Shriver Center
for Mental Retardation, Inc.
200 Trapelo Road
Waltham, Massachusetts 02254
(617) 893-3500

Edwin H. Kolodny, M.D., Director
Raymond D. Adams, M.D., Director Emeritus

Rollin W. Rickard, Administrator

MS 16
P5

June 12, 1985

Jenny M. Johansen, M.S.
Nuclear Materials Safety Section B
Division of Radiation Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Region 1
631 Park Avenue
King of Prussia, Pennsylvania 19406

Re: License No. 20-18423-01
Docket No. 030-15057
Control No. 17352

Dear Jenny M. Johansen:

Enclosed please find a point by point response to the items requested in your letter of May 3, 1985. Please note that a manual entitled "Regulations for use of Radionuclides of Eunice Kennedy Shriver Center for Mental Retardation, Inc." that we have recently prepared is also enclosed. Several of the items in our responses to your letter refer to sections in this manual. A copy of "Emergency Procedures for Spills and Contamination" which is posted at the entrance of each restricted area is also enclosed.

If you require any additional information in order to issue our new license please do not hesitate to telephone me at (617) 893-3500 ext. 132.

Thank you for your careful and thorough attention to the matters concerning our license application.

Sincerely yours,

Robert H. McCluer

Robert H. McCluer, Ph.D.
Radiation Safety Officer
and
Director, Biochemistry Department

RHM/dm

17352

9. Emergency Procedures for Spills and Contamination

a. isolate area of contamination;
   1. if hood -- seal off;
   2. if room -- block off area, prohibit entry;

b. check personnel in area for possible contamination;
   1. check clothing and extremities;
   2. if personnel free of contamination - evacuate area;

c. Notify RSO immediately --- X132 or X141
   1. give details of accident; type and quantities involved;
   2. RSO should determine course of action
   3. if necessary contact Harvard Environmental Health
      495-2061
      emergency # 495-5711

d. Radiation decontamination kits and absorbent material are available in the Biochemistry Department -- hall cabinet by room 302;

e. Decontamination should proceed under the supervision of the RSO, but is the responsibility of the principal investigator involved;

f. Confirmation of decontamination must be given by the RSO;

REGULATIONS FOR THE USE OF RADIONUCLIDES

AT

EUNICE KENNEDY SHRIVER CENTER FOR MENTAL RETARDATION, INC.

Radiation Safety Officer:	Dr. Robert McCluer X 132 or X141
Harvard Environmental Health:	Mr. Robert Johnson tel: 495-2061 Emergency tel: 495-5711

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1. GOVERNMENT REGULATIONS PERTAINING TO THE USE OF RADIOACTIVE MATERIALS.

1.1 By-Product material ("any radioactive material yielded in or made by exposure to the radiation incident to the process of producing or utilizing special nuclear material") may be used only under specific or general licenses issued by the United States Nuclear Regulatory Commission (NRC).

1.2 All licensees of the NRC are required to conform with standards for protection against radiation hazzards established by the NRC. These regulations are published in Title 10, Chapter 1, Part 20 of the Code of Federal Regulations-Energy. (CFRE)

1.3 All persons who "receive, possess, use or transfer radioactive materials in the Commonwealth of Massachusetts are subject to the rules and regulations issued by the Massachusetts Department of Public Health.

2. Control and Monitoring of Environmental Radiation and Personnel Exposure.

Federal and State regulations define areas containing radiation which do and do not require special control measures and specify maximum levels of exposure in controlled areas.

2.1 Unrestricted Area:

An area is unrestricted and does not require control measures for exposure from external radiation if an individual continually present in that area cannot receive more than 1 mrem in any one hour or 10 mrem in any consecutive seven day period.

The above is a maximal level. At EKSC unrestricted areas are those areas where no radionuclides are stored, and no processes requiring use of nuclides are carried out.

2.2 Restricted Area:

Any area which is used for the storage or processing of radionuclides will be considered a restricted area and must be controlled by the user of those radionuclides.

Control must be such that no individual over the age of 18 will receive in any one calender quarter from radioactive material (in possesion of EKSC) and occupational dose in excess of the following limits:

REMS PER CALENDAR QUARTER

Whole body; Head & trunk;
Active blood forming organs;
Lens of eye; Gonads 1.25

Hands & forearms;
Feet & ankles 18.75

Skin of whole body 7.50

REGARDLESS OF THE ABOVE LIMITS, GENERAL POLICY IS TO AVOID ALL UNNECESSARY EXPOSURE TO IONIZING RADIATION!

2.3 Personnel Monitoring:

Personnel monitoring devices are required by law and records must be kept if an individual receives or is liable to receive a dose in any calendar quarter in excess of 25% of the above values. Film badges and/or film rings are required for all users of 32P, 125I, 42K, and 45Ca.

2.4 Airborne radioactivity:

concentration limits have been established to prevent overexposure to any organ in the body as a result of breathing contaminated air. See Table 1, Appendix I for limits in uCi/cc.

2.5 Posting of Areas:

The following types of signs are required for significant levels of radiation and radioactivity:

a. "CAUTION RADIATION AREA" This sign is required 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 5 consecutive days a dose in excess of 100 mrem.

b. "CAUTION RADIOACTIVE MATERIAL" This sign is required in areas or rooms in which radioactive material is used or stored in an amount exceeding quantities listed in Table 2; Appendix I.

c. "CAUTION RADIOACTIVE MATERIAL" (label)..A durable, clearly visible label is required on any container used for the storage or transport of any radionuclide. The label must state the quantity and type of radionuclide and the date of measurement of those quantities.

3. Organization for the Control of the Use of Radionuclides at EKSC

The E.K. Shriver Center has a specific license from the U.S. Nuclear Regulatory Commission for the use of radionuclides classified as by-product materials. Under the terms of this license, the radionuclide program is administered by the Radiation Safety Officer (RSO).

3.1 Authority and Duties of the Radiation Safety Officer:

a. The RSO has the following authority:

1. approve or disapprove proposals for radionuclide uses prior to purchase or acquisition of the materials;

2. review safety procedures;

3. investigate incidents involving radioactive materials and violations of regulations;

4. suspend authorization to use isotopes;

b. The RSO has the following duties:

1. oversee the execution of established policies of radiation protection;

2. insure compliance with Federal and State regulations;

3. supervise radiation control activities;

a. personnel monitoring records;
b. institutional waste disposal records
c. institutional inventory radionuclides
d. oversee records' maintenance as required by law

4. license renewal

3.2 Control Functions:

Harvard Environmental Health and Safety is under contract with the EKSC to perform the following control functions:

a. provision of film badge or other personnel monitoring services, badges are checked on a monthly basis;

b. provision of bio-assays upon request;

c. provision of laboratory and environmental monitoring; laboratory monitoring is carried out monthly, air flow and performance of the fume hoods is monitored every six months;

d. transporting of radioactive waste for disposal;

e. technical consultation on safe and proper use of radionuclides;

f. conduct education programs in the safe use of radionuclides;

g. calibration and minor repair of survey instruments;

h. supervision of emergencies or decontamination operations;

4. <u>Authority to Use Radionuclides:</u>

No one may use or bring into the EKSC any radionuclides in amounts, which would ordinarily require a specific license from the NRC, without authorization from the RSO. Such authority will be given to principal investigators, who will then be directly responsible for the safe and proper use, storage, and disposal of the radionuclide

under their jurisdiction.

