NRC FORM 313
(10-87)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 6-30-90

APPLICATION FOR MATERIAL LICENSE

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

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

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

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

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

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

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

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

IF YOU ARE LOCATED IN:

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

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

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

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

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

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

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

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

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 31-14851-01E

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

Becton Dickinson
Mountain View Avenue
Orangeburg, New York 10962-1294

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

Mountain View Avenue
Orangeburg, New York 10962-1294

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Aloysius J. Decker Jr.

TELEPHONE NUMBER: 914-359-2700 Ex. 237

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: Byproduct Mat. | 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 REPRSSENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
[signature]	Aloysius J. Decker Jr.	Radiation Safety Officer	8/15/88

8903170159 890306
REG1 LIC30
31-14851-01E PNU

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
REN	Sp. 1 HPS	3I		S. Kimberly

AMOUNT RECEIVED	CHECK NUMBER		DATE
$700 ($470 refunded)	096344	020627	9/14/88

Becton Dickinson Immunodiagnostics
13 Mountain View Avenue
Orangeburg, New York 10962-1294
Telephone: (914) 359-2700

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7. Individual(s) responsible for radiation safety program and their training and experience.

   a. Please see the attached Radiation Safety Officer position description and RAM experience resume for Aloysius J. Decker, Jr.

   b. Radioactive material will be used under the direction of the following individuals:
   Sankar Ambady
   Patrick Haley
   James Peterson, Ph.D.
   Dan Raju
   Herman Rutner
   Michael Sloan

   Please see the attached resume sheets for each individual.

8. Training for individuals working in or frequenting restricted areas.

   Films/video cassettes/literature/visual demonstrations/discussions dealing with radiation are routinely presented to all Becton Dickinson personnel working with radionuclides by the Radiation Safety Officer who is responsible for administration of the Radiation Training Program. All records of employee training will be kept on file in the Radiation Safety and Health Physics Department.

   For the purpose of training and indoctrination, employees of Becton Dickinson will be divided into three categories based on the nature of their jobs.

   1. Authorized Users-
   This group of workers routinely handles raw material radionuclides and highly concentrated stock tracer solutions, and includes most Production, Research and Development and Process Engineering personnel.

   2. Limited Handlers-
   Those individuals whose work with radioactive materials consists of handling formulated tracers containing a concentration of radioactive material normally less than 1 uCi/mL. This category includes, but is not limited to, Quality Control, Technical Lab Services, Assembly/Fill, Traffic and Maintenance personnel.

   3. Non-handlers-
   Those employees who do not work with any radioactive materials. This group would include, but is not limited to, clerical, administrative and management personnel.

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Non users will view an appropriate film and attend a lecture on the nature and uses of radioactivity.

Authorized users and limited handlers will be required to attend radiation training sessions as described below.

Both Authorized Users and Limited Handlers will receive a minimum of two weeks on-the-job training at the beginning of their employment. During this period a minimum of two hours formal training by the Radiation Safety Officer will be provided in the principles of radiation, radiation detection, proper handling of radioactive materials, personal monitoring techniques and emergency procedures in case of a radiological incident. Instruction will include audio visual aids, lectures and handouts as required. Additional instruction will be provided if job responsibilities change.

As part of their formal training, authorized users will view a film on radiation, attend a lecture on radioactivity and its uses, view a slide show dealing with the basic concept of radiation, and receive a copy of the current radiation training primer. They will also undergo a training session on the proper gowning and ungowning procedures for iodination laboratory work, be required to read all pertinent sections of the Becton Dickinson Radiation Safety and Health Physics Manual and pass a written examination before being allowed to work with high concentrations of radioactive material. On-the-job training on a one-to-one basis will occur prior to the incorporation of any isotope by a new authorized user. Potential authorized users who are not successful in the completion of training will receive additional training as necessary prior to being allowed to work with raw material radionuclides or highly concentrated stock tracer solutions. Authorized users and limited handlers must attend refresher training annually.

