Attachment for Item 15 are selected procedures from the BioClinical Radiation Safety Manual

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PART I

PURPOSE

AUTHORITY

BIOCLINICAL GROUP RADIATION SAFETY MANUAL

I. PURPOSE

The required procedures contained in this document have been established for the following purposes:

1.1 To provide for the protection of Company personnel and of the general public against radiation hazards associated with our possession, use, transportation, and disposal of radioactive material.

1.2 To provide for the Company's compliance with applicable regulations of Federal, State, and Local Agencies.

The use, storage, transportation, and disposal of radioactive material must conform with the applicable regulations of the United States Nuclear Regulatory Commission, the Massachusetts Department of Public Health, and the Massachusetts Department of Labor and Industries.

The applicable regulations are as follows:

Agency	Regulation
NRC	Title 10, Code of Federal Regulations, Part 20
Mass. Dept. of Public Health	"Rules and Regulations to Control the Radiation Hazards of Radioactive Material and of Machines which Emit Ionizing Radiation", Section 5B, Chapter III, General Laws
Mass. Dept. of Labor & Industries	"Rules and Regulations for the Health Safety of Employees from Occupational Diseases", Industrial Bulletin No. 5
U.S. Dept. of Transportation	Title 49, Code of Federal Regulations, Part 173

II. AUTHORITY

1. The Radiation Safety Officer receives its authority from the President of the Company.

He is charged with the following responsibilities:

1.1 The establishment and continuing review of an adequate radiation protection program.

1.2 The Company's compliance with radiation protection regulations promulgated by State, Federal, and Local Agencies.

1.3 Providing such services as may be required for radiation protection and compliance with governmental regulations.

The services include the following:

(a) Registration and instruction of radiation workers

(b) Personnel monitoring of radiation exposure

(c) Radioisotope laboratory inspections, radiation surveys, and area monitoring

(d) Radioactive waste collection and disposal

(e) Calibration and repair of radiation protection instruments

(f) Environmental monitoring

(g) Monitoring shipments of radioactive material

(h) Supervision of radiation emergencies, and special decontamination operations

(i) Maintenance of radiation protection records

In addition, the Radiation Safety Officer is available for (a) consultation on laboratory design, shielding, and other radiation exposure control methods, and (b) presenting lectures and training exercises on radiation protection techniques.

2. Each Laboratory Supervisor possessing or using radioactive material or radiation sources is responsible for:

2.1 Implementing the Company's radiation protection program

2.2 Maintaining an up-to-date listing of the names of personnel who may be handling radioactive material, or who may be exposed to ionizing radiation

2.3 Allowing only those persons listed to handle or use radioactive material and/or radiation sources

2.4 The maintenance of an adequate inventory of the amount of radioactive material possessed by the laboratory, and the establishment of an adequate system to ensure that the laboratory does not exceed its radioactive material possession limits

2.5 Keeping adequate records of disposal of radioactive material.

2.6 Allowing only authorized persons to enter rooms that are specified as restricted areas for reasons of radiation protection.

2.7 Informing the Radiation Safety Officer of new radioactive-material work, or changes in existing work which may increase the possibility of radiation exposure

2.8 Ensuring that personnel wear assigned film badges or pocket dosimeters during periods of possible exposure

2.9 Establishing appropriate procedures to ensure compliance with the requirements of this document

2.10 Establishing a daily radioisotope-laboratory 'close down' procedure adequate to ensure that at the end of the work-day:

(a) Survey-meter measurements have established that external radiation and contamination levels are within permissible limits

(b) Radiation sources are properly labeled and stored

(c) Experiments that will be in progress after normal work hours, will be properly attended

(d) Each Laboratory is secured against unauthorized access

2.11 Each Individual who may use radioactive material is responsible for complying with the procedures and precautions of this document

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PART II

REQUIRED PROCEDURES

REQUIRED PROCEDURES PERTAINING TO RADIOACTIVE MATERIAL

1. Scope

These procedures apply to all Company personnel that receive, possess, use, transport, or dispose of radioactive material.

2. Registration, Authorization and Restrictions

2.1 Each person who may handle radioactive material or who may be exposed to external radiation must attend a Health Physics Orientation session.

Reference SOP No. 1 - Health Physics Training Program

2.2 Each user must be approved for a proposed use of radioactive material with specific regard to adequacy for the proposed use of his training and experience with radiation.

Reference SOP No. 1 - Health Physics Training Program

2.3 The following personnel shall be restricted from handling radioactive material:

2.3.1 Any person under the age of 18

2.3.2 Any pregnant woman

ORDERING OF RADIOACTIVE MATERIALS

PURPOSE

To ensure that radioactive materials purchased are within the limitations of the company's NRC license.

To maintain an accurate inventory of all isotopes possessed within the company.

To ensure that transfers of radioactive material are made in a safe manner.

SCOPE

This procedure covers all purchases of radioactive materials.

PROCEDURE

Purchasing Radioactive Material

1. All purchases of radioactive materials will be made with the prior notification and approval of the Health Physicist. For standing purchase orders notification need only be made of the original standing order and changes to the standing order. Purchases of less than 50 microcuries of ^{125}I are exempt from this section.

2. All incoming radioactive materials will be received according to Part II-6 of this manual, Receipt of Radioactive Materials.

3. The receiving clerk will forward a copy of the packing list for all radioactive materials received to the Health Physicist.

"OFFICIAL RECORD COPY"

RECEIPT OF RADIOACTIVE MATERIALS

PURPOSE

To inspect incoming packages of radioactive materials for contamination and dose rate as specified by NRC regulations.

To insure the integrity of the packaging of incoming radioactive materials.

SCOPE

The following procedure applies to all packages of incoming radioactive materials received.

PROCEDURE

1. Receiving

   1.1 The receiving clerk will inspect the package and place it in the area designated for the receipt of radioactive materials. The receiving clerk will immediately notify the Health Physicist of any package which appears to be damaged or leaking.

   1.2 The receiving clerk will record the following data in the Incoming Radioactive Materials Log Book: the isotope, activity, date and time of receipt and initials of the receiver.

