NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

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

APPLICATION FOR MATERIAL LICENSE

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

FEDERAL AGENCIES FILE APPLICATIONS WITH:

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

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

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

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

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

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

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

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

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

Boehringer Mannheim Corporation, Biochemicals Division
7941 Castleway Drive
Indianapolis, IN 46250

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

7941 Castleway Drive
Indianapolis, IN 46250

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dr. Kevin Kearney

TELEPHONE NUMBER

(800)428-5433 (317)849-9350

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

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

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY 3M-New

AMOUNT ENCLOSED $ 700.00

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

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

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

SIGNATURE/ CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
	Philip L. DeLong	Vice President Biochemicals Division	3-11-85

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

- [ ] < $250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] > $10M

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

c. NUMBER OF BEDS

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

- [ ] YES
- [ ] NO

RECEIVED
MAR 14 1985
REGION III

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
appl	MAY19	3M		CJ
AMOUNT RECEIVED	**CHECK NUMBER**			**DATE**
$700	000373		CONTROL NO. 78505	3/25/85

PRIVACY ACT STATEMENT ON THE REVERSE

MAR 14 1985

MAR 1985

8506050268 850510
REG3 LIC30
13-24471-01 PDR

5. Radioactive Material

Element	Form	Possession Limit
^{32}P	Nucleotides, Inorganic Phosphate	10 mCi
^{35}S	Nucleotides	5 mCi
^{3}H	Nucleotides	1 mCi
^{14}C	Nucleotides	500 μCi

6. Purposes

In vitro laboratory experiments in molecular biology and biochemistry. These experiments will focus primarily on the processing (e.g., using restriction endonucleases, polymerases, etc.), structural studies (especially sequencing) and detection (e.g., by hybridization techniques) of nucleic acids. This will be an applications laboratory in which methods of using the company's products are studied. Estimated maximum amounts of radionuclides per experiment are: ^{32}P, 500 μCi; ^{35}S, 100 μCi; ^{3}H, 50 μCi; ^{14}C, 10 μCi.
Annual usage of radioactive materials is estimated as follows: ^{32}P, 50-100 mCi; ^{35}S, 10-20 mCi; ^{3}H, 2-4 mCi; ^{14}C, $\leq$ 1 mCi.

7. Responsible Individuals

Kevin R. Kearney, Ph.D. (Radiation Protection Officer)
Leonard Mascaro Jr., Ph.D. (^{35}S, ^{14}C, ^{3}H use only)
Mary M. Welch, Ph. D.

(Resumès of these individuals follow)

RESUME

Kevin R. Kearney — Date of Birth: 2 July 1950

1983-1985	Postdoctoral Research Associate Univ. of Wisconsin Madison, WI
Training:	Private study of a radiation safety manual, followed by written examination. Material covered included: principles and practice of radiation protection, radioactivity measurement and monitoring, mathematics and calculations basic to the use and measurement of radioactivity.
Experience:	Use of ^{3}H (microcurie quantities), ^{32}P (up to 25 mCi) and ^{35}S (up to 1 mCi) for experiments in biochemistry and molecular biology (primarily nucleic acid sequencing and hybridization studies; also, <u>in vitro</u> physical studies of biological molecules (nucleic acids) and macromolecular assemblies). Radiation safety officer for a laboratory of 10-15 researchers in which ^{3}H, ^{14}C, ^{32}P, ^{33}P and ^{35}S were used.
1979-1982	Research Assistant Yale University New Haven, CT
Training:	Short course covering principles and paractice of radiation protection, radioactivity measurement and monitoring, mathematics and calculations basic to the use and measurement of radioactivity, biological effects of radiation.
Experience:	Use of ^{3}H and ^{14}C (microcurie quantities for <u>in vitro</u> physical studies of biological macromolecular assemblies). Use of laboratory X-ray apparatus.

Leonard Mascaro Jr.
Ph.D. in Biochemistry received June, 1975

I. Experience

A. Dept. of Biochemistry, Michigan State University 1971-1975. Worked with ^{14}C, maximum of 10 μCi per experiment. Experiments consisted of in vitro synthesis of plant polysaccharides from appropriate UDP-[^{14}C] sugars followed by characterization of the polysaccharide.