Special authorization is not required for use of isotopes in quantities less than those requiring a specific license, however, the RSO must be informed prior to the time any source of radioactivity is brought into the EKSC.

4.1 Application for Authorization to Use Radionuclides:

All new programs or changes in established programs involving the use of radionuclides must be discussed with the RSO or his representative. The RSO will obtain the following details:

a. Names of persons who will supervise use of the materials, and will be responsible for the safe use and proper handling of the radionuclides.

b. Specify radionuclides and maximum quantities;

c. Chemical and/or physical form;

d. Purpose for which by-product material will be used and the procedures important to the consideration of contamination and exposure control;

e. Training and experience of principal investigator and supervisory personnel;

f. Training and indoctrination provided to technicians;

g. Monitoring instrumentation;

h. Storage and disposal methods;

i. All other information needed to evaluate the safety of the proposed program;

5. <u>Responsibilities of Radionuclide Users:</u>

Each principal investigator is directly responsible for:

1. the radionuclides in his/her possession;
2. compliance with the conditions regarding the use of radionuclides as listed in the licence;
3. compliance with the regulations governing the use of radionuclides at EKSC;
4. the safe use by other investigators or technicians who work with the material under his/her supervision;

Each principal investigator has the following obligations:

1. insure that individuals working with radionuclides under his/her control, (investigators, students, technicians) have obtained training and indoctrination to enable safe working habits and prevention of exposure to others or contamination of the surroundings;

2. avoid any unnecessary exposure either to himself/herself or others working under him/her;

3. limit the use of radionuclides charged to him/her, to individuals

over whom he/she has supervision, and to locations under his/her control;

4. keep current working records of the receipt and disposition of radionuclides in his/her possession including use in research, waste disposal, transfer, storage, etc.;

5. notify the RSO of any personnel changes and changes in rooms or areas in which radioactive materials may be used or stored;

6. keep an adequate inventory of the amount of radioactive material possessed. Inventory will be checked and updated monthly;

7. post rules and instructions pertinent to laboratory operations as requested by the RSO;

8. insure that a survey meter is available to enable personnel to monitor for radiation exposure and surface contamination for radionuclides other than tritium;

A refresher course will be given annually to review regulations and procedures. This is mandatory for all personnel working with radioactive materials.

6. Work Habits and Procedures:

6.1 Preparatory:

Before any work is undertaken with quantities of radionuclides which have potential for producing significant exposure, attention should be given to precautionary measures including the use of hoods, adequacy of the hood, air monitoring, respiratory protection, etc.

For non routine or high level operations, the user will conduct a "dry run" with inactive or low level activity to test the adequacy of procedures and equipment.

6.2 Protective Clothing:

Suitable gloves must be worn whenever hand contamination is likely. Extreme care must be exercised to prevent contamination when there is a break in the skin.

Appropriate protective clothing ie., lab coats, aprons, must be worn whenever working with radioactive materials. Protective clothing must not be worn or taken out of the restricted area, unless monitored and determined to be free of contamination.

6.3 Handling Materials:

All work areas, bench tops and hoods should first be covered with protective absorbent material before beginning to work. Work which can result in contamination of bench top or other work surfaces should be done using trays lined with protective absorbent material.

6.4 Hygiene:

Personnel working in areas containing radioactive materials must "wash up" before eating, smoking, or leaving work and shall use proper monitoring equipment to make hand and shoe counts upon completing operations.

Eating, storing or preparing food is forbidden in restricted laboratory areas.

Radioactive liquids shall not be pipetted by mouth.

Smoking in the laboratories is not permitted.

All restricted areas will be secured and locked at the end of each working day.

7. Use of Radioactive Materials in Laboratory Animals:

Injections of radioactive material into laboratory animals should be performed in the restricted area of the principal investigator. All procedures must be short-term (24-48 hr). Appropriate measures, such as the use of protective absorbent material for the work area and the animal cages must be followed.

Cages housing the injected animals must be clearly labelled as to the radionuclide used, quantity injected per animal, date of injection and user. These animals are to be kept in the restricted lab area in or near the fume hood. At no time will these animals be returned to the regular animal care facility.

Animal excreta, the cage liner, and other solid waste should be placed in heavy duty plastic bags, appropriately labelled and disposed. The animal carcass, likewise, should be sealed in a plastic bag, appropriately labelled and stored in the designated freezer until disposal.

Animal handlers must be advised by the principal investigator as to the dose levels, time limitations in the area, and the handling requirements of the animals and excreta.

Animal cages must be completely decontaminated following use. This decontamination will take place only in a designated "hot sink" area. Following decontamination procedures, appropriate wipe tests and surveys will be made before cages are returned to the animal care facility.

8. Regulations Regarding the Use of 32P, 3H, 125I

In addition to the standard procedures for radionuclide use, set forth in Section 6 page 5, the following additional precautions used when working with 32P, 125I, and millicurie amounts of 3H.

8.1 Regulations for Handling 32P and 125I:

a. Employ low and high density shielding(low density ie.,

plexiglass, lucite etc. near the source). Use of a lead apron or additional protective clothing; Use of protective mask when working with volatile 125I.

b. Protection of eyes from chemical splash and unnecessary radiation. Personnel working with 1 mCi or more must wear safety glasses.

c. Use a double layer of gloves, the inner gloves should remain uncontaminated.

d. All personnel must wear film badges; when working with 1mCi or more ring badges must also be worn.

e. A survey meter must be in the area.

f. All work with volatile 125I (protein iodinations) must be carried out in a fume hood. Air flow must be check prior to beginning work.

For processes requiring the use of 1mCi or more of 32P or protein bound 125I, work should be carried out in a fume hood.

g. Vials containing 32P or 125I should be open for as brief a time as necessary and tightly capped when not in use.

Vials should be stored in lead shielded containers, which are clearly labelled as to radionuclide, quantitiy and date.

h. After each day's use, wipe tests and surveys of the area, protective clothing and extremities are required. Area should should be cleaned.

If skin contamination is detected, wash immediately with soap and plenty of water.

i. Isolate waste and dispose promptly.

j. For non-routine or high level procedures

1. Notify RSO
2. Describe procedures and precautions
3. Discuss the need for bioassays
   a. See Table 3. of Appendix I
   b. Baseline ... pre-operation bioassay
   c. thyroid scan 125I
4. Perform "dry run" to insure there will be no unexpected complications and to insure equipment is functioning properly.

8.2 Bioassays 125I 32P

a. Submission of urine samples on a regular basis for personnel working with mCi amounts of 32P; samples should be submitted within 12 hours after working with this radionuclide.

b. Personnel working with mCi amounts of 125I should have pre-operation baseline bioassay of thyroid and have routine testing throughout the operation.