   1.3 Packages of 1 millicurie or less of Iodine-125 or Cobalt-57 will be delivered to the purchaser by the receiver.

   1.4 Packages of greater than 1 millicurie of Iodine-125 or Cobalt-57 will remain in the designated area for radioactive materials and the Tracer Production Group will be immediately notified.

2. Monitoring Incoming Packages of Radioactive Materials

   2.1 The Tracer Production Group will initial the receipt of packages in the Incoming Radioactive Materials Log Book.

   2.2 The Tracer Production Group will ensure that the packages of greater than 1 millicurie of I-125 and Co-57 are wipe tested for surface contamination within 3 hours of receipt if received during normal working hours or within 18 hours if received after normal working hours.

   2.3 If removable contamination in excess of 100 cmp/100 cm^2 of package surface is detected, the Health Physicist will be notified immediately.

3. Handling Contaminated Packages

   3.1 The Health Physicist will supervise the segregation and any necessary decontamination of contaminated radioactive material packages.

3.2 If removable contamination in excess of 0.01 microcurie per 100 cm^2 or package surface is detected, the Health Physicist will immediately notify the final delivering carrier and the Regional NRC Office. The purchasing department will be notified by the Health Physicist to contact the shipper of the material.

GENERAL RADIATION PROTECTION REQUIREMENTS

PURPOSE

To provide general guidelines for radiation protection for all employees.

SCOPE

This procedure applies to all personnel where radioactive materials are being used, handled, transferred or stored except in the shipping and receiving departments where radioactive materials are sealed in packages and where there is no external contamination of the packages.

PROCEDURE

1. There will be no smoking, eating, drinking, or storage of food in any area where radioactive materials are being used, handled, transferred or stored.

2. There will be no mouth pipetting allowed.

3. Protective gloves and lab coats will be worn when handling unsealed containers of radioactive materials.

4. All containers of radioactive materials will be kept covered when not in use and will be properly stored in a posted storage area. Containers will be identified with the isotope name, activity and date (see Caution Signs and Labels).

5. Workbenches will be lined with absorbent paper to contain any spills. Absorbent paper on benches will be routinely changed.

6. All radioactive waste materials will be properly segregated and disposed of. There will be no unauthorized drain disposal of radioactive waste liquids.

7. Contaminated glassware will be segregated for proper cleaning.

8. The Health Physicist is to be immediately notified of any incident where radioactive contamination is known or suspected.

9. After handling unsealed sources of radioactive materials, hands will be washed before leaving the laboratory.

10. Lab coats and disposable gloves are not to be worn outside the laboratory after handling unsealed radioactive materials.

CAUTION SIGNS AND LABELS

PURPOSE

To insure that all storage areas and individual containers of radioactive materials are properly identified.

SCOPE

This procedure applies to all areas where radioactive materials are stored including rooms, refrigerators and freezers and all containers of radioactive materials.

PROCEDURE

1. Caution Signs

   Each laboratory, room or refrigerator or freezer will be posted with caution signs as follows:

   1.1 Any area containing greater than 10 microcuries of Iodine-125 will be posted with a sign stating "CAUTION RADIOACTIVE MATERIALS".

   1.2 Any laboratory or other area where a major portion of the body could receive in any one hour a dose in excess of five millirems or in any five consecutive days a dose in excess of 100 millirems will be posted at each point of access with a sign stating "CAUTION RADIATION AREA".

2. Labels

   2.1 Any container holding greater than 1 microcurie of Iodine-125 will be labeled "CAUTION RADIOACTIVE MATERIAL".

   2.2 Labeling is not required for laboratory containers, such as beakers, flasks and test tubes used transiently in lab procedures while the user is present.

3. Sign and Label Design

   The color and design of all signs and labels will be specified in Title 10 CFR 20.203.

RADIATION LAB PROTECTION REQUIREMENTS

PURPOSE

To provide additional radiation safety procedures for all employees working in a radiation area.

SCOPE

This procedure applies to operations in all radiation laboratories, i.e., where iodination reactions are performed.

PROCEDURE

1. Each individual must be registered with the Health Physicist to work in a radiation laboratory.

2. Film badges are to be worn at all times when working in the labs. Spare film badges are available for newly registered personnel and are signed out for each period of use.

3. Disposable gloves and disposable lab coats will be worn.

4. Whenever practical, the user should perform a trial experimental run using stable (or low activity) material to establish the adequacy of procedures and equipment.

5. All Chemical reactions utilizing free ^{125}I (not bound to a stable nonvolatile substrate) shall be performed in a fume hood specifically designed for filtering ^{125}I from exhaust effluents.

6. Prior to performing an operation requiring the use of a fume hood, radiation levels will be measured. If the level at the face of the hood is 2.5 millrads/hr., the source should be disposed or shielded. Handling tongs or a suitable remote handling device must be used for handling a source or container which emits a dose rate at contact in excess of 1 rem/hr. unless otherwise specifically authorized by the Health Physicist.

7. All in-process radioactive material and radioactive waste shall be sealed and stored in a manner that:

   7.1 Provides adequate radiation shielding

   7.2 Provides adequate protection against fire, explosion, or flooding

   7.3 Provides adequate protection against accidental breakage of primary storage containers

   7.4 Provides adequate protection against unauthorized removal

   7.5 Provides adequate containment to prevent the escape of radioactive volatiles

8. Objects and equipment that may have been contaminated with radioactive material shall be surveyed for exterior surface contamination prior to their removal from the radiation lab. If surface contamination is detected, the contaminated object shall not be removed from the laboratory without the authorization of the Health Physicist.

9. After handling unsealed radioactive material, hands shall be washed before leaving the laboratory, and exposed skin, hair and clothing shall be surveyed for contamination. The Health Physicist shall be notified immediately if, after decontamination, residual contamination of skin, hair or personal clothing is detected.

10. Each person on completion of an iodination procedure will monitor himself for ^{125}I ingestion as follows:

    Take a thyroid measurement 24 hours following the iodination utilizing a Ludlum 177 ratemeter equipped with a scintillation probe. Record the CPM on the log sheet. If the net count is greater than 100 CPM, notify the Health Physicist for a follow-up measurement.

11. The Health Physicist shall be notified immediately if any of the following circumstances is known or suspected:

    a. Exposure to external radiation in excess of the values in Appendix A.

    b. Exposure to inhalation, ingestion, or injection of radioactive material.

    c. Accidental release of radioactive material to laboratory atmosphere, surfaces, drains, or ventilation system.