B. Dept. of Medicinal Chemistry, Purdue University, 1975-1977. Worked with ^{14}C (maximum of 50 μCi per experiment) and ^{3}H (maximum of 100 mCi per experiment). Chemical and biochemical techniques were used to synthesize labelled sterioisomers of methionine. Responsible for monitoring and cleaning department "hot lab".

II. Training

A. At Michigan State University received two hours of classroom training on measurements, mathematics and biological effects of radiation. Principles and practices of radiation protection were taught by on-the-job training under supervision of major professor. [^{14}C]-Labelled products were used daily.

B. At Purdue University read University "Radiation Safety Manual" which described protection, monitoring techniques, mathematics of measurement and biological effects.

RESUME

Mary M. Welch, Ph.D.

Training (1979)

Attended formal course taught by the Radiation Safety Office at the University of Texas Medical at Houston (UTMS-Houston). The course lasted 1 day and covered radiation safety, measurement of radioactivity, calculations of results from experiments using radioactive material and biological effects of radioactivity.

Use of Radioactive Material (1976 - 1982)

1. Several compounds containing ^{14}C were used either in enzymatic assays or in in vivo studies in which the compound was injected into animals and its uptake was measured. These experiments were performed at Rice University in Houston, Texas and lasted three years. Quantity of radioactivity was less than 2 mCi.

2. [^{35}S]-methionine was incubated with bacteria cells and its incorporation into specific proteins was determined. These experiments were performed at UTMS-Houston and lasted a year. Quantity of radioactivity was less than 20 mCi.

3. [^{32}P]-nucleotides were used to end-label DNA. This experiment was performed at UTMS-Houston and lasted two months. Quantity of radioactivity was less than 1 mCi.

8. Training

Individuals (other than those mentioned in 7) who will use radioactive materials will be trained by the Radiation Safety Officer (RSO). This training will include:

a. instruction in radiation safety (general principles, laboratory practice guidelines, regulations, waste disposal, instruction by RSO and in written form (Radiation Safety Program)).

b. On-the-job training in the use of radioactive materials (under the supervision of the RSO).

c. Determination of competency to work without the presence of supervisory personnel.

Prior to their assuming duties involving use of radioactive materials, the RSO will instruct laboratory personnel, as described above. An annual radiation safety review will also be conducted by the RSO, as will any ad hoc training when any worker significantly changes his/her duties or responsibilities. The RSO will keep records of all training, including dates, topics covered and names of trainees.

Ancillary personnel (housekeeping and security) whose duties require them to work in the vicinity of radioactive material will be instructed about the hazards and precautions. The RSO will provide this service when research with radionuclides commences, when any new personnel are hired and annually thereafter. Records of this instruction will be maintained as described in the preceding paragraph.

9. Facilities and Equipment

All radionucliedes will be stored and used in one laboratory; plans for this laboratory are attached to this application (see pages 9-12). Primary areas in which radioactive materials will be used will be benches D and E, the fume hood and sink A (see diagrams). The hood will be the location for work with relatively large (>100 μCi) amounts of ^{32}P, since its rear is a wall rather than another laboratory bench. Smaller amounts of radioactive materials may be used at the benches. Bench-tops will be of a non-porous material (epoxy-resin) and will always be covered with absorbent paper. Relatively large volumes of liquid radioactive material ($\geq$ 1 liter; e.g., potentially contaminated electrophoresis buffer) will be handled near the sink, though there will be no routine waste disposal in the sink. Radioactive materials will never be stored in the dark room; their use there will be only for short periods of time (e.g., when polyacrylamide gels containing radionuclides are positioned adjacent to film and placed into a cassette for subsequent autoradiography in a freezer). The floor of the entire laboratory area is a hard-tile surface, and individual tiles can be removed in case of contamination which cannot be washed off.