8.3 Spills...125I ...32P

There are radiation decontamination kits available in the Biochemistry Department. All personnel should be notified as to the storage location of these kits.

a. 32P < 1mCi

1. inside hood - clean immediately before proceeding;
2. outside hood - isolate area, clean and decontaminate, notify RSO, confirmation that area is free of contamination is necessary before proceeding;

b. 32P > 1mCi

1. inside hood
   hood should be sealed; RSO must be notified; use absorbent materials and proceed with decontamination under the direct supervision of the RSO;
2. outside hood
   isolate area; check for personnel contamination; notify the RSO; evacuate area; proceed with decontamination with the advice of the RSO and Harvard Environmental Health and Safety.

c. 125I

1. decontaminate surface with a solution of 0.1M NaI, 0.1M NaOH, 0.1M Sodium thiosulfate; this solution will help to stabilize the material and minimize the evolution of volatile species;

2. all liquid waste must be absorbed;

3. proceed with a decontaminate or detergent to complete the the clean-up;

4. NEVER ADD ACIDS TO RADIOIODINE SOLUTIONS!

8.4 3H Compounds

a. Personnel working with mCi amounts of 3H radionuclides are required to perform all operations in a fume hood;

b. All precautions listed on page 5 apply;

c. Bioassays

Personnel planning to work with quantities in excess of those listed in Table 3, Appendix I should notify the RSO;

1. All personnel in the restricted area should submit bioassay samples prior to beginning work;

2. Routine submission of samples, thereafter, at 2 week intervals until the work is complete;

3. Final samples should be submitted within 10 days of the final

work;

9. Emergency Procedures for Spills and Contamination

a. isolate area of contamination;
   1. if hood -- seal off;
   2. if room -- block off area, prohibit entry;

b. check personnel in area for possible contamination;
   1. check clothing and extremities;
   2. if personnel free of contamination - evacuate area;

c. Notify RSO immediately --- X132 or X141
   1. give details of accident; type and quantities involved;
   2. RSO should determine course of action
   3. if necessary contact Harvard Environmental Health
      495-2061
      emergency # 495-5711

d. Radiation decontamination kits and absorbent material are available in the Biochemistry Department -- hall cabinet by room 302;

e. Decontamination should proceed under the supervision of the RSO, but is the responsibility of the principal investigator involved;

f. Confirmation of decontamination must be given by the RSO;

10. Waste Disposal Procedures

10.1 Liquid Waste Disposal

a. Disposal in appropriately designated "hot sink" areas only;

b. Quantities cannot exceed posted daily limits

c. Material must be readily soluble or dispersible in water and must be accompanied by adequate flushing with water;

d. Waste disposal quantities must be recorded on the sheet provided -- See Appendix II;

10.2 Solid Waste

All solid waste should be disposed of only in the waste barrels provided. Waste should be separated according to the categories listed below, and placed in heavy duty or double layer plastic bags.

Before disposal all bags must have a Harvard Environmental Health tag which has been properly and completely filled out. See Appendix II. The same information must be filled out on the sheet provided on top of each barrel.

Categories:

A = plastic scintillation vials .. 32P, 125I, 35S and 3H & 14C containing greater than 10,000cpm/vial.

C = glass & metal ... no scintillation vials, all radionuclides

D = paper & plastic ..3H, 14C, 32P, 35S no liquid

E = paper & plastic .. 125I,

10.3 Deregulated 3H & 14C

Plastic scintillation vials containing less than 10,000 cpm/vial of 3H & 14C only, should be placed in heavy duty plastic bags and sealed. These can then be placed in the barrel labelled "Deregulated" 3H & 14C.

11. Purchase and Receipt of Radionuclides

11.1 Purchase of Radionuclides

a. special requisition forms are necessary, these may be obtained from the RSO or his assistant;

b. the completed form is brought to the RSO or his assistant for approval and signature; the purchasing department will not process a requisition without this endorsement;

11.2 Receipt of Radionuclides

a. all radionuclides are delivered to the RSO assistant;

b. the outer container is checked for contamination by leakage

c. wipe test of the external shipping package and the final inner container are performed;

d. if removable radioactive contamination is in excess of 0.1uCi/100 cc of package surface then:

1. the primary carrier is notified;
2. the RSO is notified;
3. the NRC Inspection and Enforcement regional office is notified:

USNRC
631 Park Ave.
King Prussia, Pa. 19406
(215) 337-5000

e. no radionuclides deliveries are accepted after regular working hours;

f. each radionuclide received is labelled as to date, type of nuclide, quantity, and inventory number;

g. the radionuclide is then delivered to the principal investigator;

DEFINITIONS

Dose: quantity of radiation absorbed per unit of mass, by the body or by any portion of the body;

can be specified as quantity per unit time;

Rad: measure of the dose of any ionizing radiation to body tissue in terms of energy absorbed per unit of mass of tissue;

one rad is the dose corresponding to the absorption of 100 ergs per gram of tissue;
1 millirad (mrad) = 0.001 rad

Rem: measure of the dose of any ionizing radiation to body tissues in terms of its estimated biological effect relative to a dose of 1 roentgen of x-rays
1 millirem (mrem) = 0.001 rem;

a dose of 1 rem = dose of 1 roentgen due to x-ray, gamma radiation;

a dose of 1 rem = dose of 1 rad due to x-ray, gamma or beta radiation;

Units of Radioactivity: measured in terms of disintegrations per unit time;

1 Curie (Ci) = 3.7×10^{10} disintegrations/second (dps)

2.2×10^{12} disintegrations/minute (dpm)

1 millicurie (mCi) = 3.7×10^{7} dps

2.2×10^{9} dpm

1 microcurie (uCi) = 3.7×10^{4} dps

2.2×10^{6} dpm

APPENDIX I

APPENDIX I

Table 1

Maximum Permissible Concentrations in Unrestricted Areas

ISOTOPE	CONCENTRATION* uCi/cc
C-14	1×10^{-7}
H-3	2×10^{-7}
S-35	9×10^{-9}
I-131	1×10^{-10}
I-125	8×10^{-11}
P-32	2×10^{-9}
Ca-45	1×10^{-9}
Na-24	5×10^{-9}
K-42	4×10^{-9}
Cr-51	8×10^{-8}
Kr-85	3×10^{-7}
Xe-133	3×10^{-7}
Br-82	6×10^{-9}
Cl-36	8×10^{-10}

*Maximum concentration depends on several factors, including degree of solubility of contaminant. The lowest concentrations specified in the regulations have been listed.

Table 2

Quantities of Some Radioactive Materials Requiring Signs

Isotope	Minimum Quantity for Radioactive Materials Sign in Room* Microcuries	Minimum Quantity for Radioactive Materials Label** Microcuries
Au-198	1,000	100
C-14	10,000	1,000
Ca-45	100	10
Co-60	10	1
Cl-36	100	10
Cr-51	10,000	1,000
Cs-37 & Ba-137	100	10
Cu-64	1,000	100
Fe-55	1,000	100
Fe-59	100	10
H-3 (HTO or H_3^2O)	10,000	1,000
I-131	100	1
I-125	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
Se-75	100	10
Sr-90	1	0.1
Zn-65	100	10
Unidentified	1	0.1

*Caution signs are not required to be posted at areas on rooms containing radioactive materials for periods of less than eight hours provided that (1) the materials are constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive materials in excess of the limits established in the regulations; (2) such area or room is subject to the authorized user's control.