Employees will be certified by the Radiation Safety Officer upon the successful completion of their particular level of training. All certifications will be kept on file in the Radiation Safety and Health Physics Department.

All female employees who are assigned to work in controlled areas of the plant will be provided instruction by the Radiation Safety Officer concerning biological risks to the fetus from exposure to ionizing radiation as well as receive copies of the Becton Dickinson Policy concerning pregnancy.

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9. Facilities and Equipment

The Research and Development and Production Iodination Laboratories are considered restricted areas and protective clothing must be worn. All personnel entering these laboratories must adhere to the Radiation Safety and Health Physics regulations established by Becton Dickinson and must wear special uniforms, shoe covers, gloves, hood and beard covers, activated charcoal masks or respirators, safety glasses, and safety shoes.

Radioactive materials are manipulated in hoods and gloveboxes which have self-contained activated charcoal filters and/or vents to activated charcoal filter banks on the roof. Gloveboxes and hoods are used with lead shielding and/or leaded glass shielding. Monitoring instruments with audible and visual alarms are continuously used. Air samples are taken continuously throughout the work day and analyzed for airborn radioactive iodine on a daily basis. All iodination laboratories operate under negative pressure. Each primary exhaust system has a back-up system which automatically takes over when the primary system cannot maintain the appropriate pressure differential. Visual and audible alarms will also be triggered when this occurs.

A comprehensive contamination monitoring program is maintained as per Becton Dickinson's New York State Radioactive Materials License #273-0811. All working surfaces in controlled and uncontrolled areas are monitored on an established schedule. Further details of this program are listed in the Radiation Safety Program section of this application.

The building is fully sprinklered and of masonary construction. Security, fire protection and refrigeration systems are monitored on a 24 hour basis under contract to a private security agency.

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Item 9. Facilities and Equipment

RADIATION DETECTION INSTRUMENTS

TYPE OF INSTRUMENTS (make & model number)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr) or cpm range	WINDOW THICKNESS (mg/cm^2)	USE (Monitoring, Survey, Measuring)	
A. Beta or Gamma Scintillation Counters	Total 11					
Packard model #3330 Tri-Carb Liquid Scintillation Spectrometer	1	Beta, Gamma	0-1,999,999 cpm			X
Packard Auto-Gamma 5230 Scintillation Spectrometer	1	Gamma	0-1,999,999 cpm			X
Packard Multi Prias-4 Automatic Gamma Counter	1	Gamma	0-999,999 cpm			X
Packard Crystal II Multi-detection Gamma Counter	1	Gamma	0-999,999 cpm			X
LKB RIA Gamma Automatic Gamma Counter	1	Gamma	0-999,999 cpm			X
Micromedic Systems Inc. Apex Automatic Gamma Counter	2	Gamma	0-999,999 cpm			X
Micromedic Systems Inc. Model #4/600 Automatic Gamma Counter	1	Gamma	0-999,999 cpm			X
Schwarz/Mann Model A-24 Automatic Gamma Counter	3	Gamma	0-999,999 cpm			X
B. Thyroid Monitors Minirem Corporation model-MS-3 Thyroid Monitoring System	Total 2 2	Gamma	0-300,000 cpm	0.001 " Al	X	X