Upon receipt, radionuclides will be stored in the refrigerator/freezer in appropriately shielded containers (in the case of ^{32}P, lead). For autoradiography, electrophoresis gels (containing microcurie quantities of ^{32}P or ^{35}S) will be kept in a -70°C freezer adjacent to the storage cabinet. Solid waste will be stored in a metal waste can between the fume hood and the refrigerator/freezer. Liquid waste will be stored in the cabinets under the fume hood behind lead sheets.

Two movable acrylic shields will be available for personnel to use when working with radioactive materials. Workers will wear lab coats and double disposable plastic gloves when working with radionuclides. Lab coats will be kept in the radionuclide laboratory, as will plastic gloves. After use, the gloves will be discarded into the solid waste container.

Large signs on the doors will identify the laboratory as an area in which radioactive materials are stored and used. "Danger: Radioactive Material" tape will be used to mark all areas within the laboratory where such materials are kept or used (e.g., in the hood, under the hood, in the waste can, in the refrigerator/freezer, in the -70°C freezer).

Door 1 to the radionuclide laboratory can be bolted closed from inside the laboratory and door 2 can be securely locked from the outside (see diagram). The room will be open only during regular working hours; at all other times it will be securely closed.

Since all radioactive materials used in this laboratory will be non-organic and in solution and no iodine will be used, there will be no airborne contamination problems.

10. Radiation Safety Program

a. Radiation Detection Instruments

1. Type: Geiger - Mueller Survey Meter
Manufacturer: Ludlum Measurments, Inc.
Model Number: 3 (Probe #44-7)
Number available: 1
Radiation detected: Beta, gamma
Sensitivity Range: 0-500K cpm (approx. 0.1-200 mR/hr)

2. Type: Liquid Scintillation Counter
Manufacturer: LKB
Model Number: 1211
Number Available: 1
Radiation detected: Beta
Sensitivity Range: 1-2800 KeV, 1-10^6 cpm

b. Calibration of above instruments

1. GM Survey meter - calibrated annually by: Ludlum Measurements, Inc., Sweetwater, TX.

2. LSC - calibrated annually with standards supplied by manufacturer.

c. Personnel Monitoring Devices

Type(s):TLD badge and TLD ring
Supplier: Siemens Gammasonics, Inc.
Health Physics Services
2000 Nuclear Drive
Des Plaines, IL 60018
Exchange frequency: Quarterly

d. Survey program

A portable survey meter will be available in the laboratory. All personnel will be instructed to use it frequently during and following work with radioactive materials to determine the presence of radioactivity on working surfaces, the body and clothing.

The Radiation Safety Officer will conduct a monthly laboratory survey. This survey shall consist of:

1. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/h.

2. A series of wipe tests to measure contamination levels. The method of performing wipe tests shall be sufficiently sensitive to detect 50 cpm.

All areas associated with use, storage or disposal of radioactive materials will be surveyed.

Areas shall be cleaned if the contamination level exceeds 50 cpm/cm^2.

No ^{125}I will be used in this laboratory so we plan no bioassay program.

e. Emergency Procedures

Attached is a copy of emergency instructions to be posted near the doors of the radionuclide laboratory (pages 13-15).

f. Records Management Program

The Radiation Safety Officer will keep records of all survey results (including negative results), material inventories, receipts, use and disposal of materials and personnel exposures. These records will be available for examination by all personnel.

