Jacob Shapiro, Ph.D. (Harvard Press, 1981), a series of optional lectures based on the readings, and successful completion of at least one written examination. The readings and lectures include beta dose calculations, gamma dose calculations, use of specific isotopes, radiation counting and standardization, dose measurements, statistics, regulations, and public health aspects of radiation protection.

Attendance is taken at each of the required sessions and records are maintained. Homework problems and examinations are graded and records kept of performance. Certificates are issues to those who attend the required sessions, solve the problems, and receive a passing grade on the examination.

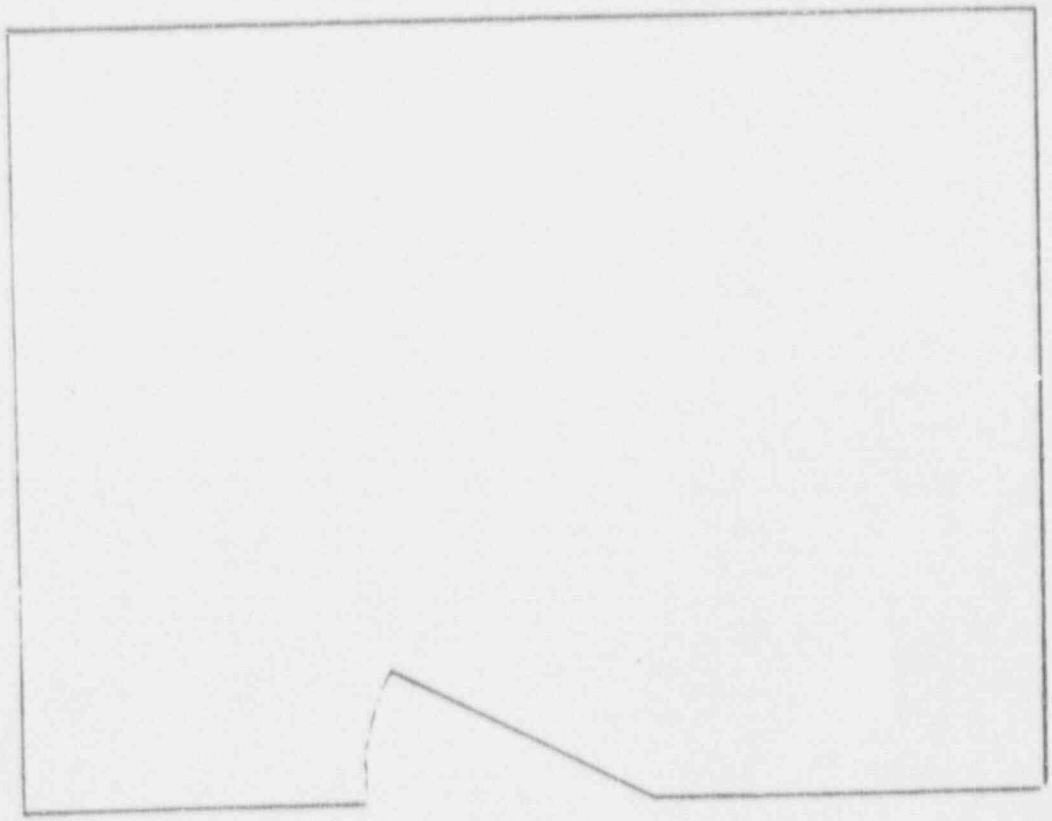
ATT 8.2

OTHER TRAINING -

Nursing staff and Ancillary staff will be instructed in Radiation Safety by the Radiation Safety Officer or his designate.

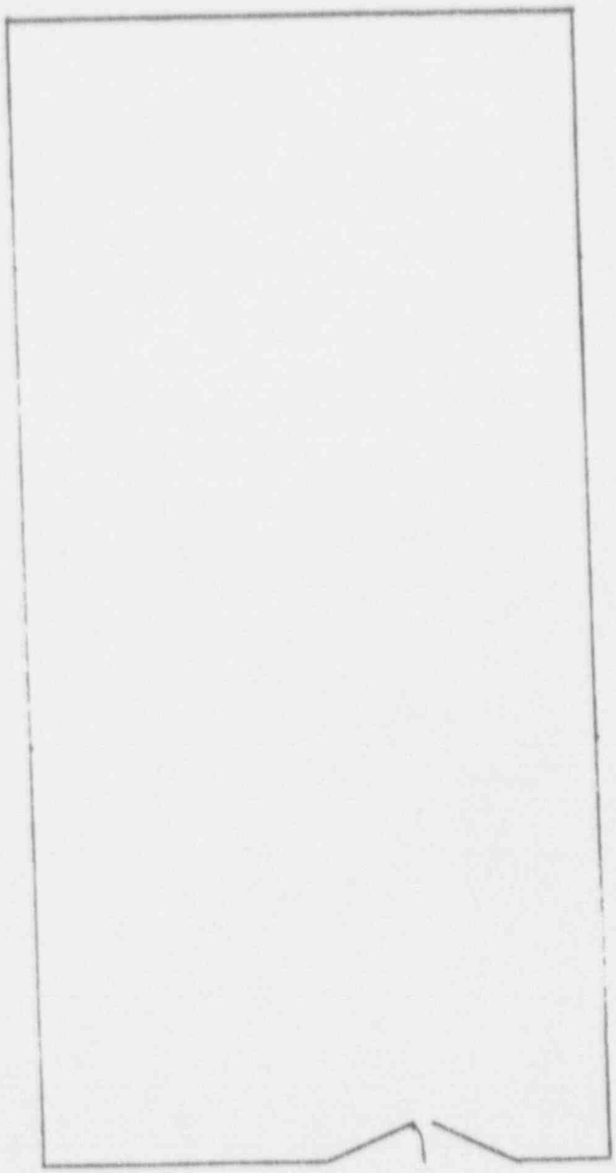
This training will be performed on a frequency determined by the Radiation Safety Officer and/or on a case by case basis.

D.-F.C.I.
Jimmy Fund Research Laboratory Room 215
Waste packing and storage room

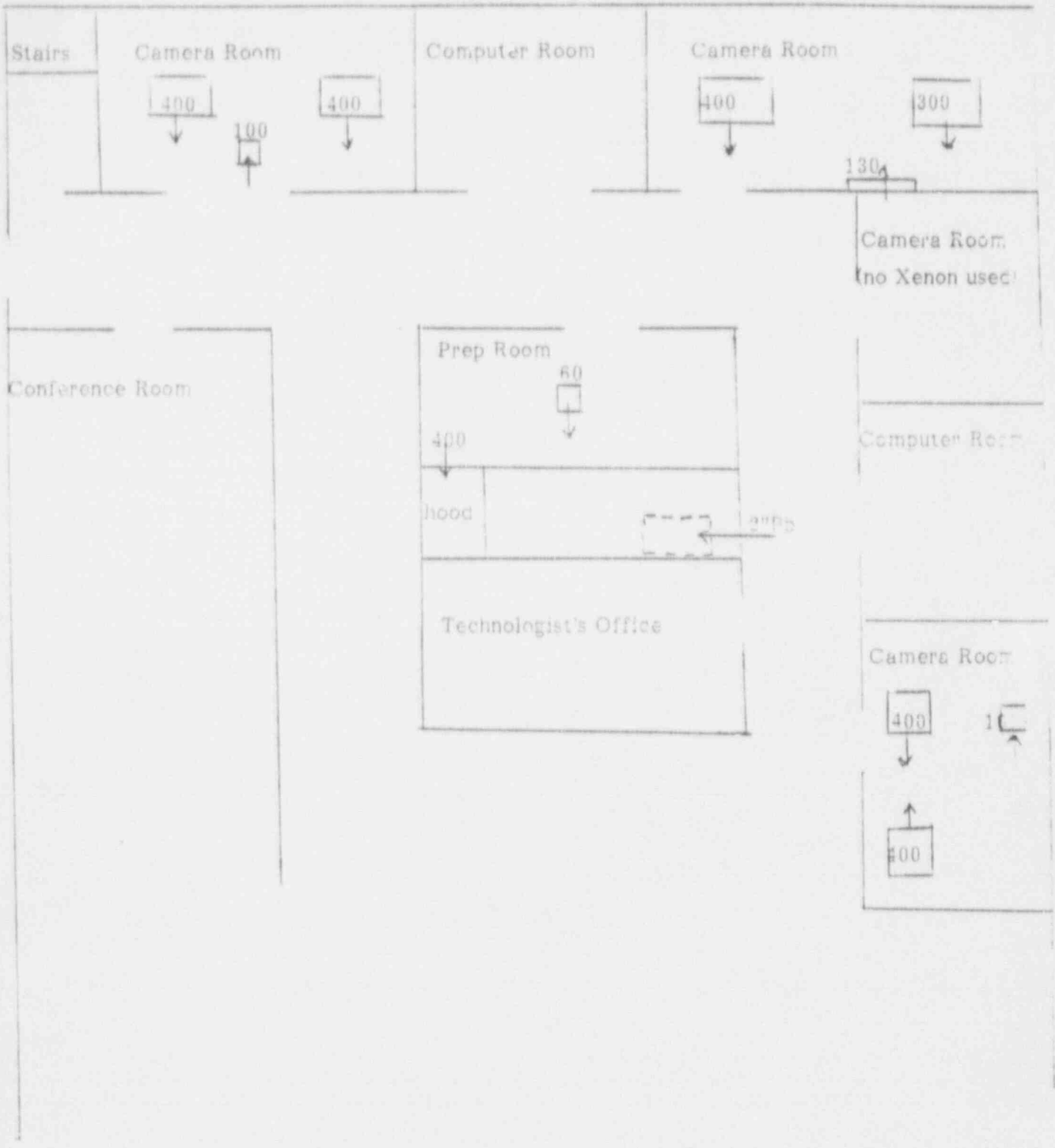


Features
1) Fire suppression system
2) Ventilation for chemical odors

D.-F.C.I.
Dana 166
Radioactive waste packing and storage room



Features
1) Fire suppression system
2) Ventilation for chemical odors


Stairs
Camera Room
400
400
100
Computer Room
Camera Room
400
300
130
Camera Room
(no Xenon used)
Conference Room
Prep Room
60
400
hood
Technologist's Office
Computer Room
Camera Room
400
400