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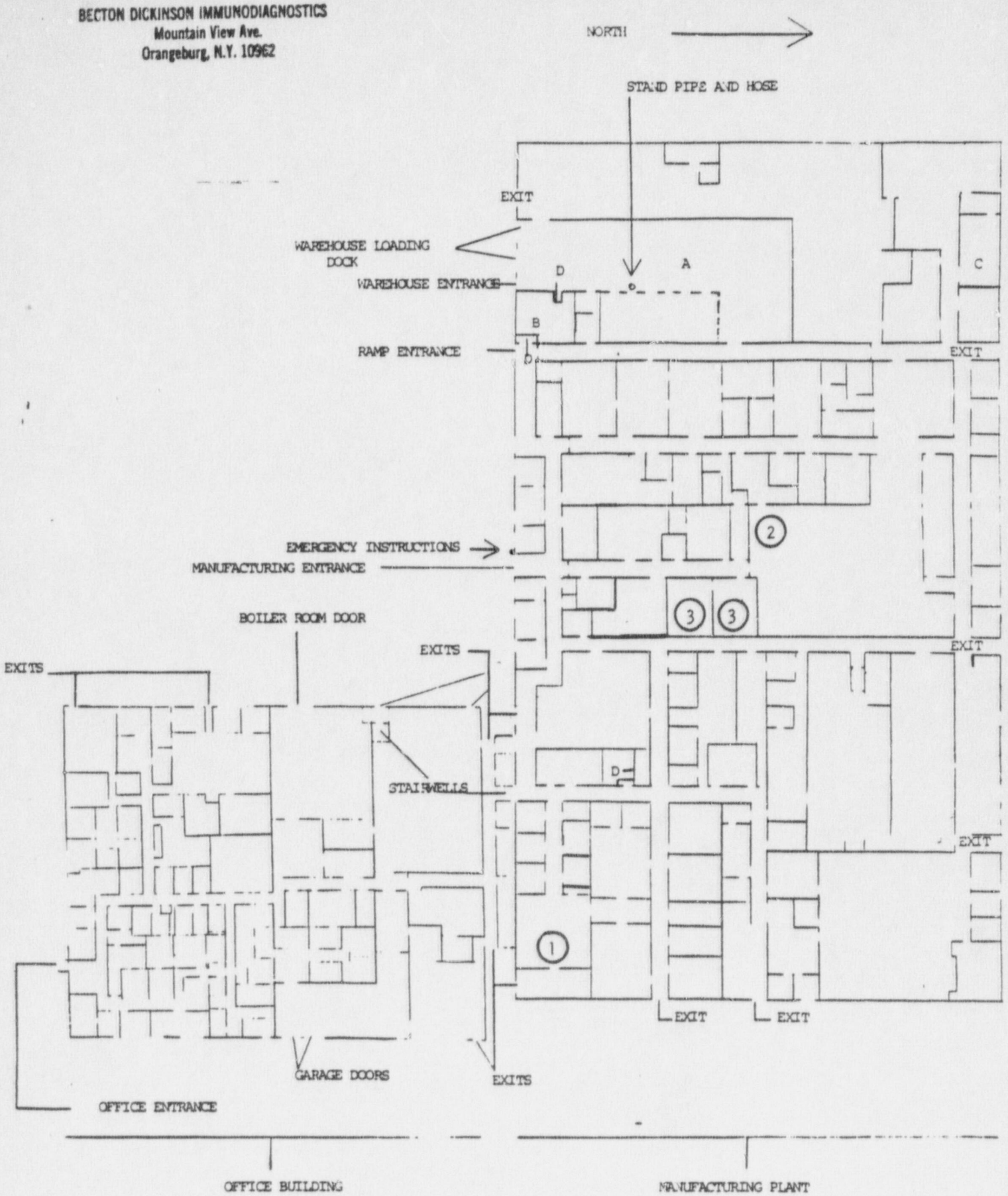
TYPE OF INSTRUMENTS (make & model number)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr) or cpm range	WINDOW THICKNESS (mg/cm^2)	USE (Monitoring, Survey, Measuring)		
C. Survey Meters	Total 3						
Warrington Laboratories	1	Alpha, Beta	0-100 mR	1.5-2		X	
Model 2652 survey meter		Gamma					
Victoreen model #440	2	Gamma	0-300 mR	1		X	
D. Rate Meters	Total 7						
Technical Associates	6	Alpha, Beta	0-500,000 cpm	1.4	X	X	
model #SML-2		Gamma	0-0.3 mR/hr	& 1.5			
Victoreen-Frisker	1	Beta, Gamma	0-500,000		X	X	
E. Isotope Calibrators	Total 3						
Capintec Incorporated	3	Gamma	Up to 2000 millicuries				X
model CRC-5							
F. Other	Total 4						
Nuclear Associates	1	Beta, Gamma	316-3160 ($cps/10^3$)	5-6	X	X	
Contamination monitor			(uci/cm^2)				
model 05-695							
Nuclear Associates	3	Gamma	0-50,000 cpm			X	
Minimonitor-125							
model #05-572							