12. A log of all radioactive material and their use is to be left in the radiation lab.

13. No person is to work inside the hot lab alone. Supervision for work after hours is to be arranged with the Health Physicist.

PROCEDURES FOR DEALING WITH A RADIATION CONTAMINATION INCIDENT

PURPOSE

To establish a procedure for emergency situations involving radioactive contamination.

SCOPE

This procedure covers all incidents where accidental radioactive contamination is known or suspected.

PROCEDURE

1. SERIOUS INJURY WITH CONTAMINATION INVOLVED

A. Notification: (any time of day)

1. Dial 497-2070 and ask for Ernest Groman or Lee Josephson during working hours; otherwise, Dr. Groman at 734-6560 or Dr. Josephson at 643-7223.

2. Tell him:

2.1 Somebody has been seriously injured at BioClinical Group.

2.2 Radioactivity is involved.

2.3 Your name.

B. Care of the injured:

1. Apply first aid, if necessary.

2. Stay with the patient until help arrives.

C. Contamination control procedures while waiting for help:

1. For localized non-volatile liquid spill:

1.1 Rope off or guard spill area against re-entry.

1.2 Assemble potentially contaminated persons in one location of laboratory and monitor them for contamination.

1.3 Wait for Radiation Safety Officer to arrive.

2. For a release of powdered volatile-liquid, or gaseous activity:

2.1 Evacuate personnel immediately, turning off any laboratory apparatus that needs constant attention.

2.2 Assemble personnel immediately <u>outside</u> the room and instruct them to stay in one location, to prevent the spread of contamination.

2.3 Close and lock the doors to prevent re-entry. If the hood fans are off, try to seal accessible openings into the laboratory to prevent further escape of airborne activity into the corridor.

2.4 Isolate the adjacent corridor against traffic and spectators.

2. MINOR INJURY WITH CONTAMINATION INVOLVED

A. Notification:

1. Dial 497-2070 and ask for Ernest Groman or Lee Josephson during working hours; otherwise, Dr. Groman at 734-6560 or Dr. Josephson at 643-7223.

2. Tell him:

2.1 A radiation contamination incident at BioClinical Group with minor injury has occurred.

2.2 Your name.

B. Care of the injured:

1. Measure clothing for contamination.

2. Remove significantly contaminated clothing and, if necessary, clothe patient in an uncontaminated laboratory coat.

C. Contamination control procedures:

Same procedures as 1.C. above.

STANDARD OPERATING PROCEDURE

HEALTH PHYSICS TRAINING PROGRAM

SOP No. 1
Date: 12/1/81
Effective: 1/15/81
Supersedes: None

PURPOSE

To establish and document a training program for radiation safety.

To ensure that all personnel who may handle radioactive materials receive the proper training for the safe performance of their assigned duties.

SCOPE

The Radiation Safety Officer will be responsible for the administration of a Health Physics Orientation for all new employees.

All personnel who are to be authorized to enter a radiation laboratory will receive additional training in radiation safety and radiation lab procedures from the Health Physicist.

PROCEDURE

1. General Orientation

1.1 The orientation will consist of the following topics:

1.1.1 Legal Basis for Radiation Protect on

1.1.2 Basic explanation of radioactivity

1.1.3 Radioactivity in use at BioClinical Group

1.1.4 Restrictions for work with radioactive materials

1.1.5 Emergency Procedure

2. Radiation Safety Training

2.1 All personnel who have authorized access to a radiation laboratory will receive radiation safety training in addition to the general orientation outlined in section 1 prior to the start of their work in that area.

Approvals:

President 12-9-81 Date

Regulatory 12-9-81 Date

STANDARD OPERATING PROCEDURE

HEALTH PHYSICS TRAINING PROGRAM

SOP No. 1
Date: 12/1/81
Effective: 1/15/81
Supersedes: None

2.2 Radiation safety training will consist of the following:

2.2.1 A review of the material in the BioClinical Group Radiation Safety Manual.

2.2.2 Explanation of Radioactivity

2.2.2.1 Definitions - curies, DPM, CPM, MR/HR

2.2.2.2 Types - alpha, beta, gamma emitters

2.2.2.3 Half Life - Specific Activity

2.2.2.4 Discussion of Time - Distance - Shielding principles and precautions and hazards of isotopes used

2.2.3 Measuring and Monitoring Use

2.2.3.1 Explanation of CMP, DPM, Counting efficiency

2.2.3.2 Gamma counter use and considerations

2.2.3.3 Survey meter use and effectiveness

3. Documentation

3.1 All training in Health Physics and Radiation Safety will be recorded and placed in the employees training file.

STANDARD OPERATING PROCEDURE

RADIATION LABORATORY ENTRY AND EXIT

SOP No. 2
Date: 12/1/81
Effective: 1/15/81
Supersedes: None

PURPOSE

To establish guidelines for the proper use and control of the radiation laboratories.

To provide adequate radiation protection for personnel working in the radiation laboratory.

To insure compliance with corporate health physics, federal, state and local regulations.

SCOPE

The Health Physicist and the radiation laboratory supervisors have the responsibility for the proper entry and use of the radiation laboratories by all personnel.

PROCEDURE

1. Registered Personnel

Those persons regularly assigned to a radiation laboratory will be registered with the Health Physicist. Prior to the start of any radiation lab duties, these personnel will attend a Health Physics orientation (SOP 1). Registered radiation lab workers will be assigned film badges to be worn at all times when working in the radiation lab. A current list of registered radiation lab workers will be maintained by the Health Physicist and provided to the radiation lab supervisors monthly. The list will also be posted next to the rack for badges. A compilation of all monthly lists will be kept by the Health Physicist.

2. Non-registered Personnel

Any non-registered personnel who wish to enter a radiation lab must receive prior approval from the Health Physicist or the radiation lab supervisor. This approval must be given each and every time non-registered personnel enter the radiation lab. (At the discretion of the Health Physicist or the radiation lab supervisor, non-registered personnel may be allowed to enter numerous times within a limited time period without having to wait for approval.)