NRC.CAL

CALIBRATION OF SURVEY INSTRUMENTS

Instruments will be designated as either monitors for surface radioactivity or survey meters. Monitors for surface radioactivity will normally be end-window rate meters and be calibrated to determine whether the activity on a surface exceeds defined limits. If limits are exceeded, remedial action will be instituted to bring the radioactivity levels below the limits. Accordingly, it is not necessary to perform accurate calibrations on all scales. Rather, a calibration will be performed to provide an accurate assessment of activity at the defined limit. Readings at other points and scales will be taken to check for operation and approximately correct response. Meters designated as survey instruments will be calibrated on all scales to give the gamma exposure rate accurately.

CALIBRATION OF END-WINDOW RATE METERS FOR SURFACE RADIOACTIVITY

1. Contamination monitors will be calibrated before first use(or within a year of purchase if calibrated by the vendor) and checked annually with a secondary standard.

2. Instruments will be checked for contamination of the detector.

3. The mechanical zero of the meter will be checked and adjusted if necessary (with the meter turned off).

4. Batteries will be checked and replaced or charged if necessary.

5. The instrument detection efficiency for a point source of known activity or particle emission rate will be obtained at one point between 20 percent and 80 of full scale on a range not requiring a significant dead time correction.

6. The instrument reading at a known exposure rate (mR/hr) will be obtained at one point between 20 percent and 80 percent of full scale on a range not requiring a significant dead time correction.

7. A check source reading will also be made at the time of calibration and recorded for checking meter performance in the future.

8. The instrument rate meter will be tested with an electronic

pulser to check that it is functioning satisfactorily on all three ranges. The meter will be adjusted to read counts per minute accurately or mR/hr according to the procedure given in item 5. In the latter case, the conversion factor from instrument reading to counts per minute will also be given.

9. If the window is not thin enough to provide only slight attenuation for all radiations monitored, it will be necessary to determine correction factors for any radiation of lower window penetration than that used for calibration.

10. The activity or particle emission rate of the calibration source will be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.

11. A record will be made of each survey meter calibration. The record will be retained for two years or until the next inspection by the Nuclear Regulatory Commission, whichever is longer. It will give 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 procedure and of the calibration source, including data on exposure rate.

d. For the designated calibration points, the instrument readings including the scales, and the correction factors.

e. The orientation of the detector relative to the source if the radiation particles enter at an angle other than perpendicular to the end window.

f. For detectors with removable protective coverings, an indication of whether the covering was in place or removed during the calibration procedure.

g. The reading with the check source, including the actual placement of the source relative to the detector.

h. The name of the person who performed the calibration and the date on which the calibration was performed.

12. The calibration sticker or tag will indicate the calibration date, source, and the correction factors or curves where the

instrument reading differs by more than 15 percent from the designated value.

CALIBRATION OF SURVEY INSTRUMENTS FOR MEASURING X AND GAMMA RADIATION

1. Survey instruments will be calibrated before first use(or within a year of purchase if calibrated by the vendor), annually thereafter, and following repair.

2. Instruments will be checked for contamination of the detector.

3. The mechanical zero on the meter will be checked and adjusted if necessary(with the instrument turned off).

4. Batteries will be checked and replaced or charged, if necessary.

5. All scale readings up to 1000 milliroentgens per hour will be calibrated with a radiation source.

6. A reading will be taken with a check source at the time of calibration for verifying the maintenance of the calibration at later dates.

7. A meter will be considered calibrated for reading without the use of correction factors if the indicated exposure rate differs from the calculated exposure rate by not more than 15 percent.

8. A meter will be considered as calibrated if a correction chart or graph is attached to the instrument.

9. The calibration source will be approximately a point source of known activity, particle emission rate, or exposure rate.

10. Meters with linear scales will be calibrated at no less than two points on each scale. The points will be between 20 percent and 80 percent of full scale.

11. The activity or exposure rate at a given distance will be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.

12. The energy response of the instrument relative to the energy at calibration will be known for the environments in which the calibrated instrument will be employed.

13. A record will be made of each survey meter calibration. The record will be retained for two years or until the next

inspection by the Nuclear Regulatory Commission, whichever is longer. It will give 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 procedure and of the calibration source, including the certified exposure rates from the source.

d. For the designated calibration points, the instrument readings including the scales, and the correction factors.

e. The calibration geometry, including the orientation of the detector relative to the source.

f. For detectors with removable protective coverings, an indication of whether the covering was in place or removed during the calibration procedure.

g. The reading with the check source, including the actual placement of the source relative to the detector.

h. The name of the person who performed the calibration and the date on which the calibration was performed.

14. The calibration sticker or tag will indicate the calibration date, a reference to the calibration record, and any correction factors needed.

DANA-FARBER
CANCER INSTITUTE

THE JIMMY FUND

44 Binney Street, Boston, MA 02115

ACCURACY TESTING

DOSE CALIBRATOR

TEST	FREQUENCY
Constancy	Daily
Accuracy	Installation/Annually
Linearity	Installation/Quarterly
Geometry	Installation/Repair

CONSTANCY

1. Use long-lived reference standard of sufficient activity. (C-57, Cs-137, Ba-133)
2. Zero instrument.
3. Assay on prescribed setting (Co-57 measured on Co-57, Cs-137 measured on Tc-99m and Ga-67, Ba-133 measured on Ba-133).
4. Assay on all other settings for commonly used radionuclide settings.
5. ± 5% from predicted value.

ACCURACY

1. Use 3 NBS traceable standards with adequate energy separation (e.g., Cs-137, Ba-133, and Co-57).
2. Measure each on appropriate settings.
3. Must agree within ± 5% (considering stated accuracy of stds.).
4. Keep log for future reference.

1/10/89 Reviewed

LINEARITY

1. Use entire first elution of generator (or maximum dose - radiopharmacy).
2. Zero instrument.
3. Assay on appropriate setting (Tc-99m).
4. Repeat at approximately 6, 24, 30 and 48 hours.
5. Plot data - $\pm$5%.

GEOMETRY

1. Assay 30cc vial of Tc-99m in 2 ml.
2. Increase vials to 4, 8, 10, 20 and 25 ml in volume with water/saline.
3. Select one volume as standard.
4. Calculate ratio of measured activities for each volume to reference volume activity.

   4 ml volume CF= $\frac{2.00\text{(at 10ml)}}{2.04\text{(at 4ml)}} = 0.98$

5. Plot all CF's vs volume on graph paper.
6. True activity = measured activity x C.F.
7. Repeat comparing syringe to 10ml in 30cc vial.
8. Difference of 200% between glass vial and plastic syringes are known. Calculate this CF.

   Alternate: Assay stock vial before and after filling syringe. Activity - difference in 2 readings.

MOLY BREAKTHROUGH

1. Must perform prior to administering of Tc-99m.
2. Conc: } 1uCi Mo-99/1mCi Tc-99m .15uci - .25uCi.
   Dose: } 5uci/patient dose
3. Establish written procedure.
4. Establish competency statements.

DANA-FARBER
CANCER INSTITUTE

44 Binney Street, Boston, MA 02115

THE JIMMY FUND

POLICY AND PROCEDURE

CALIBRTION PROCEDURE

CAPENTEC - MODEL 12R SERIAL #12313

1. Zero in calibrator.

   - obtain reading on normal averaging period
   - record readings

2. Battery test.

   - battery voltage should be 150.7 on normal averaging period
   - record reading

3. Background

   - adjust background reading on normal averaging period
   - should stabilize at +00.01 to 0.02 mCi

4. Test sources

   Record reading for following isotopes
   A) Co-157 on Co-157 setting
   B) Cs-137 on Tc-99m setting
   C) Cs-137 on Ga-67 setting
   D) Ba-133 on Ba-133 setting

daily calibration procedures

11/20/85 Replacement
7/14/86 Reviewed
1/29/87 Revised
1/10/89 Reviewed

PERSONNEL MONITORING SYSTEM

All persons handling radioactivity and/or exposed to ionizing radiation will be monitored for radiation exposure.

We will employ film-type dosimeters from R.S. Landauer Co. for whole body measurements.

We will employ TLD finger rings from R.S. Landauer Co. for extremity measurements when appropriate.

All personnel dosimeters will be changed on a monthly basis.

INSTRUMENTATION

Meters Available to the Radiation Control Unit:

2 thin end-window GM meters (currently Ludlum model 3 with 44-7 probes)

2 NaI scintillation meters (currently Ludlum model 2 and 3 with model 44-3 probes)

Meters Available to Individual Users:

The Radiation Safety Committee requires each Permit Holder to have the appropriate survey instrument(s) "readily available", and when necessary, attaches Permit conditions requiring GM or scintillation meters. The Committee decides which meter is required based on the types and quantities of radioactive materials to be used.