g. Instructions to Personnel

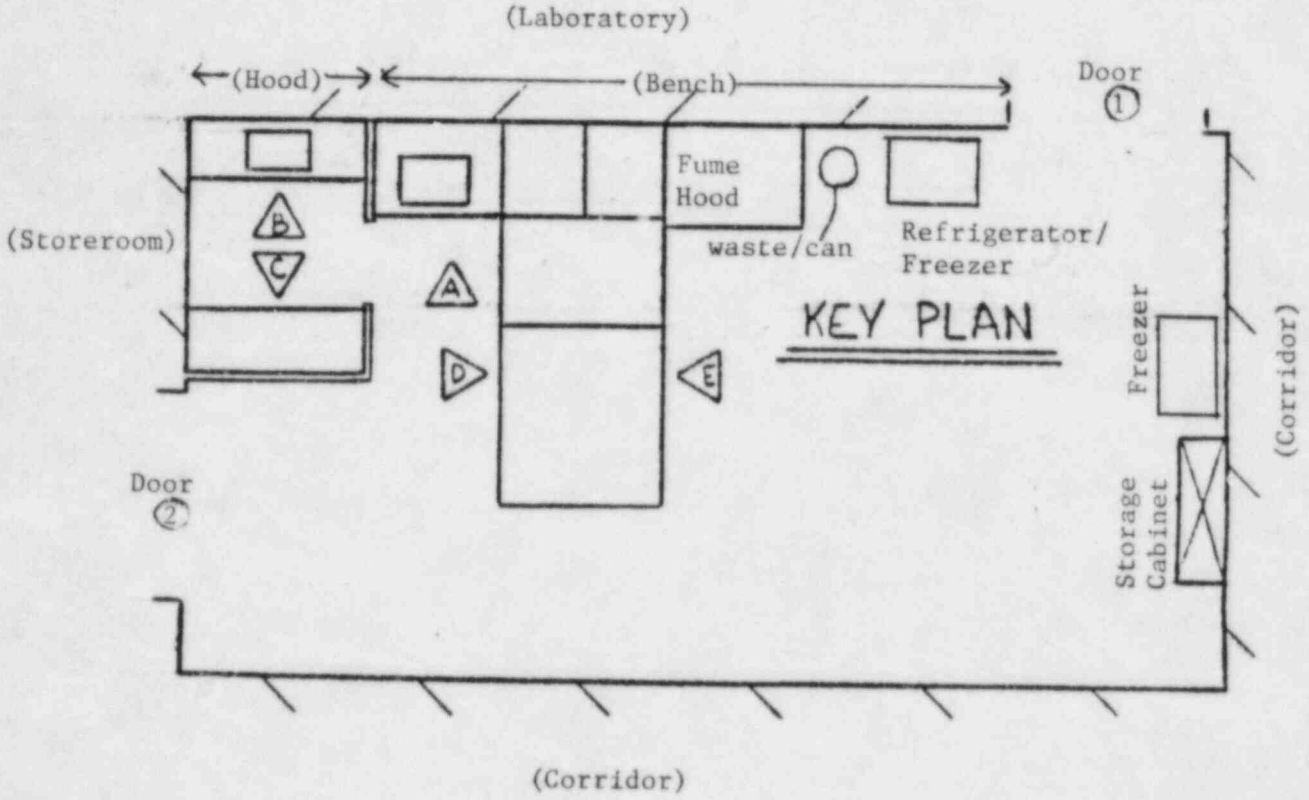
A Radiation Safety Manual will be distributed to all personnel who will use radioactive materials. A copy of this manual is included with this license application. Additionally, the Radiation Safety Officer will instruct all personnel about the proper procedures for use of radioactive materials as discussed in 8 above.

11. Waste Management

The radionuclide of which we will use most will be ^{32}P. For this material the primary method of disposal will be simply to allow it to decay. Disposal of ^{35}S will also be via decay, supplemented by waste pick-up. Long half-life radionuclides (^{3}H and ^{14}C) will be disposed of by waste pick-up. Little if any radioactive material will be released into the sewer (certainly less than permitted amounts).