Approvals:

[signature] 12-9-81		[signature] 12-9-81	
President	Date	Regulatory	Date

STANDARD OPERATING PROCEDURE

RADIATION LABORATORY ENTRY AND EXIT

SOP No. 2
Date: 12/1/81
Effective: 1/15/81
Supersedes: None

Non-registered personnel will be instructed as to proper radiation laboratory procedures and assigned a "spare" film badge to be worn inside the radiation lab. The use of each spare film badge is to be recorded on the form provided.

3. Personnel Monitoring and Entry Procedure

3.1 Film badges are to be worn at all times while working in a radiation lab. When not being worn, film badges will be stored on a rack outside the lab.

3.2 Disposable lab coats are to be worn at all times when working in a radiation laboratory. Gloves are to be worn while handling radioactive material or potentially contaminated equipment. The label machine operators of the bottling group are excepted from the requirements of wearing gloves at all times due to the specific requirements of the operation and the fact that the tracer is in a sealed vial during this operation.

4. Personnel Monitoring and Exit Procedure

4.1 Hands must be washed prior to leaving a radiation laboratory. Exposed skin, hair, and clothing will be surveyed for contamination with a survey meter having a sensitivity of detecting less than 1 nCi ^{125}I. If contamination of greater than 500 cpm above background is detected, the contaminated area will be rewashed. If contamination of greater than 1000 cpm above background is detected, the Health Physicist and/or the radiation lab supervisor will be notified and the contaminated area will be rewashed until it meets the approval of the Health Physicist or the radiation lab supervisor. Disposable lab coats will be surveyed at least once a day for contamination. Lab coats found to be contaminated will be immediately disposed of with radioactive waste.

4.2 Objects and equipment that may have been contaminated will be surveyed for surface contamination prior to removal from a radiation lab. If surface contamination is detected, the contaminated object will not be removed from the lab without the authorization of the Health Physicist.

Articles which cannot be routinely checked with a survey meter, such as samples of tracer for QC and bottled tracer vials, will be wipe tested for surface contamination. A

minimum of ten vials from each completed bottling run will be checked for contamination prior to removal from the radiation lab. One wipe may be used for more than one tracer vial. If surface contamination of greater than 100 cpm is detected, the contaminated article(s) will not be removed from the lab without the authorization of the Health Physicist.

4.3 Each person on completion of an iodination procedure will monitor himself for ^{125}I ingestion by urine assay or thyroid monitoring as required by Health Physics Procedures and "Required Procedures for Radiation Protection". All personnel who have worked in the radiation lab will report to the Health Physicist on the following Friday for thyroid monitoring.

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RADIATION LABORATORY ENTRY PERMIT
FOR NON-REGISTERED PERSONNEL

Job Description: _____

_____

Location: _____ Date: _____ Time Issued: _____

Time Expired: _____

Personnel: _____ Film Badge No. _____

_____ _____

_____ _____

Protective Precautions Taken Check

Hazards and Procedures Explained

Protective Clothing Issued

Thyroid Monitoring

Personnel Monitoring

Equipment Used Monitored

Approved by:
Radiation Lab Supervisor or Health Physicist

Entry permit good only for job and time given.

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STANDARD OPERATING PROCEDURE

RADIATION LABORATORY HOUSEKEEPING

SOP No. 3
Date: 12/1/81
Effective: 1/15/81
Supersedes: None

PURPOSE

To establish guidelines for the cleaning and maintenance of the radiation laboratories.

To assure that such cleaning and maintenance comply with current GMP and Health Physics requirements.

SCOPE

The Housekeeping Group is responsible for the general cleaning of the radiation laboratories under the direction of the Health Physicist. The registered radiation lab workers are responsible for the removal and monitoring of all waste materials, the cleaning of all laboratory equipment, benches and hoods, and the clean-up of any radioactive contamination under the direction of the radiation laboratory supervisor or the Health Physicist.

PROCEDURE

1. The Health Physicist and the supervisor of Housekeeping will establish the scope and frequency of all general radiation laboratory cleaning. The Health Physicist will train all Housekeeping personnel assigned to the radiation laboratory as follows:

   1.1 The areas to be cleaned and the frequency of cleaning.

   1.2 The materials and equipment to be used. Cleaning equipment used in the radiation laboratory are designated for that purpose only and may not leave the laboratory.

   1.3 Special cleaning to be done on a seasonal or emergency basis.

   1.4 Cleaning restrictions: lab benches, lab hoods, equipment and instrumentation and glassware.

   1.5 Radiation laboratory procedures and entry and exit procedures.

2. The Health Physicist and radiation lab supervisor will establish the scope and frequency of specific radiation laboratory cleaning operations including the following:

   2.1 The collection, monitoring and disposal of all non-radioactive waste. All waste is to be monitored for radioactive contamination prior to leaving the laboratory. All radioactive labels or markings on empty, non-contaminated packages are to be defaced.

Approvals:

President	12-9-81 Date	Regulatory	12-9-81 Date

STANDARD OPERATING PROCEDURE

RADIATION LABORATORY HOUSEKEEPING

SOP No. 3
Date: 12/1/81
Effective: 1/15/81
Supersedes: None

2.2 The collection, monitoring and survey of all radioactive wastes -- solid and liquid.

2.3 The cleaning of contaminated surfaces and equipment and the cleaning of laboratory work areas such as hoods and benches.

3. All cleaning operations will be made in accordance with established Health Physics and Radiation Laboratory Procedures. No cleaning operation may be performed without the prior approval of either the radiation laboratory supervisor or the Health Physicist.

STANDARD OPERATING PROCEDURE

RADIOACTIVE WASTE DISPOSAL

SOP No. 4
Date: 12/1/81
Effective: 1/15/81
Supersedes: None

PURPOSE

To assure the safe transfer, packaging and transport of low level radioactive waste material.

To assure compliance with DOT and NRC regulations concerning the transfer, packaging and transport of low level radioactive waste material as well as the requirements of the waste burial firm.

SCOPE

This procedure will apply to all low level radioactive waste material shipments prepared for disposal by a waste burial firm.

PROCEDURE

1. Responsibility

1.1 It will be the responsibility of the Health Physicist to assure that all shipments of low level radioactive waste are safely and properly packaged for waste disposal. The Health Physicist will maintain a current set of DOT and NRC regulations concerning transfer, packaging and transportation of radioactive waste and will maintain a current set of requirements (license) placed on the waste disposal firm.