LEAK TEST -

Leak tests on all sealed sources will be performed by HUHS in accordance with leak test procedures published in Appendix H of Regulatory Guide 10.8, Revision 2.

DANA - FARBER CANCER INSTITUTE

Regulations Governing The Use of Sources of Ionizing Radiation

AUTHORIZATION

No one may use, bring into or remove from the Institute any radioisotopes without authorization from the Radiation Control Unit. Every individual working with radioisotopes or in radiation controlled areas must be registered with the Radiation Control Unit.

TRAINING

No individual may work with radioisotopes without training and indoctrination necessary to ensure safe working habits, to prevent the exposure of others, and to avoid contamination of the surroundings.

RESPONSIBILITIES

Work with radioisotopes must be done in accordance with regulations issued by the Radiation Control Unit and available from that office.

These regulations cover maximum exposure limits, posting of areas, monitoring procedures, procurement, delivery, storage, waste disposal, records, transportation, protective clothing, contamination, work habits and procedures, accidents, and termination of work.

NOTIFICATION OF THE RADIATION CONTROL UNIT

The Radiation Control Unit shall be notified promptly of all accidents involving possible personnel and area contamination, overexposure to radiation, spread of contamination, difficulty in cleaning up a contaminated area, and of any violations or unsafe practices with radioactive material.

The Radiation Control Unit must also be notified in the event of loss or misplacement of radioisotopes and sources.

Rules For Effective Radiation Protection

1. *Avoid all unnecessary exposure to ionizing radiation.*

2. Keep external radiation exposure to a minimum by planning your work habits with minimum exposure in mind. *Do not linger unnecessarily in radiation areas. Use remote handling tools and shielding for significant sources.*

3. Keep the chances of ingestion or skin contamination and penetration to a minimum through the use of appropriate *protective clothing*, including gloves. Never work without gloves if there is a break in the skin below the wrist.

4. *Do not pipette by mouth.*

   Do not store or eat food in rooms where work with unsealed radioactive materials is taking place.

   Do not smoke while working with unsealed radioactive materials or in contaminated areas.

5. Wash hands when operations are completed. Monitor hands, clothing, and work area and record results, even if negative.

6. Keep yourself informed of all safety measures pertaining to your work, including the appropriate corrective action in the event of an accident.

7. In the event of a significant spill or accidental release:

   Restrict access to contaminated area.
   Prevent spread of contamination.
   Notify the Radiation Control Unit.

ATT. 10.4

CALL THE RADIATION CONTROL UNIT WHENEVER QUESTIONS ARISE CONCERNING A RADIATION HAZARD OR PROPER PRACTICE IN WORKING WITH RADIOACTIVE MATERIAL

In accordance with the provisions of the Code of Federal Regulations, Title 10, Part 19, Section 11, employees are notified that copies of the NRC By-product Materials License and amendments issued to DFCI, the NRC regulations in 10-CFR-19 and 20 and the DFCI Radiation Safety Manual are available for examination at the Radiation Control Unit, Enders SB-22.

RADIATION CONTROL UNIT
ENDERS RESEARCH BUILDING
SB-22

TELEPHONE: 735-7516

AFTER HOURS TELEPHONE:

ENVIRONMENTAL HEALTH AND SAFETY
HARVARD UNIVERSITY HEALTH SERVICES
75 MT. AUBURN STREET, CAMBRIDGE

495-2060

OFF HOURS RECEIVING OF RADIOACTIVE PACKAGES

1. The deliverer will notify the guard at the lobby entrance that he/she has a radioactive package.

2. Security will escort the deliverer to the Receiving area, Dana Building first floor.

3. The deliverer will place the package(s) in the 'Isotope Receiving' area (Marked with yellow signs).

4. The guard will escort the deliverer out of the building.

5. If any package is wet (which may indicate leakage of the contents) or appears damaged (in a way which could indicate leakage of contents), the guard will immediately contact Harvard University EH&S at 495-2060 and inform them of a radiation emergency at DFCI, and ask the deliverer to remain at DFCI until it can be determined if either he/she or the vehicle is contaminated. EH&S will contact the RSO or an associate for further instructions or advice.

6. Please note that the examination above is a visual check only. Institute policy established by the Radiation Safety Committee specifically prohibits security guards from handling radioactive materials.

EXHIBIT B

CURRENT INSTRUCTIONS TO TECHNICIANS CONDUCTING LABORATORY SURVEYS

PREPARATION FOR SURVEY

Prepare packages of wipes in coin envelopes; required labels, signs, and postings, including laboratory survey record form, laboratory survey list; and a survey meter with a GM and a NaI detector.

Prior to conducting an individual survey or at the beginning of the surveying day check both detectors with the quality control source and record the values.

Wear a laboratory coat, radiation dosimeter, EHS name tag, and latex/rubber gloves while performing the survey. Change the gloves frequently over the course of a survey day. Do not wear the lab coats and gloves outside of laboratory areas. Do not wear open-toed shoes.

CONDUCT OF SURVEY

Check that the lab to be surveyed is listed on the laboratory survey list. If the lab is not on the list and it is a radioactive lab or if the laboratory has been abandoned, refer it to the institution's RSO and the EHS Operational Services Coordinator so that the lab can be entered into or deleted from the data base. If the lab is not on the list and it appears that radioactive materials are used in the lab, survey the lab and check for proper posting. If the lab is on the list, check that the door is posted with a radiation warning sign in the manner required by the institution and that the laboratory map is posted just inside the door with a copy of the permitted isotopes, quantities, and rooms registered, if available at the institution.

Check the sink drains and nonradioactive trash cans with the NaI detector for the presence of radioactive material. Check the lab bench tops with the survey meter for the presence of unmarked contamination and to ensure that the workers are not subject to non-ALARA levels. When surveying the benchtop look for possible problem areas, violations or poor work habits, instruments due for calibration, and dosimetry left on the bench. Remove any dosimetry that is on the bench and inform the laboratory staff that it is an inappropriate location to store dosimetry. Record any radiation levels that are in excess of ALARA levels or in an inappropriate area. Make measurements at a distance of 1 cm, or other appropriate distance, and record with a description of the object and the Reference Point (RP). Check the lab floor and the desk areas in the lab for the presence of radioactive material. If activity is found inform the lab staff and instruct them to clean the area.

Following direct radiation measurements, identify potential areas for swipe measurements. Cover, as a minimum, the floor area, centrifuges, bench tops, and bench sides where there is a potential for spills or contamination that will not be detected by survey meter. Cover an area of approximately 100 cm^2 per swipe and place the used swipe into an envelope so as not to contaminate other items. Identify the area swiped on the envelope by means of the RP map and include a description of the area monitored.

Include all the information collected on the survey on the Survey Record Form. Document any violation or significant dose rate on a speedi-memo and have it signed by the most senior available laboratory staff member, preferably the investigator. If radioactive material was found in the laboratory trash can, show the investigator the dose/count rate with the your meter and the laboratory's meter. Record both these readings on the speedi-memo.

If significant items are identified in the survey deliver a copy of the speedi-memo to the institution's RSO at the completion of the day's work, unless other arrangements have been made. Report any particularly important items to the RSO immediately. These include personal contamination or high levels of contamination in the laboratory or in the regular trash.

Return the wipes to the counting lab for analysis. Once the swipes are assayed, enter the information into the survey report. If the result is less than 50 CPM the result can be omitted from the report. If the swipe is greater than 1000 CPM call the laboratory so that they can clean the area. If the swipe is greater than 10,000 CPM contact the lab and make a follow up measurement to ensure that the levels are reduced.

Procedures and Precautions for Use of Radioactive Gases

1. Estimated use-- 1 patient/month x 20mCi/pt = 240mCi/year

2. Xe133 is stored in the Prep. Room (#115). See attached diagram (Enclosure 11-4) for details of shielding and proximity to unrestricted areas. Air flows will be checked semi-annually with a hot-wire anemometer.

3. Xe133 is received in unit dose vials. It is inserted in a lead-shielded New England Nuclear injector gun, and injected into a spirometer.

4. In case of accidental release of Xe133 all doors in Nuclear Medicine will be closed and the effected room(s) will be evacuated for at least two hours.

5. Air concentrations in restricted areas
Maximum activity per week-- 20 mCi
Assuming a 20% loss during administration, storage, disposal, required ventilation rate is 4 cu. ft./ min.

measured ventilation rate-- >100 cu. ft./ min

estimated maximum concentration in air is restricted area-- 4 x 10**-07 uCi/ml or 4% of M.P.C.

6. Air concentrations in unrestricted areas
Expired air from perfusion and ventillation studies is breathed directly into a lead-shielded spirometer which is connected to a tandem charcoal trap. Each trap is a cylinder 15"x6". The traps are in turn connected to an exhaust system which exhausts >1000 cu. ft./min. on the roof of the building.

air flow per year-- >1.484 x 10**13 ml
assuming zero efficiency for the charcoal traps, concentration at the point of exhaust;
C < 240 mCi/ 1.484 x 10**13 ml = 1.617 x 10**-8 uCi/ml
or C < 5.4% of M.P.C.

ATT 11.1

ATT 11.2

WASTE MANAGEMENT

Sewage disposal of aqueous liquids is permitted within the limits of 10 CFR 20.303; required records are kept of all such disposals.