BECTON DICKINSON IMMUNODIAGNOSTICS
Mountain View Ave.
Orangeburg, N.Y. 10962



1 = R & D Area - See Sketch # 1
2 = Gen. Area Mfg. - See Sketch # 2
3 = Mfg. Iodination Lab. - See Sketch # 3

A = WAREHOUSE
B = SOLVENT STORAGE
C = BULK STOREROOM
D = SPILL CONTAINMENT DI

SKETCH # 1

North →

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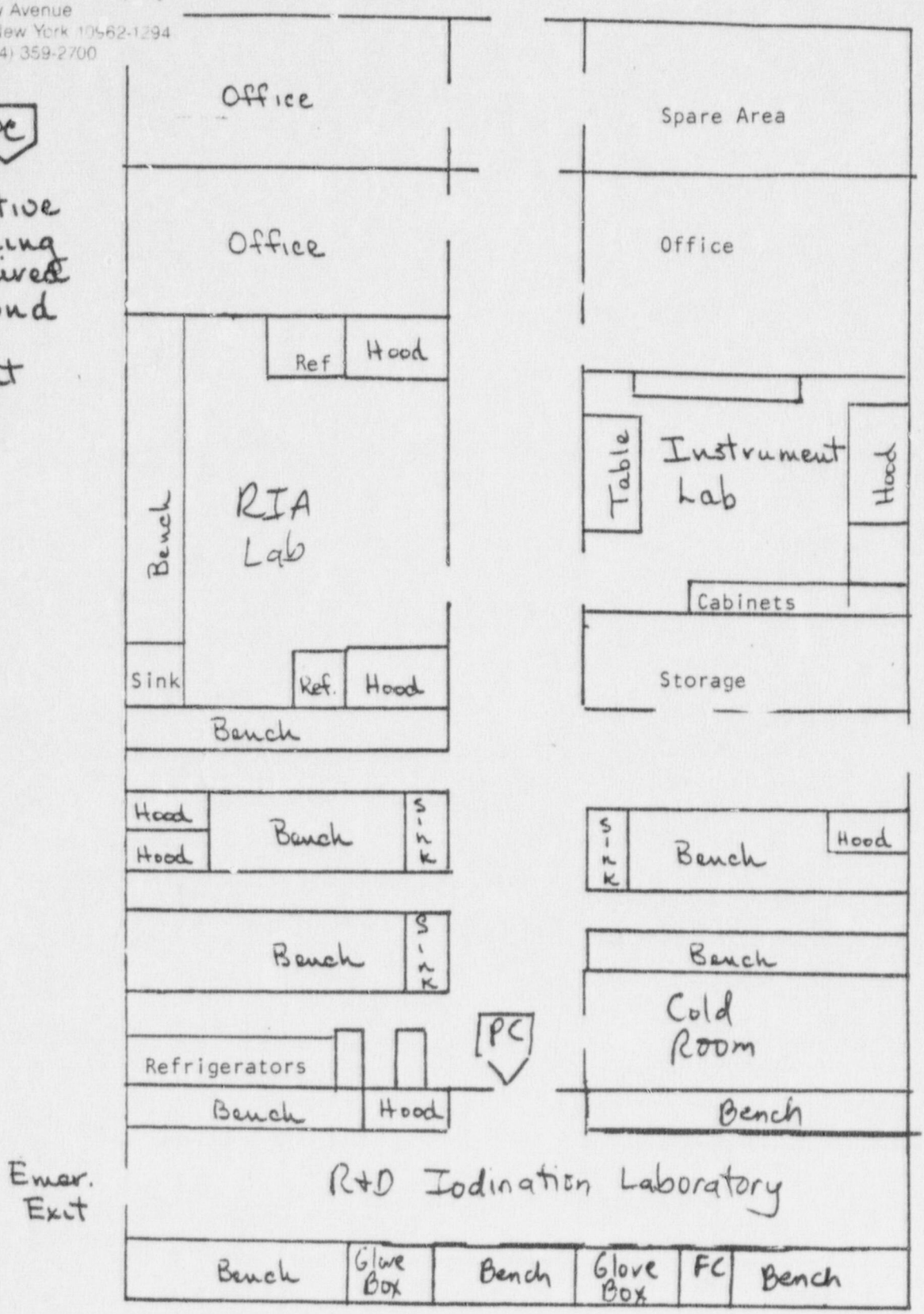
PC