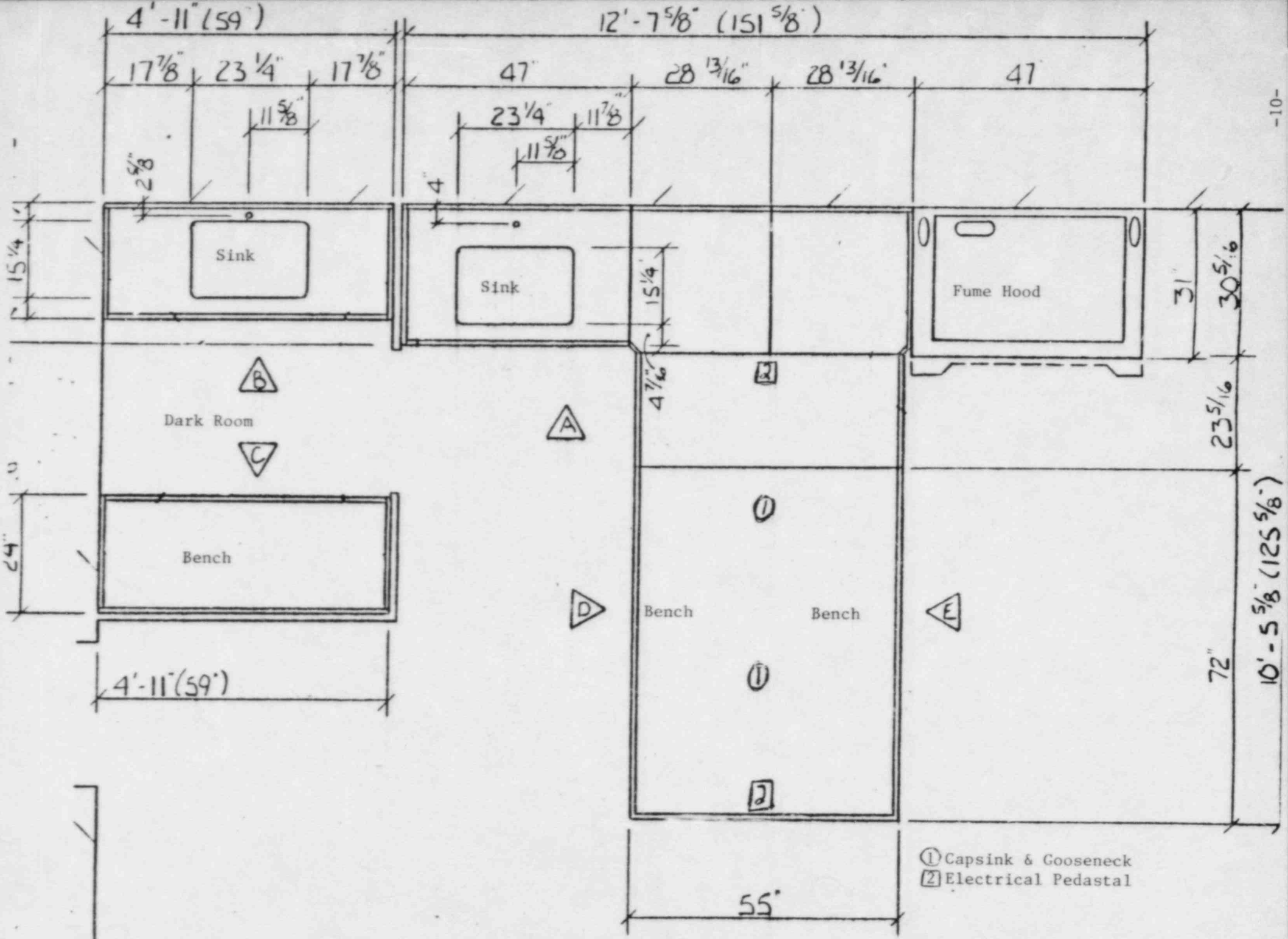
Waste pick-up, as required, will be done by:

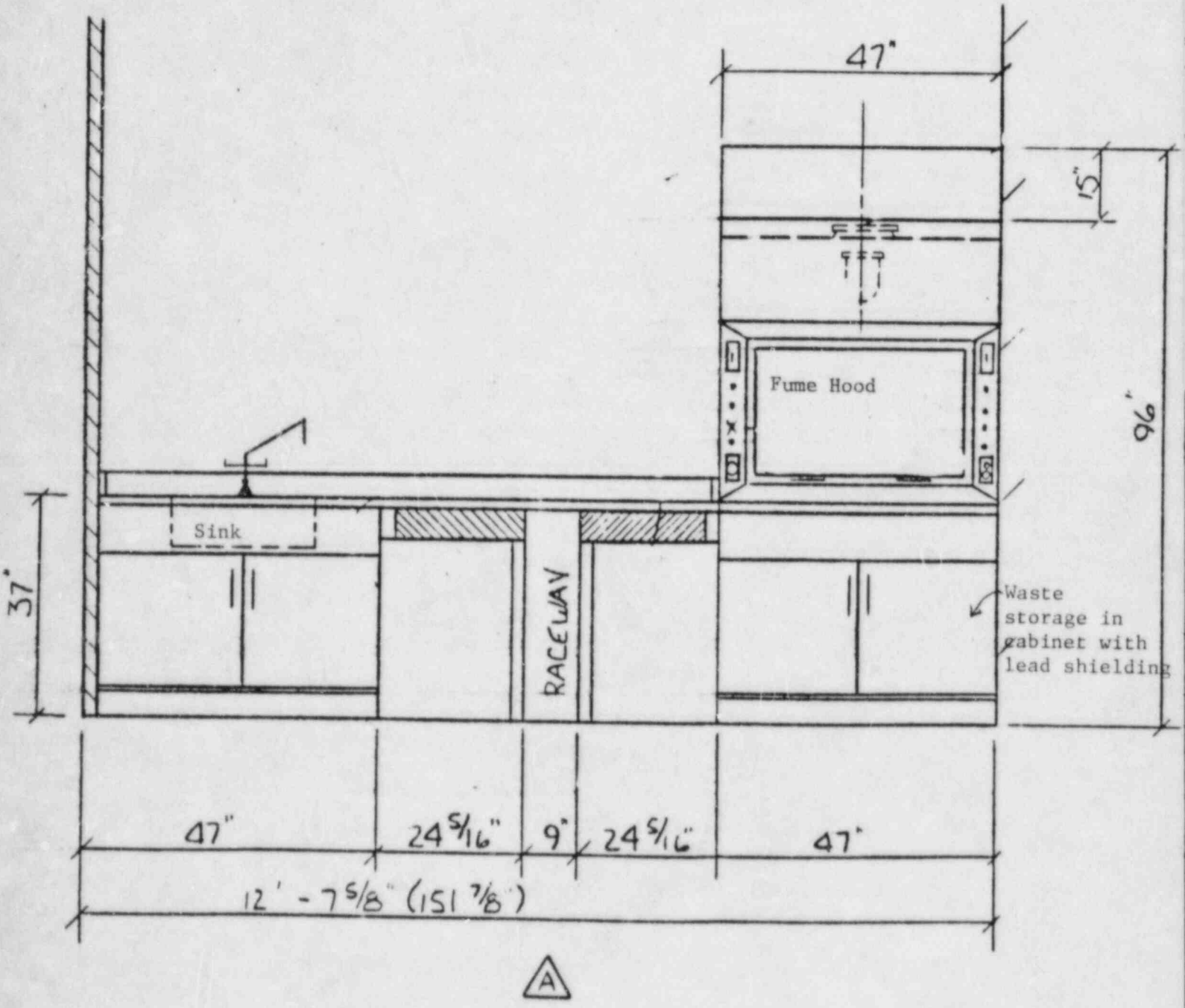
Adco Services, Inc.
P.O. Box 35
Tinley Park, IL 60477