Tc-99m and other radioisotopes with a half-life of less than sixty days may be held for at least ten half-lives, monitored with a G.M. counter and, if no activity is detected, will be disposed of via regular waste. Labels will be defaced and records kept of all such disposals.

All other radioactive wastes are disposed under the supervision of the Harvard University Dept. of Environmental Health & Safety and include incineration, decay storage, and transfer to a licensed disposal company for disposal at the Hanford Radioactive Waste site. Their procedures are described in their license # 20-00297-53. Should their procedures change, we will amend our procedures to comply.

DANA-FARBER CANCER INSTITUTE

RADIATION SAFETY MANUAL

TABLE OF CONTENTS

This manual is issued by the Radiation Safety Committee (RSC) of the Dana-Farber Cancer Institute (D.-F.C.I.) for the information and guidance of all individuals using radionuclides or equipment producing ionizing radiation at the D.-F.C.I., whether or not a Nuclear Regulatory Commission (NRC) license is required.

1. RADIATION SAFETY COMMITTEE (RSC)

1.1. Purpose

Federal regulations require the establishment of a Radiation Safety Committee before an institutional program for the medical use (including human and laboratory studies) of radionuclides will be licensed. The RSC acts to implement government regulations concerning the use of radionuclides by individual users.

The RSC has been charged by the Director for Research to serve as an advisory and supervisory body to promote the best practices in safe handling and use of radioactive sources. The services are available to all users of radionuclides and radiation-generating equipment within the area of jurisdiction of the D.-F.C.I., to Department Heads, and to Research Administration.

1.2 Organization

The members of the RSC are appointed by the Director for Research. Members include physicians and scientists experienced in the handling of radionuclides and the practice of radiation protection, and other individuals as necessary.

The activities of the RSC are directed by the Chairman. The business of the RSC is administered by the Radiation Control Unit (RCU) in cooperation with Environmental Health and Safety, a department of the Harvard University Health Services (HUHS), and appointed with the approval of the RSC. When either the Chairman of the RSC or the RSO is absent, the other will serve in place of the absent member.

Meetings of the RSC shall be called by the Chairman at his discretion, but not less than four times in one year or on petition by any member of the Committee. The Chairman and the RSO shall conduct the interim business of the RSC. Meetings are usually held on the fourth Monday of each month.

1.3 Responsibilities

a) To review and approve/disapprove all applications for the use of radionuclide within the D.-F.C.I..

b) To prescribe special conditions that will be required during a proposed use of radionuclides to insure safe use and handling. These conditions may include, but are not limited to, bioassays, minimum level of training and experience of users, availability of survey instruments, and performance of self monitoring and package opening procedures.

c) To receive and review all periodic and urgent reports concerning (i) the results of area monitoring; (ii) personnel exposures as measured by suitable dosimeters; (iii) accidents in handling, storage, or use of radionuclides; (iv) records of radionuclide procurement, use, and disposal.

d) To recommend remedial action to correct safety infractions or terminate unsafe procedures.

e) To maintain a written record of actions taken by the Committee.

f) To inform and advise Research Administration and Department Heads on all matters relating to the safe use of radionuclide and radiation-generating equipment.

Since this manual cannot cover all exigencies, the RSC is empowered to arrange for or make inspections and to institute emergency measures as it deems necessary.

2. HARVARD UNIVERSITY HEALTH SERVICES (HUHS)

2.1 Authority

Harvard University Health Services (HUHS) is the authorized representative of the RSC regarding measures to implement radiation protection and control within the Institute in cooperation with the Radiation Control Unit (RCU)

2.2 Function

The RSO is an employee of the HUHS, which provides health physics services to D.-F.C.I.. The RSO is responsible for overall radiation protection within the institution, which includes:

a) General surveillance over all activities involving radioactive material, including routine monitoring and special surveys of all areas in which radioactive material is used.

b) Determining compliance with rules and regulations, and license conditions.

c) Monitoring and maintaining special filter systems associated with the use, storage, and disposal of radioactive material.

d) Furnishing consulting services on all aspects of radiation protection to personnel at all levels of responsibility.

e) Distributing and processing personnel monitoring equipment, determining the need for and evaluating bioassays, keeping personnel exposure and bioassay records, and notifying individuals and their supervisors of exposures approaching maximum permissible amounts and recommending appropriate remedial action.

f) Conducting training programs and otherwise instructing personnel in the proper procedures for the use of radioactive material prior to use refresher training at periodic intervals and as required by changes in procedures, equipment, and regulations.

g) Supervising and coordinating the waste disposal program, including keeping waste storage and disposal records and monitoring effluents (see section 2.3).

h) Performing leak tests on all sealed sources.

i) Maintaining an annual inventory of all radioisotopes at the Institute and limiting the quantity of radionuclides at the Institute to the amounts authorized by the license.

j) Authority to terminate immediately a project that is found to be a threat to health or property.

k) Maintaining other records not specifically designated above, e.g., receipt, transfer, and survey records.

2.3 Function of the Radiation Control Unit (RCU)

The RCU will receive, monitor, record, and disburse radioactive material to the Institute as outlined in section 5.3.

The RCU will provide storage facilities for all radioactive materials not in active use.

The RCU will maintain and operate facilities for the disposal of radioactive waste. This includes a locked freezer for animal carcasses, a locked radioactive barrel storage room for solid waste. Disposal of gaseous waste must be by special arrangement with the RSO.

The RCU will supervise a facility for radioiodinations.

3. LICENSING AND REGISTRATION REGULATIONS

3.1 Government Regulations

"By-Product material" is material yielded in, or made radioactive through, nuclear reactions utilizing plutonium, uranium-223, or uranium-235. Such by-product material with atomic number 3 - 83 and tritium may be used only under special or general licenses issued by the United States Nuclear Regulatory Commission (NRC). The regulations covering the procurement of licenses are published in Title 10, Chapter 1, Part 30, of the Federal Register.

All licensees of the NRC are required to conform with standards for protection against radiation hazards established by the NRC. These standards are published in Title 10, Chapter 1, Part 20, of the Federal Register. Copies of these regulations may be obtained from the RSO, Radiation Control Unit, Enders SB-22, or from HUHS, 46 Oxford St., Cambridge.

3.2 Institute Regulations

No person may use any radionuclides in any amount without authorization from the RSC. The authorization to use radionuclides will be embodied in a permit issued by the Chairman of the RSC upon recommendation by the RSC. Permits are issued for a period of two years. In emergencies the RSC may issue a temporary permit for a maximum of twenty days. If a permit renewal application is filed prior to the expiration date of a current permit, the permit will remain in effect until the RSC takes final action on the renewal.

The use of radionuclides for investigational purposes on humans requires review by the Human Subjects Protection Committee, and may require approval by the Radioactive Drug Research Committee. Informed consent will be obtained from the subjects, or from the parent or legal guardian in the case of minors.

3.3 Responsibility of Permit Holders

Those persons who have been granted a D.-F.C.I. permit to use radinuclides are responsible for the safe use of radiation sources by individuals under their supervision, including the following:

a) Compliance with the D.-F.C.I. rules for the safe handling of radioactive materials (section 5 through 9 of this manual) and the Federal Regulations 10 CFR 19,20,21.

b) Ensuring that employees under their supervision are instructed in the use of safety devices and procedures.

c) Adequate planning of an experiment or procedure to assure that necessary safety precautions are taken.

d) Providing the RSO with the names of all personnel involved in operational procedures and any changes in personnel.

e) Direction of personnel under their control to comply with recommendations of the RSC or the RSO to wear dosimeters, submit urine samples, report for thyroid scans as required (see section 6.5), and to control and reduce their total exposure and other radiation hazards as directed.

f) Limit use of radionuclides under their permit to those over whom they have direct supervision.

g) Maintenance of required current records of receipt, use, storage, and disposal of radionuclides.

h) Limit use to approved rooms or areas within D.-F.C.I.

i) Establish a program of self-monitoring by individuals working under the permit.

j) Establish a means of compliance with the Institute's package receiving and monitoring procedures.

3.4 Responsibility of the Individual User of Radionuclides

Each person at D.-F.C.I. who has any contact with sources of ionizing radiation has the following responsibilities:

a) To receive instruction in radiation safety as determined appropriate by the Permit Holder and the RSC.

b) To keep his exposure to radiation at the lowest possible level and specifically below the maximum permissible exposure as stated in section 6.

c) To wear recommended radiation dosimeters, such as film badges, and finger rings.

d) When appropriate, to survey his/her hands, shoes, body, and clothing for radioactivity and remove all loose contamination before leaving the laboratory (see appendix I).

e) To use all appropriate protective measures including protective clothing, remote pipetting devices, ventilated and shielded glove boxes and hoods.

g) To refrain from smoking, eating, drinking and applying cosmetics in radionuclide laboratories.

h) To monitor work areas as appropriate.

i) To maintain good laboratory practices, such as keeping work areas and equipment clean and orderly.

j) To use proper labels on equipment being used with radioactivity.

k) To place all radioactive waste in proper containers, equipped with proper labels.

l) To report immediately the details of a spill or other accident involving radioactivity to the RSO and to be familiar with emergency proccedures (see section 9).

m) To conduct decontamination procedures as directed by the RSO.

n) To read the Radiation Safety Manual and to become familiar with the regulations.

o) To submit the required bioassay samples and report for the required scans as detailed in section 6.5.

3.5 Enforcement

To insure that the requirements set forth in these regulations are met, surveys of each laboratory using radionuclides will be made by HUHS monthly or more frequently at the discretion of the RSC. Survey reports will be sent to permit holders.