Protective Clothing Required Beyond This Point



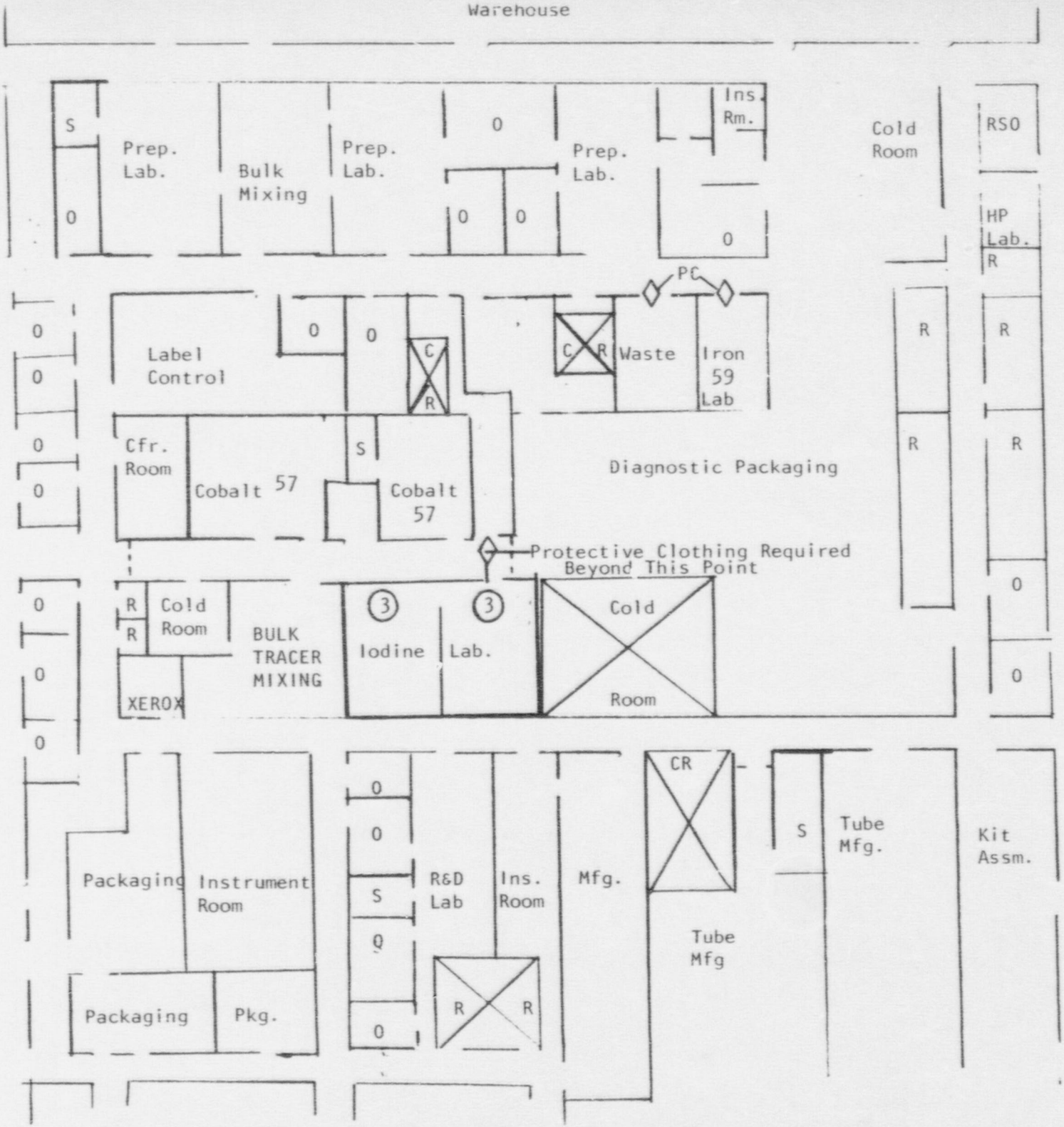
PC = Protective Clothing Required Beyond This Point