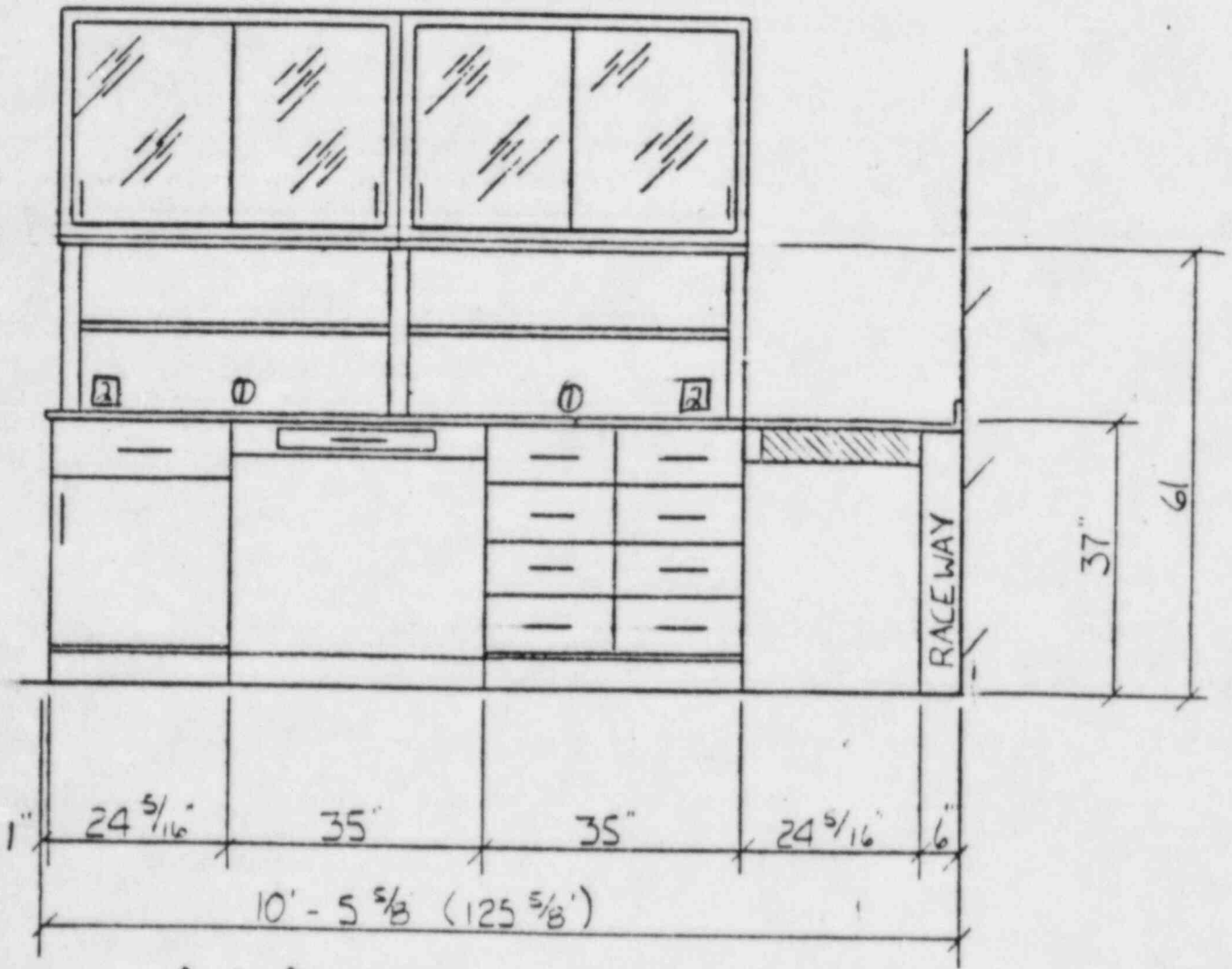


CONTROL NO. 78505

Radionuclide Laboratory
Boehringer Mannheim Corporation,
Biochemicals Division
7941 Castleway Drive
Indianapolis, IN 46250


4'-11" (59")
12'-7 5/8" (151 5/8")
17 7/8"
23 1/4"
17 7/8"
47"
28 13/16"
28 13/16"
47"
11 5/8"
23 1/4"
11 7/8"
11 5/8"
2 5/8"
4"
Sink
Sink
Fume Hood
15 1/4"
15 1/4"
31"
30 5/16"
4 7/16"
23 5/16"
Dark Room
A
B
C
D
E
Bench
Bench
Bench
24"
72"
10'-5 5/8" (125 5/8")
4'-11" (59")
55"
1 Capsink & Gooseneck
2 Electrical Pedastal


47"
15"
96"
Fume Hood
Sink
37"
RACEWAY
Waste storage in cabinet with lead shielding
47"
24 5/16"
9"
24 5/16"
47"
12' - 7 5/8" (151 7/8")
A



△D & △E TYPICAL REVERSED

CONTROL NO. 78505

EMERGENCY PROCEDURES

Minor Spills Involving No Significant Radiation Hazard to Personnel

1. Notify all persons in the room at once.
2. Confine the spill immediately.
   a) liquid spills:
      1. Don protective gloves.
      2. Drop absorbent paper on spill.
   b) Dry spills:
      1. Don protective gloves.
      2. Dampen area thoroughly, taking care not to spread the contamination.
3. The spread of radioactive contamination can be diminished by restricting the number and movements of persons in the spill area until the extent of shoe and clothing contamination is ascertained.
4. Notify the Radiation Safety Officer as soon as possible.
5. Decontaminate the area.
6. Monitor all persons involved in the spill and clean up; decontaminate if necessary.