Violations will be brought to the attention of the RSC.

The RSO has the authority to stop operations as described in section 2.2.

4. PROCUREMENT OF A PERMIT TO USE RADIONUCLIDES

4.1 Application for a Radionuclide Permit

The RSC is empowered to recommend to the Director for Research, D.-F.C.I., that Permits be granted to responsible users of radioactive materials.

The following process should be followed by the applicant who wishes to use radioactive material in any amount for any purpose:

a) Obtain from the RCU an Application for Permit to Use Radioisotopes at the D.-F.C.I.

b) Return to the Chairman of the RSC the completed typed application forms.

c) The applications are initially reviewed by the RSO, and then circulated to each member of the RSC for a one week review period. Upon approval by the RSC, a completed Permit is forwarded to the Director for Research with the Committee's recommendation that the Director approve and sign the permit. The Director may delegate to the Chairman of the RSC the authority to sign permits.

4.2 Radionuclide Permits for Human Use

It should be noted that the general requirements for a permit to administer radioactive materials to humans are extremely restrictive. The prerequisites are:

a) The user must be a physician licensed by the Commonwealth of Massachusetts to dispense drugs in the practice of medicine.

b) The physician must have training and experience in the medical use of radionuclides as outlined below.

c) For studies with new radionuclides or new applications of currently used radionuclides, complete protocols must be submitted in accordance with the permit application form.

d) Approval of the RSC, Human Subjects Protection Committee and when appropriate, the Radioactive Drug Research Committee must be obtained before administration of a new radiopharmaceutical agent or the use of a new radionuclide procedure in human subjects.

In evaluating applicants for Permits for the Human Use of Radionuclicdes, the RSC will be guided by the following:

a) General Human Use is authorized only in the Division

4. PROCUREMENT OF A PERMIT TO USE RADIONUCLIDES

a) Application for a Radionuclide Permit

The RSC is empowered to recommend to the Director for Research, D.-F.C.I., that Permits be granted to responsible users of radioactive materials.

The following process should be followed by the applicant who wishes to use radioactive material in any amount for any purpose:

a) Obtain from the RCU an Application for Permit to Use Radioisotopes at the D.-F.C.I.

b) Return to the RCU completed typed application forms.

c) The applications are initially reviewed by the RSO, and then circulated to each member of the RSC for review at its next meeting. Upon approval by the RSC, a completed Permit is forwarded to the Director for Research with the Committee's recommendation that the Director approve and sign the permit. The Director may delegate to the Chairman of the RSC the authority to sign permits.

b) Radionuclide Permits for Human Use

It should be noted that the general requirements for a permit to administer radioactive materials to humans are extremely restrictive. The prerequisites are:

a) The user must be a physician licensed by the Commonwealth of Massachusetts to dispense drugs in the practice of medicine.

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d) Approval of the RSC, Human Subjects Protection Committee and when appropriate, the Radioactive Drug Research Committee must be obtained before administration of a new radiopharmaceutical agent or the use of a new radionuclide procedure in human subjects.

In evaluating applicants for Permits for the Human Use of Radionuclicdes, the RSC will be guided by the following:

a) General Human Use is authorized only in the Division

of Nuclear Medicine, and permits for general use will be issued only to staff physicians within the Division who have met the appropriate NRC requirements as specified in Regulatory Guide 10... Appendix A (e.g., certification by the American Board of Nuclear Medicine).

In evaluating applications for the Human Use of Radionuclides, the RSC will be guided by the following statement of policy adopted by the D.-F.C.I. as recommended by the Harvard Medical School.

Internal Beta-Gamma Emitters

Tracer doses in humans shall be kept to the lowest practicable level. The Radiation Safety Committee shall review all applications to determine whether the amount of activity proposed for administration to humans may be reduced by reasonable improvements in the sensitivity of measuring systems to be employed, having regard to the current state of the art, or by choice of an alternate radionuclide capable of fulfilling the purpose of the application.

a) Patients: Adult humans who are ill and who are expected to receive benefit from a diagnostic procedure involving the administration of radioactive materials shall receive amounts such that the total absorbed dose in any twelve-month period to the critical organ* shall not ordinarily exceed 10 rad multiplied by the Relative Sensitivity Factor (RSF) which is given in the table below. Children in this category (all patients below 18 years of age) shall not ordinarily receive more than a total absorbed dose to the critical organ of 1.0 x RSF rad.

The RSF listed in the table below are derived from the recommendations of the International Commission on Radiological Protection.**

TABLE

Critical Organ	RSF
whole body, gonads, or blood-forming	1
skin, thyroid, or bone	3
all other organs	3

b) Volunteers: When persons are given tracer doses without the expectation of personal medical benefit, the informed and signed consent of the person or legal guardian, and the approval of the Human Subjects Protection Committee shall be obtained. The amounts of radioactivity administered shall ordinarily be limited such that the total absorbed dose in any twelve-month period to the critical organ does not exceed 2.5 x RSF rad for adults or 0.25 x RSF rad for children. The cumulative dose shall not ordinarily exceed 2.5 x RSF rad before age 18 and 10 x RSF rad before age 30. Whenever possible, such persons should be at least 30 years of age. Consideration in all cases should be given to previous radiation exposure from any source, including repeat exposures;

c) Pregnant Women Special problems in connection with pregnant women, whether they are patients or volunteers. Ordinarily for the protection of the fetus in the second or third trimester, the maximum annual dose level specified above for children shall apply. Extreme caution shall be exercised regarding the administration of radioactivity during the first trimester of pregnancy, and it is the responsibility of the physician to consider the contingency of pregnancy even within a week or two of normal menses.

External Beta-Gamma Emitters

In evaluating proposals to use beta or gamma emitters external to the body for diagnostic purposes, the Radiation Safety Committee will be guided by the policy in the section above.

Internal Alpha Emitters

Since alpha-emitting radionuclides are particuarly hazardous, special consideration must be given by the Radiation Safety Ccommittee when alpha emitters are to be administered to humans.

*The critical organ is that organ which will receive the largest fraction of the dose permitted to that organ.

**I.C.R.P. Publication 5, 1964; Publication 9, 1966, Pergamon Press.

5. PROCUREMENT OF RADIONUCLIDES

5.1 Purchasing Procedures

5.1.1 Purchasing by and delivery to the D.-F.C.I.: Radionuclides are purchased in the same way as any other item, except that the requisition must include: (1) The isotope and activity must be specified, (2) The Permit holder's name and Permit number must be explcitly stated, (3) the person (and extension) to be notified of the package's delivery should be listed as the 'Originator'.

The prepared requisition form is then submitted to the Purchasing Department (JRFL 118) where it is checked against the Permit to insure that the purchaser is authorized for the amount and type of radionuclide requested. A Purchase Order Number is then issued, in the usual manner.

5.1.2 Purchasing by or for other institutions with delivery to D.-F.C.I.: In certain cases, an investigator may order a radionuclide through Harvard University or other institutions for delivery to the D.-F.C.I.. In this case, it is the responsibility of the Permit holder to obtain and complete a notification of transfer of isotopes. A D.-F.C.I. permit to use radionuclides is mandatory for this arrangement.

No radionuclides may be purchased by D.-F.C.I. for delivery to another institution without approval of the RCU.

5.2 Transport

When radioactive material is purchased by and delivered to the D.-F.C.I., and later transported to another institution or across any public way, a transportation permit is required before the radioactive material can leave the premises of this Institute. This is also the case when radioactive material is delivered to another institution and later transported by the investigator to the D.-F.C.I. complex. A transportation permit must be obtained from the RSO of the D.-F.C.I. or from Harvard University Health Services. The material must be packaged in accord with NRC and Department of Transportation regulations.

5.3 Reception

Radionuclides entering the D.-F.C.I. complex are to be delivered to the Receiving Department (Dana 165). This is not necessary for transfers under a Transportation Permit.

Receiving will notify the 'originator' upon delilvery. The user must, within three hours, pick up the package and complete the 'Receipt of Radioactive Materials'. See Appendix II for details of the package opening and monitoring procedures.

Receiving will notify the 'originator' when the package arrives. Federal regulations require that each package be picked up, monitored and opened according to the procedures in Appendix II within three hours of delivery (eighteen hours if delivered outside of normal working hours). The 'Receipt of Radioactive Materials' must be completed and forwarded to the Radiation Control Unit.

After removal of the radioactive material, the packing material must be checked with the appropriate survey instrument. If the packaging is not contaminated it may be disposed in the regular waste, after the Radioactive Materials labels have been removed or defaced. If the packaging is contaminated it must be disposed of as detailed in section 6.8.4 or 6.8.5 of this Manual.

In unusual cases the RSO may authorize delivery directly to the user. Such special cases would include receipt of very short half-life material, or such large quantities of gamma emitters that transport through the hospital would be impractical. In such cases, special arrangements must be made with the RSO for the maintenance of necessary records by the Permit Holder.

6. RULES FOR THE SAFE HANDLING OF RADIONUCLIDES

6.1 Classification of Areas

6.1.1 Unrestricted areas: An unrestricted area is any area, entry into which is not controlled by the permit holder or the RSC for purposes of protection of individuals from exposure to radiation and radioactive materials. Such areas must conform to the following rules:

a) If an individual were continuously present in the area, he could not receive a dose exceeding 2 mrem in any one hour or more than 100 mrem in any seven consecutive days; or

b) If, when allowance is made for expected occupancy time and variations in dose rate, no individual is likely to receive a dose exceeding 500 mrem in a calendar year.