BECTON DICKINSON

SKETCH # 2

North →

O = office
CR= cold room
S = storage
R = rest room



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SKETCH # 3

North →

Becton Dickinson and Company
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Orangeburg, New York 10962-1294
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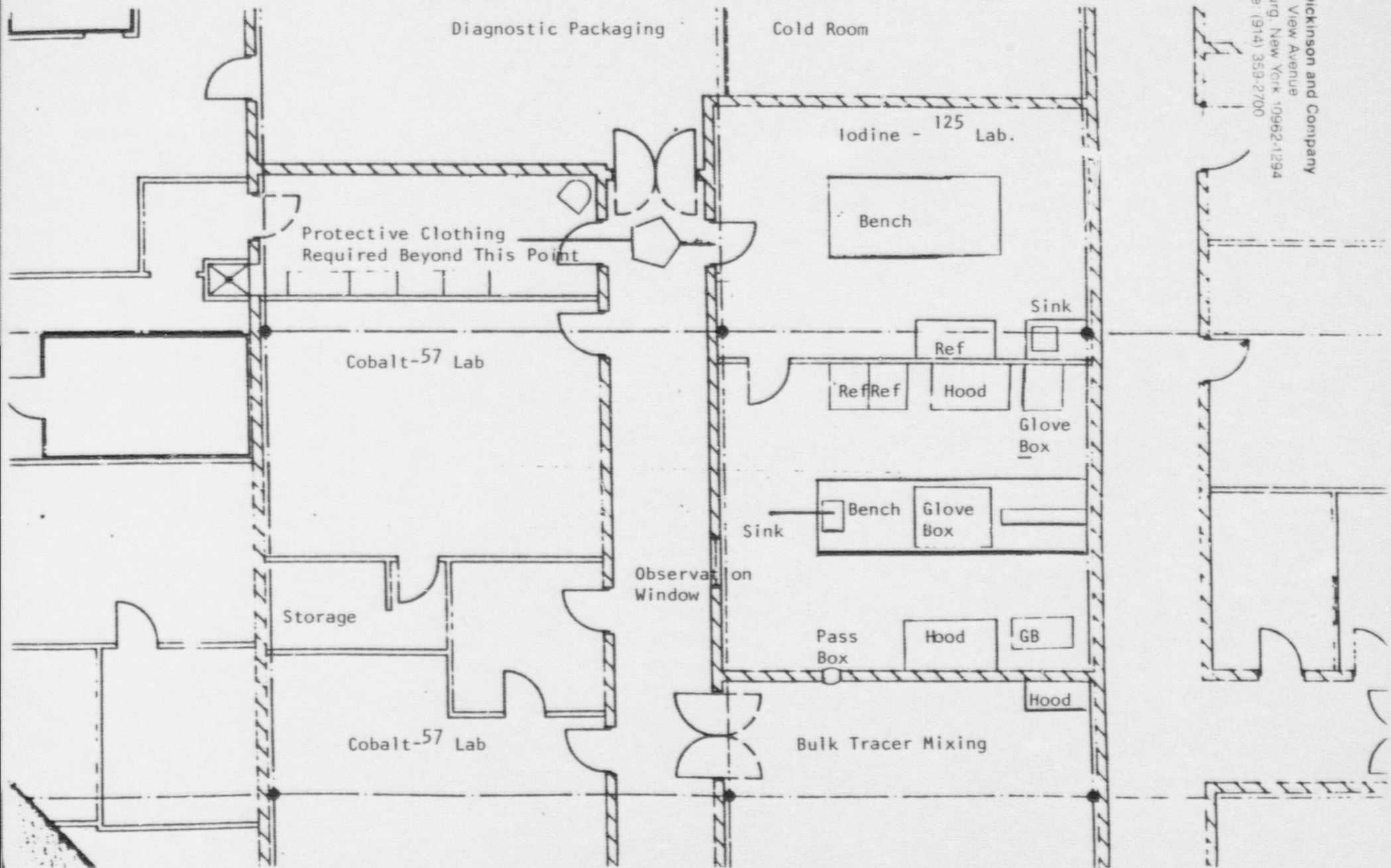