1.2 The Health Physicist will maintain a current list of qualified personnel who are involved in the transfer, packaging and transportation of low level radioactive waste.

2. Training

2.1 The Health Physicist will provide training and periodic re-training in DOT, NRC and waste burial requirements to all personnel involved in the waste disposal process. Detailed instructions and a copy of this SOP will be provided as a part of this training. The Health Physicist will maintain a record of training dates, attendees and subject material.

2.2 The Health Physicist will provide training and periodic re-training to those employees who operate the processes which generate waste to assure that the volume of low level radioactive waste is minimized and that such waste is processed into acceptable chemical and physical form for transfer and shipment to a low level radioactive waste burial facility.

Approvals:

[signature] 12-9-81 [signature] 12-9-81

President Date Regulatory Date

STANDARD OPERATING PROCEDURE

RADIOACTIVE WASTE DISPOSAL

SOP No. 4
Date: 12/1/81
Effective: 1/15/81
Supersedes: None

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3. Packaging of Low Level Radioactive Waste

3.1 Solid waste disposal

Solid radioactive waste material may be placed directly into radioactive waste drums. Such waste includes: tubes, lab trash, pipet tips, lab soakers, disposable clothing, contaminated articles, empty vials, etc. If the amount of radioactive materials exceeds 250 μCi, the amount is to be written on a disposable sheet attached to the drum or reported to the Health Physicist.

3.2 Liquid waste disposal

3.2.1 No liquid radioactive waste or container of liquid waste may be placed into a radioactive waste drum without special packaging. Liquid aspirator waste is to be placed in plastic jugs designated for this purpose. Aspirator waste jugs will not be placed in radioactive waste drums. Containers of liquid radioactive waste are to be disposed of by pouring the liquid into a drum with a plastic liner containing enough absorbent material to absorb twice the amount of liquid.

3.2.2 Liquid radioactive waste from iodination procedures, hot fractions, etc., are to be placed in a plastic jug filled with absorbent material. There should be enough absorbent to absorb twice the amount of liquid placed in the jug. Filled jugs will be sealed and placed in radioactive waste drums. A waste disposal log will be kept showing the amount of activity placed in the jug and the final disposal date. Radioactive waste drums will be marked with appropriate information as to contents.

3.2.3 No liquid radioactive waste may be placed in any drum for disposal without enough absorbent material inside the drum to contain twice the amount of liquid.

4. Preparing Radioactive Waste Drums for Shipment

4.1 Sealing Drums

Each drum is to be securely bolted closed prior to shipment. The cover gasket is to be checked to be certain it is intact, and the ring should fit evenly around the drum. Drums are to be checked for signs of free liquid inside. Any drum suspected of containing improperly packaged liquid is to be put aside and the Health Physicist notified.

4.2 Survey and Monitoring

Each individual drum is to be wipe tested on the top and sides for removable contamination. Any drum with removable contamination in excess of 100 cpm above background is to be washed down and rechecked. Each drum is to be monitored for radiation levels along the surface of the drum and at one meter from the drum. Readings are to be recorded on the labeling for each drum. (Section 4.3)

4.3 Labeling

Each radioactive waste drum will be labeled as follows:

4.3.1 Shipping label: the shipping label will be filled in with information containing the following:

The quantity of radioactive material
The isotopes
The physical form of the material
The chemical form of the material
The radiation dose rate at the highest point at the surface
The radiation dose rate at one meter
The transport group of the isotopes (49CFR Part 390)

In addition, the result of the final wipe test or certification that the drum is free of removable external contamination will be noted, dated and initialed.

If the drum weighs over 110 lbs., its gross weight will be marked on the shipping label.

If the drum contains liquid scintillation vials or animal carcasses, the appropriate box on the shipping label will be checked.

4.3.2 DOT Label

Two DOT diamond labels will be affixed to opposite sides of each drum. There are three different labels for radioactive materials depending on the radiation dose rate at the surface of the drum. DOT label use is as follows:

Radioactive White I - 0.5 mr/hr or less at surface
Radioactive Yellow II - 0.5 to 50 mr/hr at surface
Radioactive Yellow III - greater than 50 mr/hr at surface

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The DOT label will be filled in with the total quantity of activity in the drum, the isotopes and the radiation dose rate at one meter (TI).

5. Limitations

Transfer of radioactive material for burial is to be made only to a licensed waste disposal or waste transportation company. No liquid radioactive material will be transferred for burial. No drum of radioactive material consigned for burial shall contain greater than 3 curies of radioactive material or shall have a radiation dose rate greater than 200 mr/hr at the surface of 10 mr/hr at one meter. Shipping and DOT labels will be completely filled out prior to shipment.

6. Transfer

Transfer of low level radioactive waste material to a licensed disposal service firm will be supervised by trained BCG personnel. BCG personnel will not enter the carrier truck or assist the disposal service personnel with loading low level waste onto the truck. A receipt for the transfer of low level radioactive waste must be obtained from the waste disposal company indicating the total number and volume of drums transferred and the isotopes and quantities of isotopes being transferred. All figures on the receipt will be double-checked against a total taken by BCG personnel prior to transfer.

DEPARTMENT OF SOCIAL AND HEALTH SERVICES
OLYMPIA, WASHINGTON

LOW-LEVEL RADIOACTIVE WASTE SHIPMENT CERTIFICATION FOR
COMMERCIAL GENERATOR/PACKAGERS, AND BROKERS AND CARRIERS

The following certification, completed as applicable, is made to the State of Washington:

Certification is hereby made to the State of Washington that Radiation Shipment Record No. _____ of low-level radioactive waste has been inspected in accordance with requirements of the Governor of Washington's Executive Order dated November 19, 1979, prior to its shipment. Further certification is made that the inspection has revealed no items of noncompliance with all applicable laws, rules and regulations.

The undersigned shall indemnify and hold harmless the State of Washington, in an amount not to exceed $1,000,000.00 per individual who may be injured, provided that indemnification shall not exceed $5,000,000.00 in total, for each occurrence, from any and all claims, suits, losses, damage, injury and expenses to any person whomsoever or to property arising or growing out of or in any manner connected with the activities performed under this order.