**These are also minimum quantities requiring specific licenses from the AEC when an institution does not have a license.

**Daily permissible sink disposal limits.

APPENDIX I

ACTIVITY LEVELS OR CONCENTRATIONS[a] ABOVE WHICH
TRITIUM BIOASSAY PROGRAMS SHOULD BE PROVIDED

Table 3a.

Types of operation	HTO[b] and Other Tritiated Compounds (Including Nucleotide Precursors)	Tritium (HT or T_2)[c] Gas in Sealed Process Vessels[d]	HTO Mixed with More Than 10 kg of Inert H_2O or Other Substances
Processes in open room or bench with possible escape of tritium from process vessels	0.1 Ci	100 Ci	0.01 Ci/kg
Processes with possible escape of tritium carried out within a fume hood of adequate design, face velocity, and performance reliability	1 Ci	1000 Ci	0.1 Ci/kg
Processes carried out within gloveboxes that are ordinarily closed but with possible release of tritium from process vessels and occasional exposure to contaminated box and box leakage	10 Ci	10,000 Ci	1 Ci/kg

[a] Quantities present (<10 kg) may be considered to be either the amount processed by an individual at any one time (when accidental intake is more likely) or the amount of activity that entered into the process (throughput) during any one month (when routine handling of repeated batches is the more likely source of exposure). Concentrations in the right-hand column may be used when activity in process is always diluted in more than 10 kg of other reagents, as in nuclear reactor coolant systems.

[b] HTO is a symbol for a water molecule in which a tritium atom (T) is present in place of a normal hydrogen atom (H).

[c] A molecule of hydrogen gas contains two hydrogen atoms. Either one of these atoms may be replaced with T to form HT, or two T atoms may combine to form T_2 gas.

[d] This assumes that adequate air monitoring has established that there is no tritium leakage or that no significant amount of tritium gas can be converted to HTO before intake.

USNRC Regulatory Guide - Draft; Division 8; Task OP 713-4; June 1983

ACTIVITY LEVELS ABOVE WHICH BIOASSAY FOR I-125 OR I-131 IS NECESSARY

Table 3b.

Types of Operation	Activity Handled in Unsealed Form Making Bioassay Necessary* — Volatile or Dispersible*	Activity Handled in Unsealed Form Making Bioassay Necessary* — Bound to Nonvolatile Agent*
Processes in open room or bench, with possible escape of iodine from process vessels	1 mCi	10 mCi
Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability	10 mCi	100 mCi
Processes carried out within gloveboxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage	100 mCi	1000 mCi

*Quantities may be considered the cumulative amount in process handled by a worker during a 2-month period, e.g., the total quantity introduced into a chemical or physical process over a 2-month period, or on one or more occasions in that period, by opening stock reagent containers from which radioactive iodine may escape. Quantities in the right-hand column may be used when it can be shown that activity in process is always chemically bound and processed in such a manner that I-125 or I-131 will remain in nonvolatile form and diluted to concentrations less than 0.1 mCi/mg of nonvolatile agent. Capsules (such as gelatin capsules given to patients for diagnostic tests) may be considered to contain the radioiodine in nonfree form, and bioassay would not be necessary unless a capsule were inadvertently opened (e.g., dropped and crushed). However, certain compounds where radioiodine is normally bound are known to release radioiodine when the material is in process, and the left-hand column may then be applicable. In those laboratories working only with I-125 as radioimmunoassay (RIA) kits, the quantities of I-125 are very small and in less volatile forms, thus, bioassay requirements may be judged from the right-hand column. In field operations, where reagent containers are opened outdoors for simple operations such as pouring liquid solutions, the above table does not apply; bioassay should be performed whenever an individual employee handles in open form (e.g., an open bottle or container) more than 50 mCi at any one time.

Operations involving the routine use of I-125 or I-131 in an open room or bench should be discouraged. Whenever practicable, sealed bottles or containers holding more than 0.1 mCi of I-125 or I-131 should be opened at least initially within hoods having adequate face velocities of 0.5 m/sec or more.

USNRC Regulatory Guide 8.2 September 1979

APPENDIX II

SINK DISPOSAL RECORDS

MONTH OF:_____

LAB:_____

Allowable limits/day:

3H	1.0 mCi	45Ca	10.0 uCi
14C	0.1 mCi	42K	10.0 uCi
35S	0.1 mCi	125I	1.0 uCi
32P	10.0 uCi	36Cl	1.0 uCi

DATE	ISOTOPE	AMOUNT(mCi-uCi)	USER

Appendix II

CAUTION

RADIOACTIVE MATERIAL

CATEGORY: _____

ISOTOPE: _____

CHEMICAL NAME: _____

ACTIVITY (μCi): _____

DATE: _____

LICENSEE: Dr. Robert McClue:

DEPT.: Eunice Kennedy Shriver Cent. ~~For Mental Retardation, In~~

BLDG: 200 Trapelo Road

ROOM: ~~Waltham, Massachusetts 02~~

EHS OFFICE USE ONLY

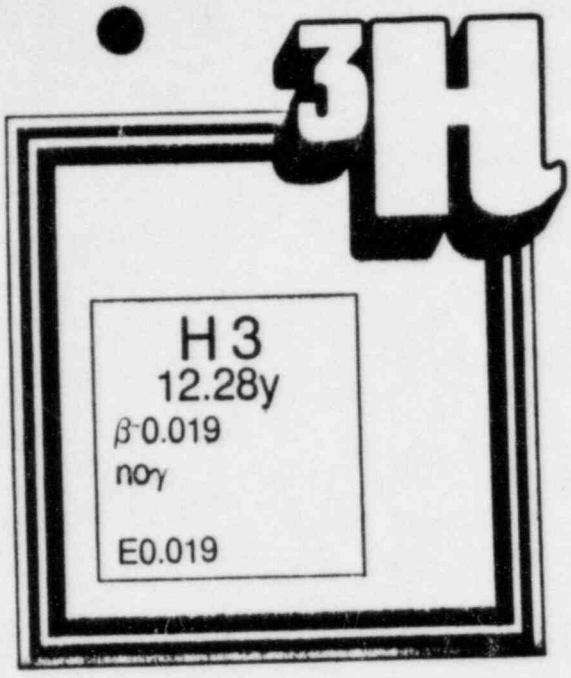
INTEREX DRUMS: _____

FIBER DRUMS: _____

ENVIRONMENTAL HEALTH AND SAFETY
HARVARD UNIVERSITY

SOLID WASTE DISPOSAL TAG

APPENDIX III



PHYSICAL DATA

Maximum energy: 0.019 MeV (100%)[1]

Maximum range in air: about 1/6 inch[2]