6.1.2 Restricted areas: All areas within the Institute in which dose levels do not conform to the standard for unrestricted areas shall be restricted and under the authority of the RSC for radiation safety purposes. Warning signs (see below) shall be prominent, displayed at the entrances to each restricted area, and the permit holder responsible for work with radionuclides in the area shall be responsible for controlling access to the area.

Both Federal and State Regulations define restricted areas containing radiation which requires special control measures as:

a) Radiation Area -- Any area accessible to individuals in which there exists ionizing radiation at such levels that a major portion of the body of such individuals could receive an absorbed dose greater than 5 mrem in any one hour or in any five consecutive days a dose in excess of 100 mrem.

b) High Radiation Area -- Any area accessible to individuals in which there exists ionizing radiation at such levels that a major portion of the body could receive in any one hour an absorbed dose greater than 100 mrem.

6.2 Required Signs and Labels

Signs are required by law to denote areas and/or containers with levels of radiation or radioactivity specified in the following sections.

6.2.1 "Caution Radiation Area": In areas accessible to personnel in which a major portion of the body could receive in any one hour a dose of 5 mrem or in any five consecutive days a dose in excess of 100 mrem.

A sign is NOT required:

a) On a room containing a sealed source if the radiation level 12" from the surface of the source container or housing does not exceed 5 mrem/hr. The container might in this case require labelling with a sign as described below.

b) In rooms or wards with patients containing radioactive material where the dose rate is such that the room qualifies as an "unrestricted area" or if there are personnel in attendance who shall take precautions to prevent exposure of any individual to dose rates in excess of those requiring a "Radiation Area" sign.

6.2.2 "Caution Radioactive Materials": This sign shall be posted in areas where materials are used or stored in amounts exceeding quantities in Table 1, column 1 (see page 18).

This sign shall also be displayed on containers containing amounts of activity exceeding those in Table 1, column 2. Such labels when used on containers shall, whenever possible (and always for containers used for storage), state the quantities and kinds of radioactive materials and the date of measurement of each quantity.

A label is NOT required if the concentration of the material in the container does not exceed the maximum permissible concentration of radioactive materials in restricted areas (see 10CFR20, App. B, Table I, column 2).

A label is NOT required for laboratory containers, such as beakers, flasks and test tubes used transiently in laboratory procedures, when the user is present.

6.2.3 Other signs: Other signs are required for HIGH RADIATION AREAS (dose rate greater than 100 mrem/hr) and for AIRBORNE RADIOACTIVITY AREAS. The RSO must be consulted regarding control measures in these areas.

6.3 Survey and Contamination Levels

Federal Regulations require that surveys be made "incident to" the use of radioactive material. Current interpretation of this regulation requires that individual users should check their hands, clothing, and work areas at the end of each active day and that records be kept of these surveys. The permit holder is responsible for routine surveys of the lab and personnel. The purpose of the surveys conducted by HUHS is to augment, not replace, daily checks by individual users. Specific procedures and guidelines are in Appendix I.

Removable surface contamination levels shall be effectively controlled and decontamination measures, when necessary, instituted at once (See Appendix I for guidelines). Personal contamination must be removed upon detection. Contaminated lab coats may be sent to the laundry if the contamination is less than 200 cpm on a thin end window G-M tube, and referred to the RSO if greater than 200cpm.

Radioactive contamination levels of air and water in restricted areas must be controlled such that the levels in microcuries/ml specified in 10CFR20, APP. B, Table I, are not exceeded. In unrestricted areas contamination levels in air and water shall not exceed those specified in 10CFR20, APP B, Table II.

6.4 Personnel Monitoring

6.4.1 General: Personnel monitoring devices are required by law and records must be kept, if an individual received or is liable to receive a dose in any calendar quarter in excess of 25% of the values listed in section 6.4.2. (5% for individuals under 18).

Such monitoring will normally take the form of film badges worn on the chest or at the waist. It is mandatory in all areas requiring a "Radiation Area" sign. Where hand dose may exceed 25% of the relevant limit below, finger ring or wrist dosimeters must be worn.

Situations may occur in which special precautions are dictated by unusual levels of radiation, variations of these levels, or the kind of radiation. When there are reasons to suspect that such a situation exists, it should be discussed with the RSO, who will recommend proper procedures.

6.4.2 Maximum permissible dose levels: In restricted areas, control must be such that no individual over 18 years of age (excluding patients) will receive in any one calendar quarter a dose in excess of the following limits, except as specified in the table:

whole body, head and trunk, active blood-forming organs, lens of eyes, gonads	1.25 rem
hands, forearms, feet, ankles	18.75 rem
skin of the whole body	7.50 rem

Doses to the whole body in excess of the above limits are permissible providing that during any calendar quarter the dose does not exceed 3 rem and that the cumulative dose in rem does not exceed 5(N - 18) where N=age in years. In such cases full documentation of past radiation exposure must be obtained on Form NRC-4.

The maximum whole body exposure of individuals under the age of 18 must be limited to 0.5 rem per calendar year. Caution should be exercised in assigning minors to work with radioactive materials. For women with diagnosed pregnancy, the whole body exposure should not exceed 125 mrem per quarter.

All areas in the vicinity of D.-F.C.I., which may be irradiated by sources under the control of the Institute, shall meet the standards for unrestricted areas.

6.5 Handling of Radioactive Materials

a) Before any work is undertaken with quantities of radionuclides which may produce significant external or internal exposure, attention shall be given by the permit holder to precautionary measures including the use of hoods, remote handling equipment and air monitoring. The RSO must be consulted for recommendations on specific operations.

b) Work which may result in contamination of work area should be done over trays lined with heavy absorbent paper.

c) Eating, storing and preparation of food, and smoking are forbidden in a laboratory or room where work with unsealed radioactive sources is taking place or where contamination may exist.

d) Personnel working in areas containing radioactive materials shall wash their hands thoroughly before eating, smoking or leaving work.

e) No pipetting by mouth is permitted.

f) Impervious gloves should always be worn when handling unsealed radioactive sources of all types. They must be worn when working with open vessels containing alpha emitters or with equipment possibly contaminated with these materials.

garments should be worn by all individuals handling radioactivity. In cases where millicurie amounts of activity are being handled and there is a likelihood of spillage and personal contamination, the laboratory coat must be monitored for contamination before sending to the laundry. It must not otherwise leave the laboratory.

h) Urine samples must be submitted to the RSO as detailed below. Each person who performs chemical iodinations involving 1000 microcuries or more must report for a thyroid scan within one month of each iodination.

Requirements for Bioassay for Tritium

I. Conditions Requiring Bioassay

A. Routine bioassay is required whenever an individual processes, at any one time, 10 millicuries or more of Hydrogen-3 labeled nucleotide precursor or 100 millicuries or more of Hydrogen-3 in any other form.

B. Special bioassays may be requested by the RSO, e.g., following a spill, hood malfunction, or other unusual circumstance.

II. Frequency

A. The sample is required within 48 hours of processing the above levels of Hydrogen-3, and then every 2 weeks as long as the individual continues to work with these levels.

B. In continuing operations the sampling frequency may be changed to quarterly if, after 3 months, the average urinary tritium concentration from specimens obtained during the 3-month period does not exceed 3 microcuries/liter.

6.6 Storage

a) Containers must be properly labeled and area signs posted where necessary.

b) Radionuclides requiring a "Radioactive Materials" label must be stored in areas under the control of the permit holder. The storage area shall be locked or otherwise secured against unauthorized removal of the material. Whenever practical, the radioactive material shall be packed so that the dose rate one foot from the surface of the container does not exceed 5 mrem/hr. Otherwise, the radionuclides shall be stored in a container, shielded if necessary, such that the radiation at a distance of one foot from the container does not exceed 10 mrem/hr. The area is a Radiation Area, and an area warning sign must be posted in addition to the label on the container.

Special precautions shall be taken so that the probability of an explosion or fire in the storage area is very small. Radionuclides requiring refrigeration should be stored in a "sparkproof" refrigerator. Such a refrigerator is one with the controls on the outside of the unit.

6.7 Transportation

6.7.1 Transportation on hospital premises: Permit holders and personnel under direct supervision of permit holders are permitted to transport radioactive material on hospital premises on the following conditions:

a) Radionuclides requiring a "Radioactive Materials" label must be enclosed in non-shatterable carrying cases or containers before being transported through corridors, or between buildings. Preferably, the radionuclides should be contained in a glass or other suitable chemically resistant container which in turn is packed in a metal carrier.

b) Containers for the transportation of beta sources requiring a "Radioactive Materials" label must provide shielding thicker than the maximum range of the beta rays in the material.

c) Gamma ray emitters shall be transported in closed containers, shielded if necessary, such that the dose rate at one meter does not exceed 10 mrem/hr (this rule follows the I.C.C. shipping regulations).

If these conditions are not satisfied, the RSO should be contacted to arrange transport.

6.7.2 Transportation outside hospital premises: In order for any radioactive material to leave or enter the hospital premises, the RSO must give his consent in the form of a "Transportation Permit". The material must be packaged and labelled in accord with NRC and Department of Transportation Regulations. In addition, material that is transported on foot should be routed to encounter minimum pedestrian traffic.

6.8 Radioactive Waste Disposal

6.8.1 Storage of Wastes:

a) It is recommended that each laboratory possess a metal waste can with a foot operated lid, which displays a radioactive materials label in a prominent position. The waste can should be equipped with a disposable liner.

b) Radioactive wastes must be stored in areas where they can be secured against unauthorized removal.