Except for any violation of applicable existing state or federal statute or regulation respecting packaging and shipment, inspection and acceptance of any item, or container or material covered by this certification by the State of Washington or a duly authorized contractor shall release the party who executed this certificate from any and all requirement of indemnification from injury or loss.

SECTION A:
FOR THE GENERATOR/PACKAGER: _____
(Company Name)

PERMIT NUMBER: _____

VOLUME OF WASTE IN THIS SHIPMENT: _____

DATE: _____ BY: _____

TITLE: _____

SECTION B:
FOR THE BROKER: _____
(Company Name)

PERMIT NUMBER: _____

VOLUME OF WASTE IN THIS SHIPMENT: _____

DATE: _____ BY: _____

TITLE: _____

SECTION C:
FOR THE CARRIER: _____
(Company Name)

VOLUME OF WASTE IN THIS SHIPMENT: _____

DATE: _____ BY: _____

TITLE: _____

DSHS ROF-31A
DSHS 13-424 (4/80)

PART III

HEALTH PHYSICS PROCEDURES

HEALTH PHYSICS PROCEDURE

SURVEYS AND MONITORING

Date Effective: 12/15/81

PURPOSE

To provide a procedure for surveys and monitoring of areas on a scheduled basis.

SCOPE

This procedure applies to all areas where radioactive materials are used or stored.

PROCEDURE

1. Surveys

1.1 The Health Physicist will maintain a schedule of all surveys to be performed along with diagrams of each area to be surveyed.

1.2 Wipe tests are made by smearing a piece of paper over an approximately 100 cm^2 area. All wipe tests are counted in a well type counter for Iodine-125. Wipe tests are also made as necessary for Cobalt-57.

1.3 Results of surveys are recorded on a form noting the date of the survey, each location of wipe test, the counter used and the name of the person performing the survey.

1.4 All areas wipe tested which exceed the following limits will be cleaned and resurveyed until they are below the limits.

Net counts per minute at all locations, limits:

Iodine-125 - 100 cpm
Cobalt-57 - 100 cpm

1.5 The Health Physicist will maintain records of all scheduled wipe test surveys, results and cleaning if required.

2. Location and Frequency of Surveys

Wipe tests will be scheduled as specified in the following areas:

2.1 Wipe tests will be performed once a week in all radiation laboratories and at least once a month in all general testing laboratories. Laboratory wipe tests will include commonly used equipment and materials i.e., benches, floors, refrigerators, instruments, etc. Specific locations for each wipe test will be determined by the Health Physicist. Special surveys may be performed at any time.

2.2 All incoming packages of radioactive materials will be wipe tested per BioClinical Group Radiation Safety Manual Part II(4) "Receiving Packages of Radioactive Material".

2.3 Drums of radioactive waste will be wipe tested prior to shipment for disposal.

2.4 Sinks designated for drain disposal of liquid, soluble radioactive material will be wipe tested after each disposal.

2.5 Lyophilization equipment will be wipe tested after freeze drying of radioactive materials, prior to its reuse.

2.6 Sealed vials of radioactive tracer will be wipe tested during and after each bottling operation and prior to release of the vials for Production Inventory.

2.7 Outgoing shipments of radioactive materials will be periodically wipe tested. This will be performed at least once every three months.

3. Monitoring

3.1 Each radiation laboratory using radioactive material must be provided with appropriate radiation detection instruments that are approved by the Radiation Safety Officer.

3.2 During and immediately following the use of radioactive materials, personnel shall use an appropriate radiation detection instrument to establish that radiation exposure and contamination-spread are being adequately controlled.

3.3 Each radiation worker who may receive a radiation dose in excess of *25% of Section I of Appendix I will be provided by the Radiation Safety Officer with appropriate film badges and/or bioassay services.

3.4 When provided, film badges shall be worn in the manner specified by the Radiation Safety Officer whenever occupational radiation exposure may be received. When not being worn, film badges shall be stored in a location where they will receive minimal radiation exposure above background.

*5% for persons under the age of 18

HEALTH PHYSICS PROCEDURE

BIOASSAY PROCEDURE

Date Effective: 12/15/81

PURPOSE

To provide a program to detect and measure internal radiation exposure.

SCOPE

Bioassays for thyroid burden of Iodine-125 will be performed as scheduled by this procedure. Confirmatory measurements will be made as required. Additional bioassays will be made by the Health Physicist where internal radiation exposure is known or suspected.

PROCEDURE

1. Thyroid Monitoring for Iodine-125

   1.1 Thyroid measurements are made in-house using a calibrated Ludlum Model 177 ratemeter with a Model 44-3 gamma scintillation probe. The instrument is set to slow response and a background measurement is taken. The probe is held directly against the base of the throat for at least one minute and the net counts per minute are recorded.

   1.2 Thyroid measurements for Iodine-125 are made as follows:

      1.2.1 A baseline measurement is taken for all registered radiation laboratory workers prior to beginning work.

      1.2.2 Each individual who handles more than 250 microcuries of unsealed Iodine-125 is required to monitor their own thyroid and record the results.

      1.2.3 All individuals who have worked in a radiation laboratory will be monitored at least once during that week by the Health Physicist. Any other interested personnel may have their thyroid monitored by the Health Physicist upon request.

2. Confirmatory Measurements

   2.1 Confirmatory measurements of thyroid burdens of Iodine-125 will be performed at Harvard University Health Services as follows:

      2.1.1 All registered radiation lab workers who work full time in a radiation laboratory will be sent for a confirmatory measurement at least twice each year.

      2.1.2 Any individual showing an increase of 10 nanocuries or greater of total Iodine-125 thyroid uptake within five working days will be sent for a confirmatory measurement.

2.1.3 Any individual initially achieving a thyroid burden of 10 nanocuries of Iodine-125 by in-house measurement will be sent for a confirmatory measurement.

3. Notification, Maximum Thyroid Burden, Calibration

3.1 The Health Physicist will be immediately notified of any personnel thyroid monitoring which indicates an increase in thyroid burden of 10 nanocuries or greater of Iodine-125. The Health Physicist will be immediately notified of any incident where internal radiation exposure is known or suspected.