Hydrogen-3 (Tritium) Decay Table Half Life: 12.3 years

Years	Months 0	1	2	3	4	5	6	7	8	9	10	11
0	—	995	991	986	981	977	972	968	963	959	954	950
1	945	941	936	932	928	923	919	915	910	906	902	898
2	893	889	885	881	877	873	869	865	860	856	852	848
3	844	841	837	833	829	825	821	817	813	810	806	802
4	798	794	791	787	783	780	776	772	769	765	762	758
5	754	751	747	744	740	737	733	730	727	723	720	716
6	713	710	706	703	700	697	693	690	687	684	680	677
7	674	671	668	665	661	658	655	652	649	646	643	640
8	637	634	631	628	625	622	619	616	614	611	608	605
9	602	599	597	594	591	588	585	583	580	577	575	572
10	569	567	564	561	559	556	553	551	548	546	543	541
11	538	535	533	530	528	526	523	521	518	516	513	511
12	509	506	504	501	499	497	494	492	490	487	485	483

OCCUPATIONAL LIMITS[1]

Maximum permissible air concentration based on a 40-hour working week: 5×10^{-6} μCi ml^{-1} [3]

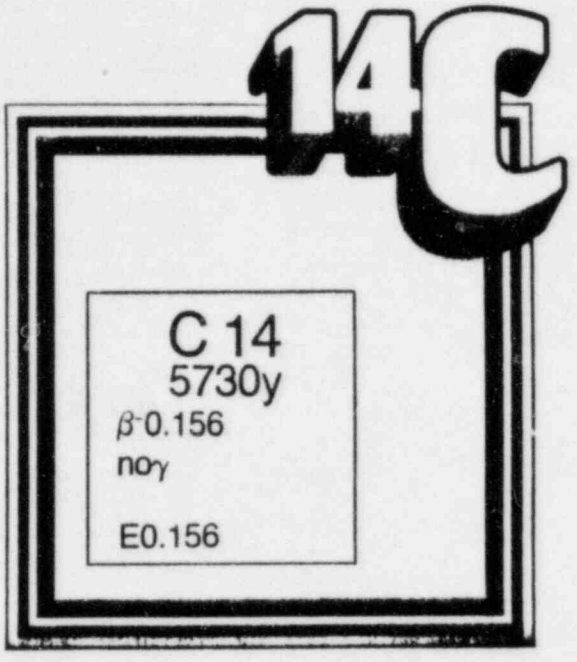
Maximum permissible body burden: 1mCi[4]

DOSIMETRY

Millicurie quantities of tritium do not present an external exposure hazard because the low energy betas emitted cannot penetrate the outer layer of skin. The critical organ for tritium uptake is the whole body water. Three to four hours after intake, tritiated water is uniformly distributed in all body water.[5] On average, tritiated water is eliminated with a 10-day biological half-life. Elimination rates may be increased by increasing water intake.[5]

SPECIAL PRECAUTIONS

Many tritium compounds readily penetrate gloves and skin. Handle these compounds remotely, wear two pairs of gloves and change the outer layer at least every twenty minutes. Tritiated DNA precursors are considered more toxic that tritiated water.[6] However, they are generally less volatile and do not normally present a significantly greater hazard.



PHYSICAL DATA

Maximum beta energy: 0.156 MeV (100%)[1]

Maximum range in air: about 8.6 inches[2]

OCCUPATIONAL LIMITS

Maximum permissible air concentration based on a 40-hour working week: $4 \times 10^{-6} \mu Ci\ ml^{-1}$ [3]

Maximum permissible body burden: $300 \mu Ci$[4]

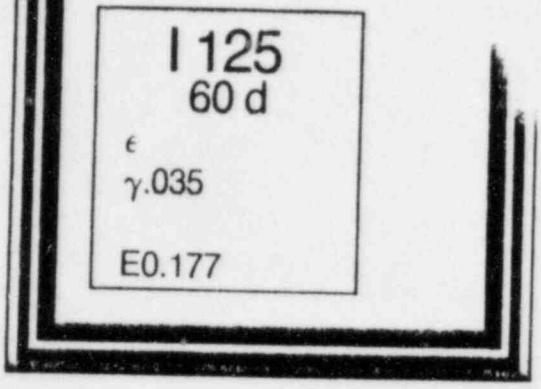
DOSIMETRY

Millicurie quantities of ^{14}C do not present a significant external exposure hazard because the low-energy betas emitted barely penetrate the outer skin layer. The critical organ for uptake of many ^{14}C-labeled carbonates is the bone.[5] The critical organ for uptake of many other ^{14}C-labeled compounds is the fat.[4] Most ^{14}C labeled compounds are rapidly metabolized and the radionuclide is exhaled as $^{14}CO_2$. Some compounds and their metabolites are eliminated via the urine. Biological half-lives vary from a few minutes to 25 days, 10 days being an acceptably conservative value for most compounds.[4]

SPECIAL PRECAUTIONS

Some ^{14}C-labeled compounds may penetrate gloves and skin; handle these compounds remotely, wear two pairs of gloves and change the outer layer frequently. Special caution should be observed when handling ^{14}C-labeled halogenated acids. Since these compounds may be incorporated in the skin, give local dose commitments in the order of 10--100 rad per μCi deposited.

^{125}I



PHYSICAL DATA

Principal radiation emissions:[1]
Gamma: 0.035 MeV (6.5%)
Kα X-rays: 0.027 MeV (112.7%)
Kβ X-rays: 0.031 MeV (25.4%)

Unshielded exposure rate at 1cm from 1mCi point source: 1.4R h^{-1} [7]

Half-value layer for lead shielding: 0.02mm[7]

Iodine-125 Decay Table Half Life: 60 days

Days	0	2	4	6	8	10	12	14	16	18
0	—	977	955	933	912	891	871	851	831	812
20	794	776	758	741	724	707	691	675	660	645
40	630	616	602	588	574	561	548	536	524	512
60	500	489	477	467	456	445	435	425	416	406
80	397	388	379	370	362	354	345	338	330	322
100	315	308	301	294	287	281	274	268	262	256
120	250	244	239	233	228	223	218	213	208	203
140	198	194	189	185	181	177	173	169	165	161
160	157	154	150	147	144	140	137	134	131	128
180	125	122	119	117	114	111	109	106	104	102
200	099	097	095	093	090	088	086	084	082	081
220	079	077	075	073	072	070	069	067	065	064
240	063	061	060	058	057	056	054	053	052	051

OCCUPATIONAL LIMITS

Maximum permissible air concentration based on a 40-hour working week: 5×10^{-9} μCi ml^{-1} [3]