6.8.2 Disposal of liquid waste: Any laboratory may dispose of radioctive waste into a sink designated by the RSO if the following conditions are met:

a) A record is kept giving the date, the nuclide(s) and the amount of activity discharged for the day. Such records will be inspected monthly during the survey and the totals will be submitted annually to the RSC via the RSO.

b) The material is soluble in water.

c) The quantity of material discharged per day into the sink does not exceed the minimum amount requiring a radioactive materials label (Table I, column 2). If possible, only one sink in each laboratory should be designated for radioactive waste disposal.

Liquid waste may be disposed of via the radioactive waste barrels if it is solidified with an approved absorbent material (normally Speedi-Dri).

The RSO must be consulted for disposal of waste under other conditions, unless special permission has been granted in the permit itself.

The foregoing restrictions do not apply to excreta from individuals undergoing diagnostic or therapeutic procedures with radioactive materials.

6.8.3 Disposal of gaseous waste: The RSO must be consulted for disposal of gaseous waste, unless permission has been granted in the permit.

6.8.4 Disposal of solid waste: Disposal of solid radioctive waste may be arranged via the central waste disposal facilities operated by the HUHS (Dana 166 & JFB 215). The contents will be packaged for disposal periodically under the supervision of the HUHS. Tags are supplied by HUHS and must be filled out with all the information requested.

6.9 Design of New Facilities The design of all facilities involving the use, handling or storage of radioactive materials shall be reviewed by the RSC to assure the maintenance of adequate environmental protection.

6.10 Training of Personnel

All personnel working with specifically licensed quantities of radioactive materials who have not previously taken a course in radiation safety must attend a course to be specified by the RSC. New Employees may begin work with such radioactive materials before such a course has been taken only if the approved user instructs such employees in safe handling

methods at the start of the work. Such instrucction shall not replace attendance at a formal course, when available. The responsibility of the permit-holder for the safety of his employees is emphasized.

6.11 Safe Handling of Cadavers Containing Radioactive Material

If a patient containing less than 5 mCi of radioactive material dies in the hospital, no special precautions are necessary.

If a patient dies in the Institute and contains more than 5 mCi, the doctor signing the death certificate shall inform the pathologist and the RSO of this fact prior to autopsy. The funeral director's form shall be completed and approved by the RSO.

7. ANIMALS CONTAINING RADIOACTIVE MATERIALS

7.1 Handling

All aspects of the use of radionuclides in animals will be in accordance with the regulations of the Radiation Safety Manual (Section 7), the Animal Care Committee, D.-F.C.I., and the Harvard University Health Services.

Use of radionuclides in animals will be restricted to designated rooms. Injections of radioactive materials in animals should be carried out in trays covered with absorbent material on the bottom. Rubber or plastic gloves shall be worn for all levels of radioactivity.

All instructions in the section on "Handling of Radioactive Materials" apply.

7.2. Cages

Animals containing radioactive materials should be kept in cages (disposable if possible) apart from other animals, and the cages shall be clearly marked as follows:

a) Name of the radionuclide, on a yellow tag or label.

b) Amount of radioactive material injected per animal.

c) Date of injections.

d) Permit-holder's name and telephone extension.

e) "Caution Radioactive Material" labeling must be affixed to the cage when so required, according to the section on "Required Signs and Labels".

f) Adequate ventilation must be provided in instances where animals are stored after an injection of radioactive materials that may be volatilized and dispersed in the room. Such ventilation must be via an approved flue.

7.3. Disposal

All animal excreta which may contain radioactivity shall be collected and may be disposed through the sewage system if in a suitable form, i.e., not mixed with sawdust or wood shavings. The rules in the section on "Radioactive Waste Disposal" apply. Excreta not containing C-14, S-35, H-3 or other low energy beta emitter and showing no significant activity above background when monitored by a survey meter appropriate to the radionuclide involved may be discarded with normal trash in a suitable container.

If disposal cannot be made in either of these ways, the excreta shall be labeled with the name of the radionuclide and the estimated amount of activity, and stored prior to disposal by the Harvard University Health Services.

The carcasses or dissected parts of injected animals shall be wrapped in absorbent material and placed in a watertight container so as to prevent dripping during transportaton from one area to another.

Animals placed in a freezer or refrigerator prior to disposal by HUHS must be properly labeled.

Disposal by incineration of the carcasses, dissected parts, or excreta of animals containing radioactivity at any level is not permitted by the individual investigator. This is handled by the Harvard University Health Services.

8. NURSING CARE OF PATIENTS RECEIVING RADIOACTIVE MATERIALS

8.0 PREFACE

Radionuclides are administered to patients for diagnostic urposes and for therapy. The hazards for nursing personnel, visitors, and other patients increase with increased levels of radioactivity used. Only minor precautions are necessary in nursing care of patients who have received tracer doses of radioactive material for diagnostic tests. For therapeutic doses, some special precautions are necessary in order to give the patients proper care without unduly exposing nursing personnel.

8.1 Hazards of Radionuclides

Hazards may arise from:

a) Exposure of nursing personnel to the radiation emitted from patients.

b) Contamination of the skin with radioactive materials, leading to skin exposure and ingestion of radioactive materials.

Information about special radiation hazards associated with the patient should be given by the physician responsible for the administration of the radioactive material.

8.2 General Principles of Protection

a) Skin contamination, ingestion, or inhalation hazards can be minimized by practicing good housekeeping, hand washing and clean work procedures.

1) Radioactive materials should not be allowed to come into contact with the skin.

2) Where radioactivity is present, personnel should not be allowed to eat, drink, smoke or apply cosmetics.

b) External irradiation of the body may be reduced by:

1) Taking precautions in handling contaminated equipment.

2) Spending the minimum of time close to patients with therapeutic doses of radioactivity.

8.3 General Precautions

a) The length of time personnel should remain at any particular distance from the patient should be determined by the doctor licensed to administer the radionuclide, and/or the RSO.

b) Wash hands after contact with the patient. Give particular attention to fingernails. Avoid working with open cuts.

c) No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, utensils, or bedding unless specifically ordered.

8.4 Special Instructions

a) All radioactive materials are to be administered to patients under the direction of a licensed physician.

b) All containers housing radioactive materials which are brought to a division or patient area of the hospital shall bear appropriate labels as to their content and indicate their radioactivity and maximum dose rate at the surface of the container at a specified date and time. If it is intended that the substance be used for a particular patient or patients, the name(s) shall appear on the label together with the appropriate time(s) and date(s) for administration.

c) If it is anticipated that radiation safety precautions will be necessary upon the administration of a radioactive material to a given patient it is imperative that prior arrangement be made to insure the availability of proper facilities such as a private room.

8.5 Nursing Care of Patients Receiving TracerDoses of Radionuclides For Diagnostic Studies

8.5.1 GENERAL INSTRUCTIONS

a) Routine nursing care can be carried out without any danger because of the small amounts of radioactivity used.

b) Patients are allowed visitors in accordance with the usual hospital rules.

8.7.2 Special instructions

a) If there are any special instructions for a particular case, they will be noted on the patient's order sheet.

b) Nurses who are required to hold infants or small children given diagnostic doses of gamma-emitting radionuclides (such as technetium-99m) must be at least 18 years of age and should not hold the patient for longer than absolutely necessary during the first 24 hours after administration of the radionuclide. Pregnant women should not hold the patient for the first 24 hours after a diagnostic dose of technetium-99m. Under these circumstances, badges are not required.

8.6 Nursing Care of Patients Receiving Therapeutic Radionuclides

Inasmuch as Therapeutic administration if radionuclides under the auspices of the Joint Center for Radiation Therapy (JCRT), specific guidelines are not given here, and nurses are requested to contact the JCRT at 2-8509.

8.7 X-Ray Therapy Regulations

8.7.1 General principles

a) There is no radiation hazard to nurses or other personnel from patients receiving X-ray therapy. Routine nursing care may be used.

b) Patients are allowed visitors in accordance with the usual hospital rules.

c) No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, utensils or bedding (none of these objects can be made radioactive by X-ray machines).

9. EMERGENCY INSTRUCTIONS

In case of a spill or other accident, alert nearby personnel, confine the spill, block off and mark area, decontaminate, and monitor before moving temporary signs or barricades. If personnel contamination is involved, remove contaminated clothing, wash skin, and monitor; seek medical advice if contamination perists and/or injury has occurred. Report all accidents and injuries immediately to the RSO and the laboratory supervisor. The individual responsible for a spill is responsible for decontamination. Custodial personnel

are prohibited from involvement, unless specifically authorized by the RSO.

9.1.4 How to Notify Radiation Safety Personnel

The RSO shall be notified immediately of all accidents involving possible body contamination or ingestion of radioactivity, overexposure to radiation, contamination of equipment, spread of contamination or difficulty in cleaning up a contaminated area.

The RSO must be notified immediately in the event of loss of radioactive materials.

In an emergency involving radiation or radioactive materials, call HUHS at 495-2061 and inform them of the nature of the emergency. In an off-hours emergency, also call HUHS at 495-2060, and tell them that a radiation emergency has occurred at D.-F.C.I.. They will contact the RSO.

9.2 Procedures for Dealing with Spills and Contamination

All spills of radioactive material must be cleaned up promptly. The responsibility for cleaning or for calling for experienced help rests with the individuals responsible for the spill.