3.2 Any employee with a thyroid burden of greater than 30 nanocuries of Iodine-125 will be instructed not to enter a radiation laboratory until a confirmed measurement shows a thyroid burden of less than 30 nanocuries.

3.3 The Health Physicist will calibrate each Ludlum 177 ratemeter used for thyroid monitoring to determine conversion of counts per minute from the thyroid to nanocuries. A thyroid phantom filled with a known amount of Iodine-125 will be used in the calibration. In addition, all confirmatory measurements made will be compared for consistency with in-house measurements. If in-house measurements differ by $\pm$ 10% from confirmatory measurements, the Ludlum 177 ratemeter will be recalibrated.

4. Records

The Health Physicist will maintain all records of thyroid monitoring, confirmatory measurements and calibration of ratemeters.

HEALTH PHYSICS REGULATIONS

^{125}I Thyroid Measurements

Each individual who handles more than 250 microcuries ^{125}I in an iodination procedure is required to take a thyroid measurement the following morning using a Ludlum 177 Ratemeter with a scintillation probe 44-3. The results are to be recorded on this sheet. If the count rate is greater than 200 CPM above background, notify Ernest Groman or Lee Josephson immediately.

DATE	INDIVIDUAL	TIME OF IODINATION	AMT. ACTIVITY	REACTION	SUBSTRATE	THYROID		
						DATE	TIME	CMP ABOVE BACKGROUND

THYROID MONITORING

Date: _____

By: _____

Instrument: _____

_____

Name	BKG	CPM	NET CPM	nCi	COMMENTS

ML10

HEALTH PHYSICS PROCEDURE

FILTER CHANGING IN RADIATION LAB HOOD STACKS

Date Effective: 12/15/81

PROCEDURE

To provide for routine replacement of charcoal filters in radiation hood stacks.

To assure for proper face velocity of radiation lab hoods.

To maintain effluents from radiation lab hoods to levels below the concentration specified in 10 CFR (20.103 and 20.106), Appendix B, Tables I and II, Column I.

SCOPE

This procedure applies to all charcoal filter changing operatins in all radiation lab hood stacks.

PROCEDURE

1. Frequency

   Charcoal hood filters will be changed as necessary to maintain effluent levels below the Appendix B limits and to maintain a hood face velocity of at least 100 feet per minute.

2. Personnel Precautions

   2.1 All personnel involved in filter changing operations shall wear disposable outer garments, gloves, masks and film badges.

   2.2 All personnel involved in filter changing operations will have a thyroid measurement within 24 hours of this operation.

3. Filter Change Procedure

   3.1 The hood(s) involved in the procedure will be emptied of its contents prior to the actual filter change.

   3.2 Floor coverings are to be put down where needed when removing contaminated filters.

   3.3 Contaminated filters are to be placed in radioactive waste drums and surveyed for radioactivity upon removal.

   3.4 Duct work is to be cleaned after removal of old filters and prior to installation of the new filters.

   3.5 All waste materials, cleaning materials, disposable clothing, etc., are to be placed in radioactive waste drums.

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4. Monitoring and Surveys

4.1 Hoods are to be wipe tested after each filter change to be certain that there is no contamination spread due to the removal of contaminated filters.

4.2 Duct work is to be wipe tested to assure that it is free from removable contamination prior to installation of new charcoal filters.

4.3 Spent filters are to be surveyed for total radioactivity prior to disposal.

4.4 Air flow readings are to be taken before and after filter changes to determine the decrease in air flow due to the old filters.

4.5 Air samples will be taken inside the lab and in the hood stack beyond the filter before and after the hood filter change to determine any increase in ambient airborne contamination levels and any decrease in effluent air contamination as a result of replacing the charcoal filters.

5. Waste Disposal

Radioactive waste drums are to be labeled in accordance with 10 CFR, 20.203 and promptly removed to a proper storage area pending removal by an approved radioactive waste disposal company.

HEALTH PHYSICS PROCEDURE

LABORATORY FUME HOODS

Date Effective: 12/15/81

PURPOSE

To provide a procedure to check that all fume hoods are operating properly to assure personnel safety.

SCOPE

This procedure describes methods, frequency, limits and documentation for the operation of laboratory fume hoods. Biogard hoods and laminar flow cabinets are not included in this procedure.

PROCEDURE

1. Measurements of hood flow rates are to be made monthly.

2. With the hood running, the sash open, six measurements of the air flow are made with a velometer and recorded (see attached form). Readings at each measurement are recorded on the form and averaged to determine the hood flow rate.

3. The limit for the minimum average hood velocity minimum is 100 feet per minute.

4. Documentation: Hood air flow records will be completed noting the hood number, location, date and name of the inspector. Records will be maintained of hood performance, maintenance and repair.

5. Hoods Which are Out of Specification: Any hood which does not meet the requirement of Section 3 will be tagged "out of service" and closed from use. The user of the hood will be immediately notified and instructed to transfer the contents of the hood to another, properly operating hood. The Safety Coordinator will be notified of any hood which is below specification. The Health Physicist will be immediately notified of any radiation lab hood which is below specification.

HEALTH PHYSICS PROCEDURE

AIR MONITORING FOR RADIOIODINE

Date Effective: 12/15/81

PURPOSE

To demonstrate compliance with the NRC Regulations of Title 10 CFR Part 20 concerning allowable air concentrations in restricted and unrestricted areas.

SCOPE

Air samples are taken for ^{125}I on a continual basis in the radiation laboratories both for ambient air levels and for hood exhaust concentration.

Spot check air sampling of ambient air levels in each facility may be taken at random intervals or when deemed necessary, such as in the event of a release of ^{125}I.

PROCEDURE

1. Air samples for ambient and exhaust concentrations of ^{125}I will be taken every day in the radiation labs. Samples may be accumulated on one filter for up to a maximum of one week.

2. Samples are taken by pulling air from a specific location through a charcoal impregnated filter paper. A regulator is used to adjust the sample air flow to 3-4 liters per minute. Each sample is timed in minutes in order that the total volume of air sampled may be determined. Charcoal impregnated filter papers are to be tested periodically for efficiency in removing ^{125}I from the air.