Maximum permissible body burden: 3.97μCi

Maximum permissible thyroid burden: 1.19μCi

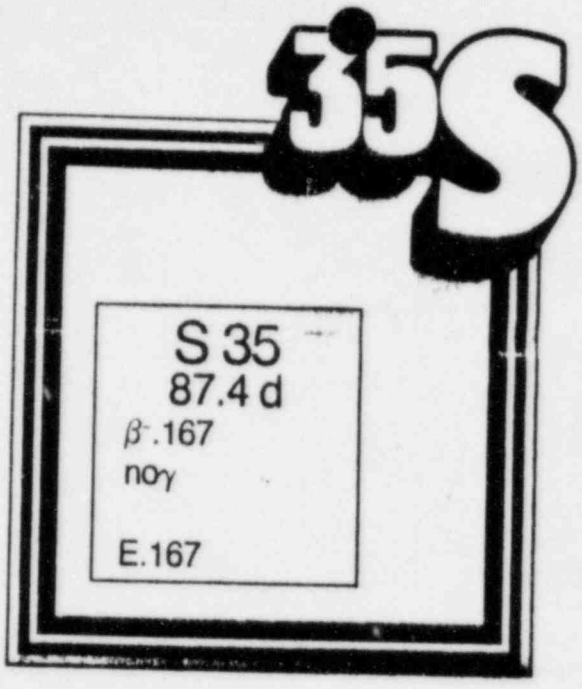
DOSIMETRY

The thyroid is the critical organ for radioiodine uptake. Thirty percent of the soluble radioiodine intake to the body may be assumed to accumulate in the thyroid. Although individual metabolisms vary over a wide range, radioiodine can be assumed to be eliminated via the urine (138 days being a reasonably conservative biological half-life for radioiodine in the thyroid).[4]

SPECIAL PRECAUTIONS

1. Store mCi quantities of ^{125}I at room temperature in containers surrounded by 1/8" thick lead.
2. Use tools to prevent direct handling of potentially contaminated vessels and unshielded multi mCi sources, and wear two pairs of gloves, changing outer pair frequently.
3. Conduct periodic thyroid counts to determine personal uptake.

^{35}S



PHYSICAL DATA

Maximum beta energy: 0.167 MeV (100%)[1]

Maximum range in air: about 9.6 inches[2]

Sulfur-35 Decay Table Half-Life: 87.4 days

Days	0	3	6	9	12	15	18	21	24	27
0	1000	976	954	931	909	888	867	847	827	807
30	788	770	752	734	717	700	683	667	652	636
60	621	607	592	579	565	552	539	526	514	502
90	490	478	467	456	445	435	425	415	405	395
120	386	377	368	359	351	343	335	327	319	312
150	304	297	290	283	277	270	264	258	252	246
180	240	234	229	223	218	213	208	203	198	194
210	189	185	180	176	172	168	164	160	156	153
240	149	146	142	139	136	132	129	126	123	120
270	118	115	112	109	107	104	102	99	97	95
300	93	90	88	86	84	82	80	78	77	75
330	73	71	70	68	66	65	63	62	60	59
360	58	56	55	54	52	51	50	49	48	46

OCCUPATIONAL LIMITS

Maximum permissible air concentration based on a 40-hour working week: $3 \times 10^{-7} \mu Ci\ ml^{-1}$[3]

Maximum permissible body burden: $400 \mu Ci$[4,5]

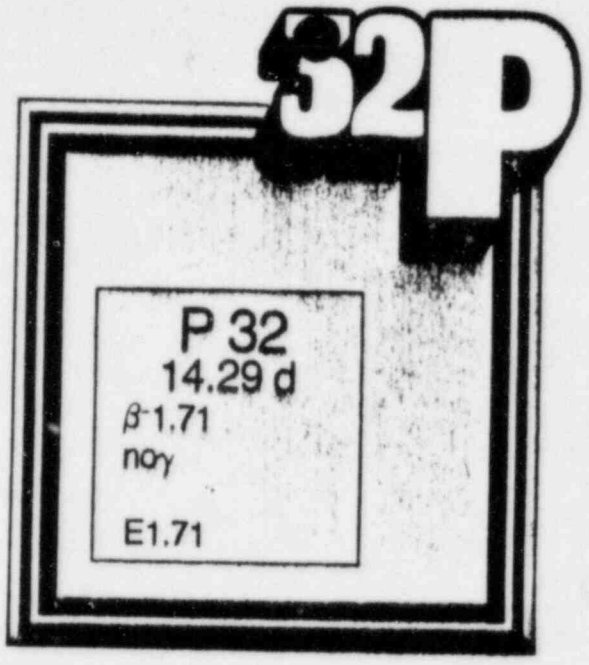
DOSIMETRY

Millicurie quantities of ^{35}S do not present a significant external exposure hazard since the low energy emissions barely penetrate the outer layer of skin. The critical organ for ^{35}S is the whole body.[5] The elimination rate of ^{35}S depends on the chemical form. Most ^{35}S-labeled compounds are eliminated via the urine, 90 days being an acceptably conservative biological half-life.[4]

SPECIAL PRECAUTIONS

Sulfur-35 may be difficult to distinguish from Carbon-14 because the beta emissions are of similar energy. If both radionuclides are being used in the same area, establish controls which are conservative for both radionuclides.

^{32}P



PHYSICAL DATA

Maximum beta energy: 1.71 MeV (100%)[1]

Maximum range in air: 20 feet[2]

Maximum range in plexiglass: 3/10 inch[2]

Phosphorus-32 Decay Table Half-Life: 14.3 days

Days	Days 0	.5	1	1.5	2	2.5	3	3.5	4	4.5
0	1000	976	953	930	908	886	865	844	824	804
5	785	766	748	730	712	695	678	662	646	631
10	616	601	587	573	559	545	532	520	507	495
15	483	472	460	449	438	428	418	408	398	388
20	379	370	361	353	344	336	328	320	312	305
25	297	290	283	277	270	264	257	251	245	239
30	233	228	222	217	212	207	202	197	192	188
35	183	179	174	170	166	162	158	155	151	147
40	144	140	137	134	130	127	124	121	118	116
45	113	110	107	105	102	100	98	95	93	91
50	88	86	84	82	80	78	77	75	73	71
55	69	68	66	65	63	62	60	59	57	56
60	54	53	52	51	49	48	47	46	45	44

OCCUPATIONAL LIMITS

Maximum permissible air.concentration based on a 40-hour working week: $7 \times 10^{-6} \mu Ci\ ml^{-1}$ [3]

Maximum permissible body burden: $6 \mu Ci$[4]

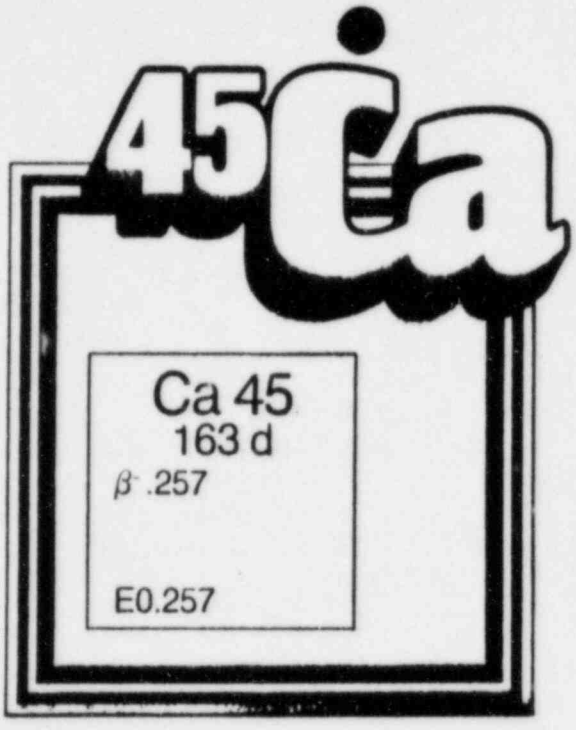
DOSIMETRY

The bone is the critical organ for intake of transportable compounds of ^{32}P.[4] Phosphorus metabolism is complex, with 30% being rapidly eliminated from the body, 40% possessing a 19-day biological half-life, and the remaining 30% being eliminated by radioactive decay.[5] The lung and lower large intestine are the critical organs for inhalation and ingestion of non-transportable ^{32}P compounds, respectively.