Major Spills Involving Significant Radiation Hazard to Personnel

1. Notify all persons not involved in the spill to vacate the room at once.
2. If the spill is liquid, and the hands are protected, right the container.
3. If the spill is on the skin, flush thoroughly.
4. If the spill is on clothing, discard outer or protective clothing at once.
5. Switch off all fans and air conditioners.
6. Vacate the room.
7. The spread of radioactive contamination can be diminished by restricting the movements of potentially contaminated persons to a local zone just outside of the spill area until the extent of shoe and clothing contamination is ascertained.
8. Every person who might have been contaminated should be monitored for radioactivity, and, if contaminated, should remove his clothes and be decontaminated. If no means are available for monitoring, it should be assumed that the person is contaminated.

9. Notify the Radiation Safety Officer as soon as possible.

10. Immediately take the necessary steps to decontaminate personnel involved.

11. Decontaminate the area. (Personnel involved in the decontamination must be adequately protected).

12. Monitor all persons involved in the spill and cleanup to determine adequacy of decontamination.

13. Permit no person to resume work in the area until a survey is made and approval of the Radiation Safety Officer is secured.

14. Prepare and submit to the Radiation Safety Officer within 14 days a complete written history of the accident and subsequent activity related thereto.

Injuries to Personnel Involving Radiation Hazard

1. Wash minor wounds immediately, under running water, while spreading the edges of the wound.

2. Report all radiation accidents to personnel (wounds, over-exposure, ingestion, inhalation) to the Radiation Safety Officer as soon as possible.

3. Immediately call a physician qualified to treat radiaton injuries.

4. Permit no person involved in a radiation injury to return to work without the approval of the Radiation Safety Officer and the attending physician.

5. Prepare and submit to the Radiation Safety Officer within 14 days a complete written history of the accident and the subsequent activity related thereto.

Fires or Other Major Emergencies

1. Notify all other persons in the room and building at once.

2. Attempt to put out fires if radiation hazard is not immediately present.

3. Notify Safety Department.

4. Notify the radiation Safety Officer.

5. Govern fire-fighting or other emergency activities by the restrictions of the Radiation Safety Officer.

6. Following the emergency, monitor the area and determine the protective apparatus necessary for safe decontamination.

7. Decontaminate under supervision of Radiation Safety Officer.

8. Permit no person to resume work without approval of Radiation Safety Officer.

9. Prepare and submit to the Radiation Safety Officer within 14 days a complete written history of the emergency and subsequent activity related thereto.

Persons to notify in case of emergency in the Radionuclide Laboratory:

Radiation Safety Officer: Kevin Kearney 257-4619

Directcr of Technical Services: Len Mascaro 849-2521

Operations Manager: Carol Lash 849-8403

BOEHRINGER MANNHEIM BIOCHEMICALS

To: Dr. Kevin Kearney, Dr. Len Mascaro, Dr. Mary Welch, Ms. Carol Lash Date: March 8, 1985

From: Phil DeLong

Subject: Radiation Safety

1. The above four individuals will serve as the "Radiation Safety Committee" for BMB. This committee is responsible to be familiar with all pertinent federal safety regulations for the use of radioisotopes and to institute appropriate safety procedures for the use of radioisotopes at BMB. This committee will meet at least once a quarter to review procedures and monitor training in isotope safety.

2. Kevin Kearney is appointed as Radiation Safety Officer for BMB and chairman of the Radiation Safety Committee. Dr. Kearney is authorized to review the day-to-day use of radioisotopes at BMB and to prohibit any use that is considered to be dangerous to health or property.

Phil DeLong
Vice President & General Manager

mk

CONTROL NO. 78505