3. Hood exhaust air samples are taken through a 1/4" O.D. tubing which has been inserted into the hood exhaust duct just past the main hood filters and prior to the exhaust outlet. Each point of exhaust from a radiation lab hood will be equipped with sampling apparatus.

4. After sampling, the charcoal filters are placed in 12x75 mm tubes and counted for ^{125}I in a well type gamma counter.

5. The Radiation Safety Officer must be notified immediately if there is a release into the environs of airborne radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed the limits specified for such material in Appendix B, Table II, 10 CFR 20.

6. Documentation: The Health Physicist will record all necessary data and test results for air sampling. Air sampling requirements are contained in Title 10 CFR Parts 20.103 and 20.106. Maximum permissible concentrations are contained in Appendix B, Tables I and II, Column I.

   Hot lab ambient and exhaust air sample concentrations will be averaged and recorded weekly. Calculations of the concentrations of ^{125}I in air samples will take into account the following factors:

   a. The flow rate of the sample.
   b. The time of the sample.

c. The efficiency of the sample filter.
d. The efficiency of the instrument on which the filter was counted.

Any special conditions or considerations for a sample will be recorded with the final calculations.

Air concentrations for radiation lab ambient air and exhaust will be recorded weekly. Weekly totals will be averaged quarterly and annually.

7. **Calibration: The Health Physicist will calibrate the flowmeters used for** air sample volume determination at least twice a year per NRC Regulatory Guide 8.25 "Calibration and Error Limits of Air Sampling Instruments for Total Volume of Air Sampled".

HEALTH PHYSICS PROCEDURE

DRAIN DISPOSAL OF LIQUID RADIOACTIVE WASTE

Date Effective: 12/15/81

PURPOSE

In order to comply with Title 10, part 20, Sections 20.303 and 20.106 of the Federal Register, the Company must maintain control of the amounts of radioactivity discharged into the sewerage system, or released to the atmosphere, so that both the required limits on concentration and total activity (per day and per year) are not exceeded.

SCOPE

This procedure covers all soluble liquid radioactive waste which is drain disposed. There will be no drain disposal of liquid radioactive waste that is not soluble or dispersible in water.

PROCEDURE

1. Disposal into Waste Collection Containers

   All liquid radioactive waste will be placed in properly labeled collection containers provided according to the following rules:

   1.1 The total amount of radioactive material put into any one container must be controlled so that the radiation level at one foot from the container is less than 5 mr/hr and less than 200 mr/hr at the surface.

   1.2 Material must not be put into a waste collection container if there is any possibility of a chemical reaction during storage that might cause fire or explosion or cause the release of chemically toxic or radioactive gases. Solutions should be adjusted to pH4-10 prior to disposal into a liquid waste container.

   1.3 Animal tissue, excretia, or material containing aflotoxin, live viruses, etc., shall not be put into a radioactive material waste collection container, unless the procedure has been specifically authorized by the Radiation Safety Officer. Special disposal procedures must be arranged with the Radiation Safety Officer prior to the start of work that will produce this kind of waste material.

   1.4 Do not put solid objects, including test tubes and bottles, into a liquid-waste collection container.

   1.5 Put organic radioactive-waste solution (including contaminated scintillation solutions) into containers that are specifically designated for the collection of such solutions.

2. Disposal into Sanitary Sewerage Systems

   Radioactive waste may not be discharged into the sanitary sewerage system except under the direction of the Health Physicist. Disposal of liquid radioactive waste, including waste collection containers, is permitted under the direction of the Health Physicist providing the following conditions are met:

2.1 The sink into which the material is to be disposed has been labeled as being approved for radioactive waste disposal.

2.2 The waste will be assayed for total activity. If necessary, waste will be properly stored to allow for decay to a final activity suitable for disposal. A record of the amount of each nuclide disposal into the sewerage system will be kept by the Health Physicist.

2.3 The radioactive material must be soluble or dispersible in water.

2.4 The quantity released into the sewerage system in one day may not exceed the larger of:

(i) (10 μCi of ^{125}I), or

(ii) the quantity which, if diluted by the average daily volume of water released into the sewage system, will result in an average concentration will not exceed the limits of Appendix B, Table I, column 2, or

(iii) the quantity which, if diluted by the average monthly quantity of water released by the licensee, will not result in an average concentration exceeding the limits of Appendix B, Table I, column 2.

The gross quantity of material released may not exceed 1 curie per year.

Appendix B, Table I, Column 2 is 4×10^{-5} nCi/ml for ^{125}I.

2.5 The Health Physicist will use the Company water bill and the activity determined from waste assays to ensure that the limits of Section 2.4 are met.

3. Documentation: All releases of radioactive material into the sewage system will be recorded by the Health Physicist. A record will be kept of the dates of disposal and the amounts of each nuclide disposed. An average daily and monthly total of waste will be recorded and the average concentration of material released will be calculated using the company water bill from the City of Cambridge to determine the average daily or monthly dilution factor.

APPENDIX A

I. Maximum Permissible Doses for registered personnel:

(a) Except as provided in paragraph b, radiation doses shall not exceed the following:

	rems per calendar quarter
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or glands	1.25
2. Hands and forearms, feet and ankles	18.75
3. Skin of whole body	7.5

(b) An individual may exceed (a) provided that it is authorized by the Radiation Safety Officer, and that:

1. During any calendar quarter his whole body dose from all sources of radiation does not exceed three rems;
2. The accumulated occupational dose does not exceed 5 (N-18) rem, where "N" equals age in years at the individual's last birthday; and
3. There is on file in the Regulatory Affairs Department an appropriate record (as specified in 10 CFR 20) of the individual's accumulated occupational whole body dose.

II. Maximum permissible doses for minors, and for persons who are not registered:

(a) One-tenth of the values listed in I(a) of this appendix.

III. The above values in I. and II. are in addition to natural background radiation exposure and radiation exposure administered for medical reasons.

Appendix B

TABLE 1

	Column 1	Column 2
Isotope	Air uCi/ml	Water uCi/ml
I-125 Soluble	5×10^{-9}	4×10^{-5}

TABLE 2

	Column 1	Column 2
Isotope	Air	Water
	uCi/ml	uCi/ml
I-125 Soluble	8×10^{-11}	4×10^{-7}