SPECIAL PRECAUTIONS

1. Store ^{32}P behind lucite shields; add lead on the outside of the lucite to increase shielding.
2. Wear extremity and whole body dosimeters while handling mCi quantities.
3. Use shielding to minimize exposure while handling ^{32}P.
4. Do not work over open container; use tools to handle indirectly unshielded sources and potentially contaminated vessels.

^{45}Ca



PHYSICAL DATA

Maximum beta energy: 0.257 MeV (100%)[1]

Maximum range in air: about 19 inches[2]

Calcium-45 Decay Table Half-Life: 163 days

Days	Days 0	5	10	15	20	25	30	35	40	45
0	1000	979	958	938	918	899	880	862	844	826
50	808	791	775	759	743	727	712	697	682	668
100	654	640	626	613	600	588	575	563	551	540
150	528	517	506	496	485	475	465	455	446	436
200	427	418	409	401	392	384	376	368	360	353
250	345	338	331	324	317	311	304	298	291	285
300	279	273	268	262	257	251	246	241	236	231
350	226	221	216	212	207	203	199	195	191	186
400	183	179	175	171	168	164	161	157	154	151
450	148	145	141	138	136	133	130	127	125	122
500	119	117	114	112	110	107	105	103	101	99
550	96	94	92	91	89	87	85	83	81	80
600	78	76	75	73	72	70	69	67	66	64

OCCUPATIONAL LIMITS

Maximum permissible air concentration based on a 40-hour working week: $3 \times 10^{-6} \mu Ci\ ml^{-1}$ [3]

Maximum permissible body burden: $30 \mu Ci$[4]

DOSIMETRY

Millicurie quantities of ^{45}Ca do not present a significant external exposure hazard because the low energy betas emitted barely penetrate gloves and the outer skin layer. The critical organ for uptake of ^{45}Ca is the bone.[5] The majority of ^{45}Ca is deposited in the bone and is retained with a long biological half-life of 1.8×10^4 days.[4] A smaller fraction is rapidly eliminated. Calcium-45 is initially eliminated via the urine but eventually half the radionuclide is eliminated via the feces.[5]

LICENSE LIMITS

BY-PRODUCT MATERIAL	FORM	MAXIMUM INSTITUTIONAL AMOUNT
Hydrogen - 3	any	2000 mCi
Carbon - 14	any	100 mCi
Sulfur - 35	any	100 mCi
Phosphorus - 32	any	35 mCi
Iodine - 125	protein bound	2 mCi
Potassium - 42	any	0.2 mCi
Chloride - 36	any	0.2 mCi
Calcium - 45	any	5 mCi

UNITED STATES NUCLEAR REGULATORY COMMISSION
Washington, D.C. 20555

NOTICE TO EMPLOYEES

STANDARDS FOR PROTECTION AGAINST RADIATION (PART 20), NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS (PART 19), EMPLOYEE PROTECTION

WHAT IS THE NUCLEAR REGULATORY COMMISSION?

The Nuclear Regulatory Commission is an independent Federal regulatory agency responsible for licensing and inspecting nuclear power plants and other commercial uses of radioactive materials.

WHAT DOES THE NRC DO?

The NRC's primary responsibility is to ensure that workers and the public are protected from unnecessary or excessive exposure to radiation and that nuclear facilities including power plants are constructed to high quality standards and operated in a safe manner. The NRC does this by establishing requirements in Title 10 of the Code of Federal Regulations (10 CFR) and in licenses issued to nuclear users.

WHAT RESPONSIBILITY DOES MY EMPLOYER HAVE?

Any company that conducts activities licensed by the NRC must comply with the NRC's requirements. If a company violates NRC requirements, it can be fined or have its license modified, suspended or revoked.

Your employer must tell you which NRC radiation requirements apply to your work and must post NRC Notices of Violation involving radiological working conditions.

WHAT IS MY RESPONSIBILITY?

For your own protection and the protection of your co-workers, you should know how NRC requirements relate to your work and should obey them. If you observe violations of the requirements, you should report them.

HOW DO I REPORT VIOLATIONS?

If you believe that violations of NRC rules or of the terms of the license have occurred, you should report them immediately to your supervisor. If you believe that adequate corrective action is not being taken, you may report this to an NRC inspector or the nearest NRC Regional Office.

WHAT IF I WORK IN A RADIATION AREA?

If you work with radioactive materials or in a radiation (controlled) area, the amount of radiation exposure that you may legally receive is limited by the NRC. The limits on your exposure are contained in sections 20.101, 20.103, and 20.104 of Title 10 of the Code of Federal Regulations (10 CFR 20). While those are the maximum allowable limits, your employer should also keep your radiation exposure as far below those limits as is "reasonably achievable."

MAY I GET A RECORD OF MY RADIATION EXPOSURE?

Yes. Your employer is required to tell you, in writing, if you receive any radiation exposure above the limits set in the NRC regulations or your employer's license. In addition, if your job involves radiation, you may request from your employer a record of your annual radiation exposures and a written report of your total exposure when you leave your job.

HOW ARE VIOLATIONS OF NRC REQUIREMENTS IDENTIFIED?

NRC conducts regular inspections at licensed facilities to assure compliance with NRC requirements. In addition, your employer and site contractors conduct their own inspections to assure compliance. All inspectors are protected by Federal law. Interference with them may result in criminal prosecution for a Federal offense.

MAY I TALK WITH AN NRC INSPECTOR?

Yes. Your employer may not prevent you from talking with an NRC inspector and you may talk privately with an inspector and request that your identity remain confidential.

MAY I REQUEST AN INSPECTION?

If you believe that your employer has not corrected violations involving radiological working conditions, you may request an inspection. Your request should be addressed to the nearest NRC Regional Office and must describe the alleged violation in detail. It must be signed by you or your representative.

HOW DO I CONTACT THE NRC?

Notify an NRC inspector on-site or call the nearest NRC Regional office collect. NRC inspectors want to talk to you if you are worried about radiation safety or other aspects of licensed activities, such as the quality of construction or operations at your plant.

CAN I BE FIRED FOR TALKING TO THE NRC?