It is convenient to classify spills as major or minor. A major spill gives an exposure rate of more than 2 mR/hr at 1 foot distance or contains more than 0.3 mCi of radioactive material.

9.2.1 Procedure for dealing with minor spills and contamination: Most accidents will involve only minor quantities of radioactivity (i.e., in the microcuries level).

a) Put on gloves to prevent contamination of hands.

b) Drop absorbent paper or cloth on spill to limit spread of contamination.

c) Place contaminated cleaning materials into plastic bags or other closed containers. Seal and label.

d) Mark area of spill as "contaminated" as soon as possible if immediate decontamination is not instituted. A wet spill shall not be allowed to dry and become powdery if significant amounts of radioactivity are involved. This might produce serious air contamination.

e) Notify RSO by calling [illegible]

f) Start approved decontamination procedures as soon as possible.

If the body is suspected of being contaminated:

a) Scan with alpha and beta-gamma survey meters to determine the contaminated areas of the body.

b) Do not immediately attempt decontamination if cuts, abrasions or open wounds are observed.

c) If cuts, abrasions or open wounds are contaminated, dry-clean the area with suction apparatus and swabs (wet cleaning might increase absorption).

d) If the skin is contaminated in the area of cuts, abrasions and open wounds, use wet swabs in a direction away from the cut, abrasion or open wound, taking care not to spread activity over body or into wound.

If the skin appears to be intact, use decontamination procedures:

a) Wet hands and apply mild soap.

b) Work up good lather, keep lather wet.

c) Work lather into contaminated area [illegible] gently for 3 minutes. Apply water frequently.

d) Rinse thoroughly with lukewarm water (limit water to contaminated areas).

e) Repeat above procedures twice.

f) If the radiation level is still above [illegible], initiate more powerful decontamination procedures after consultation with the RSO (495-2061).

9.2.2 For all major accidents, including explosions and release of airborne radioactivity and leakage of sealed gaseous and powdered sources:

IF POSSIBLE, CUT OFF THE RELEASE OF RADIOACTIVE MATERIAL FROM THE SOURCE TO THE ENVIRONMENT.

a) Report incident to RSO (495-2061) immediately

e) Type of shielding.

f) Person(s) responsible for management.

g) Any other information considered pertinent in support of the application.

Individuals wishing to use equipment producing ionizing radiation must request Committee approval in a letter written by the head of the department concerned. This does not apply to physicians who are under the supervision of the Radiologist-in-Chief of the hospital.

From time to time, the Radiation Safety Committee will request a radiation survey of such equipment.

10.2 Nonlicensed Radionuclides

Accelerator produced and/or naturally occurring radionuclides in any quantity are subject to all portions of these regulations which govern by-product materials (it should be noted that the NRC does not have jurisdiction over such nonlicensed radionuclides).

Any user of nonlicensed radionuclides must conform to the radiation safety practices as outlined by the RSC of the D.-F.C.I.

For the laboratory or human use of nonlicensed radionuclides, application for a permit must be made to the RSC and Committee approval must be obtained prior to use.

10.3 Sublicense Quantities of Radionuclides

By-product material in less than the minimum amount requiring a license by the NRC may be used only after application for a Permit has been made to the RSC and RSC approval received by the individual investigator.

TABLE 1

QUANTITIES OF SOME RADIOACTIVE MATERIALS REQUIRING SIGNS

RADIONUCLIDE	Column 1 Minimum Quantity for Radioactive Material Sign on Room MICROCURIES	Column 2 Minimum Quantity for Radioactive Material Label on Container MICROCURIES
Au-198	1,000	100
Br-82	100	10
C-14	1,000	100
Ca-45	100	10
Cl-36	100	10
Co-60	10	1
Cr-51	10,000	1,000
Cs-137	100	10
F-18	10,000	1,000
Fe-55	1,000	100
Fe-59	100	10
H-3 (HTO or T2O)	10,000	1,000
I-125	10	1
I-131	10	1
K-42	100	10
Na-24	100	10
P-32	100	10
Ra-226	0.1	0.01
S-35	1,000	100
Sc-46	100	10
Sr-89	10	1
Sr-90 - Y-90	1	0.1
Tc-99m	1,000	100
Y-90	100	10
Zn-65	100	10
Unidentified	1	0.1

[This Table is based on Appendix C, 10 CFR 20 (December 1982)]

APPENDIX I

FREQUENCY AND PROCEDURES FOR CONDUCTING LAB SURVEYS

Frequency

It is good laboratory practice to monitor your hands, clothing, and work areas as soon as possible after work with radioactive materials. A weekly survey is required after working with 100 uCi or more of I125 or I131 or 5 mCi or more of any other isotope. The results of all such surveys must be noted on the "Personal Survey Form" (available from the RCU), or similar record.

Procedures

Personal Surveys should be carried out in two parts to determine both radiation levels and removable contamination levels.

1. Radiation Levels

Monitoring area with radiation survey meter sufficiently sensitive to detect 0.1 mR/hr. The record of the results should include the location, date, type of meter used, initials of person conducting the survey, and any measured dose rates, including the point at which the measurement was made.

2. Removable Contamination Levels

A series of wipe tests should be taken in all areas where activity is handled in unsealed form. The "wipe" should be a piece of filter paper (Whatman No. 1 recommended) or a piece of paper towel 1-2 inches on a side. The location of the wipe test should be indicated on the Personal Survey Form and should be chosen for maximum probability of contamination, e.g., areas where frequent pipetting is carried out.

An end window GM counter normally may be used for assaying beta emitters at or above C-14 energies; low energy beta emitters (e.g., H-3) will require liquid scintillation counting. A gamma-scintillation counter (e.g., NaI well counter) should be used for pure gamma emitters (e.g., I-125, Cr-51).

Results of all wipe tests and meter checks required by NRC regulations (10 CFR 20) must be recorded and available for inspection, even if the results are negative. For negative results a simple entry such as N.D.C. (no detectable contamination), or N.D.A. (no detectable activity) will suffice.

ACCEPTABLE LIMITS -- EXPOSURE

All isotopes in storage should be shielded to reduce the exposure at normally occupied areas to less than 0.1 mR/hr, and MUST be shielded to reduce to the exposure to less than 10 mR/hr at 12" from the surface If the surface dose rate exceeds 2 mR/hr the area must be posted in accordance with section 6.

If an individual is occupationally exposed then exposure rate limits do not apply, but an employee's total exposure must be ≤ 1250 mRem/13 weeks. On a basis of 40 hr/week of exposure, the maximum exposure rate would have to be ≤ 2.5 mR/hr. In practice, the radiaton levels should be kept as low as is practicable and always below applicable limits.

Acceptable limits -Contamination

An individual wipe test should routinely cover approximately 100 - 150 cm2. A cleanup should be initiated for beta-gamma contamination at no more than about 200 DPM. Any alpha contamination should be removed immediately. At approxmately 10000 DPM a Contamination Zone should be established until the contamination is removed.

Contamination levels may also be estimated with a survey meter. As a rough rule of thumb, establish a Contamination Zone if readings are greater than 100 CPM for Group I and II radionuclides (e.g., Pb-210, Bi-210, Ra-226, Am-241, Cl-36, Ca-45, Co-60, I-125, I-131), and greater than 1000 CPM for Groups III and IV (e.g., C-14, P-32, S-35, Fe-55, Rb-86, Pb-203), measured with a thin window GM counter. This instrument will not detect H-3, so wipe tests must be used.

APPENDIX II
Procedures for Safely Opening Packages
Containing Radioactive Material

Federal regulations (10CFR20.205) require that radioactive packages be inspected and monitored within three hours of receipt (eighteen hours if delivered after hours). The Permit holder is responsible for compliance with that regulation. The following procedure is suggested:

1. Wipe test package for removeable contamination. If removeable contamination exceeds 0.01 uCi/100 sq. cm, stop procedure and notify RCU.

2. Note radiation limits stated on package, verify, and record on receipt (hard beta and gamma). If exposure rate > 10 mr/hr at three feet or 200 mr/hr and surface, stop procedure and notify RCU.

3. Place package in chemical fume hood.

4. Open outer package, and remove packing slip. Open inner package and verify that the contents agree in name and quantity with the packing slip. Gloves must be worn.

5. Measure radiation field of unshielded container. If necessary place package behind shielding to reduce field to allowable limits (hard beta and gamma).

6. Check for breakage of seals or containers, loss of liquid, or change in color of absorbing material.

7. Wipe test inner contents and record results on receipt. NOTE: The liner, shield, and isotope container may have surface contamination; they should be discarded as radioactive waste.

8. Record date, purchase order number, isotope and activity on the receipt.

9. Forward the receipt to the Radiation Control Unit, Enders SB-22.

03 14	10763	00000	LICENSE	700.00	.00	700.00

VEND 092943 NUCLEAR REG COMM CHK 0128194 700.00

44 Blurry Street, Hoobar, MA 02115

128194

VENDOR NO	CHECK NO	MO	DAY	YR
092943	0128194	03	23	89

PAY TO THE ORDER OF NUCLEAR REG COMM

00000

AMOUNT OF CHECK	
****700	.00
DOLLARS	CENTS

****700DOLLARS .00CENTS

VOID IF NOT CASHED WITHIN 120 DAYS

THE FIRST NATIONAL BANK OF BOSTON
BOSTON, MASSACHUSETTS 02115

AUTHORIZED SIGNATURE

⑈128194⑈ ⑆011000390⑆523 624 20⑈