No. Federal law prohibits an employer from firing or otherwise discriminating against a worker for bringing safety concerns to the attention of the NRC. You may not be fired or discriminated against because you:

- ask the NRC to enforce its rules against your employer;
- testify in an NRC proceeding;
- provide information or are about to provide information to the NRC about violations of requirements;
- are about to ask for or testify, help, or take part in an NRC proceeding.

WHAT FORMS OF DISCRIMINATION ARE PROHIBITED?

No employer may fire you or discriminate against you with respect to pay, benefits, or working conditions because you help the NRC.

HOW AM I PROTECTED FROM DISCRIMINATION?

If you believe that you have been discriminated against for bringing safety concerns to the NRC, you may file a complaint with the U.S. Department of Labor. Your complaint must describe the firing or discrimination and must be filed within 30 days of the occurrence.

Send complaints to:

Office of the Administrator
Wage and Hour Division
Employment Standards Administration
U.S. Department of Labor
Room S3502
200 Constitution Avenue, N.W.
Washington, D.C. 20210

or any local office of the Department of Labor, Wage and Hour Division. Check your telephone directory under U.S. Government listings.

WHAT CAN THE LABOR DEPARTMENT DO?

The Department of Labor will notify the employer that a complaint has been filed and will investigate the case.

If the Department of Labor finds that your employer has unlawfully discriminated against you, it may order you to be reinstated, receive back pay, or be compensated for any injury suffered as a result of the discrimination.

WHAT WILL THE NRC DO?

The NRC may assist the Department of Labor in its investigation. NRC may conduct its own investigation where necessary to determine whether unlawful discrimination has prevented the free flow of information to the Commission. Also, if the NRC or Department of Labor finds that unlawful discrimination has occurred, the NRC may issue a Notice of Violation to your employer, impose a fine, or suspend, modify, or revoke your employer's NRC license.

UNITED STATES NUCLEAR REGULATORY COMMISSION REGIONAL OFFICE LOCATIONS

A representative of the Nuclear Regulatory Commission can be contacted at the following addresses and telephone numbers. The Regional Office will accept collect telephone calls from employees who wish to register complaints or concerns about radiological working conditions or other matters regarding compliance with Commission rules and regulations.

Regional Offices

REGION	ADDRESS	TELEPHONE
I	U.S. Nuclear Regulatory Commission Region I 631 Park Avenue King of Prussia, PA 19406	215 337-5000
II	U.S. Nuclear Regulatory Commission Region II 101 Marietta St., N.W., Suite 2900 Atlanta, GA 30323	404 221-4503
III	U.S. Nuclear Regulatory Commission Region III 799 Roosevelt Road Glen Ellyn, IL 60137	312 790-5500
IV	U.S. Nuclear Regulatory Commission Region IV 611 Ryan Plaza Drive, Suite 1000 Arlington, TX 76011	817 860-8100
V	U.S. Nuclear Regulatory Commission Region V 1450 Maria Lane, Suite 210 Walnut Creek, CA 94596	415 943-3700

NRC FORM 3
(9-84)

3. D) Hood minimum flow rates

The minimum flow rate for our hoods is between 120-150 linear feet/ minute. We will check the flow rates for all of our hoods at regular six month intervals.

4. A) Rollin Rickard, Administrator of the Shriver Center, and Dr. Robert H. McCluer, Director of Biochemistry and Radiation Safety Officer, will supervise and be responsible for the radiation protection program at the Eunice Kennedy Shriver Center for Mental Retardation, Inc.

4. B) Every six months Rollin Rickard, Administrator of the Shriver Center, will audit the records(surveys, film badges, survey meter certification etc.) of the services provided by Harvard EH&S.

4. C) Please see the manual, Regulations for the Use of Radionuclides at Eunice Kennedy Shriver Center Inc., enclosed as Appendix.

4. D) There are extensive fully accredited animal facilities on the fourth floor of the research building. However, experiments involving radioactive materials in animals are restricted to the the laboratory of the principal investigator involved. Please see Section 7. page 6, of the enclosed Appendix.

4. E) Please see Section 8. page 6, of the enclosed Appendix.

4. F-I) The only sealed source we have is a compound sealed source of Americum-241 and Radium 226. This sealed source is confined within our Packard scintillation counter, model 3380, and is used as an external standard for calculating quenching. At no time is it accessible to personnel.

This sealed source has always been included in our license request and/or renewal. This may not be necessary. Please advise regarding the Americum-241, it is understood that the Radium-226 need not be listed.

4. J) Please see Appendix Section 8.2 page 7 and Section 8.4 page 9.

4. K) Please see Appendix Section 9. page 9.

4. L) All procedures such as protein iodinations and tritium labelling experiments that may release volatile or gaseous radioactive materials are restricted to fumes hoods as stated in the enclosed Appendix on pages 7 & 8. Experiments involving the use of greater than 100 mCi amounts of volatile or gaseous radionuclides must have prior approval by the RSO. Monitoring and bioassay requirements are descibed in the Appendix.

5. A) This Institution is and always has been intimately affliated with Harvard University. The Director and all of the senior staff members have Harvard appointments. All of the facilities and services of the University are available to us. We thus submit that Harvard University is authorized to be responsible for and can provide waste packaging services to our facility. Nevertheless, the RSO and his assistant will supervise such packaging to assure that the requirements of the commericial waste disposal broker are met.

1. While we routinely survey all packages, both the external container and the inner package, it noted that in Title 10, Part 20, paragraph 20.205 all packages contain less than 10 mCi of 3H, 14C,35S, or 125I, and packages containing than 100 mCi of radionuclides with half-lives of less than 30 days, su as 32P are exempt from survey. Also see page 10 of Appendix.

2. We have prepared a booklet on NRC regulations and the procedures for safe handling of radionuclides at the Eunice Kennedy Shriver Center. Please see the enclosed Appendix. This booklet is given out to all primary investigators and will be kept in the laboratory areas. All personnel working in those restricted areas will be required to read this booklet.

   We have a video tape of the Harvard Course to be shown to new employees to serve in the interim between the regularly scheduled Harvard couse.

   We will show this video tape annually to the entire staff, and discuss the procedures for the use of radionuclides at EKSC - mandatory attendance will be taken.

3. A) There are now three survey meters available in the biochemistry deparment:

   1. Eberline Model E-120
      measures both cpm and mRm/hr
      beta, gamma

   2. Mini Instruments LTD model 5-10E
      measures in cps
      beta, gamma,
      1.5-2.2 mg/cm; area = 6.4 cm squared

   3. Mini Instruments LTD Series 900 model E
      measures cps
      beta, gamma
      1.5-2.2 mg/cm; area= 6.4 cm squared

   There are also two survey meters in the molecular neurogenetics department:

   1. Eberline Model E-120 see above

   2. Technical Assoc. Model PUG - 1AB
      measures cpm

3. B) We confirm the Harvard Environmental Health and Safety does calibrate these instruments every six months and provide certification.

3. C) 1. Name of supplier = Harvard Environmental Health and Safety
   2. Film badges and ring badges
   3. Checked and changed monthly