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10. Radiation Safety Program

The radiation safety of Becton Dickinson, Orangeburg, New York and its employees is maintained by the Radiation Safety and Health Physics Department whose manual is subject to approval by the New York State Department of Labor, the agency under whose auspices Becton Dickinson is permitted to operate. The following tests are performed on a routine basis by full-time health physics technician under the supervision of the Radiation Safety Officer:

1. Thyroid bioassay for Iodine-125
2. Air Sample Analyses
3. External Radiation Surveys
4. Sewer Sample Analyses
5. Surface Smears of Controlled and Uncontrolled Areas
6. Hood and Glovebox Air Flows
7. Monitoring of External Emission Points
8. Whole Body and Ring TLD Badges (outside contractor)
9. Urine, breath, and blood tests as needed

All data from these analyses are recorded and filed in the appropriate ledger as per applicable Federal and New York State regulation.

Thermoluminescence dosimeter /TLD/ Personnel Monitoring devices (whole body and ring) are provided on a monthly basis by:

Teledyne Isotopes
50 Van Buren Avenue
Westwood, New Jersey 07675

Survey meters are calibrated every 6 months by the NDL Organization, Inc., P. O. Box 791, Peekskill, New York 10566. Two Victoreen 440's and one Warrington Laboratories Model 2652 survey meters are available.

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11. Waste Management

All radioactive waste is processed at a central collection area in the Orangeburg facility which is kept locked and marked with the appropriate radioactive warnings. Radiation Safety and Health Physics Department Personnel collect all radioactive waste and insure the proper packaging of such waste for disposal.

Radioactive waste receptacles are conspicuously labelled with the appropriate warning signs and lettering.

Wastes are stored in covered steel drums inside a locked area used solely for waste purposes. Survey equipment is available to detect and measure radiation emanating from wastes.

Radioactive waste manifest records are maintained by the Radiation Safety and Health Physics Department.

Low level radioactive waste burial site use permit(s) where required will be kept on file in the Radiation Safety and Health Physics Office.

Radioactive waste generated at Becton Dickinson will be disposed of through the services of a licensed outside disposal contractor. The current contractor is the NDL Organization, Inc., P. O. Box 791, Peekskill, New York 10566.

POSITION DESCRIPTION

POSITION TITLE: SAFETY OFFICER INCUMBENT: A. DECKER

DEPARTMENT: _____ LOCATION: ORANGEBURG, NEW YORK

DIVISION: BECTON DICKINSON ORANGEBURG PLANT

GENERAL FUNCTION:

Reporting to the Plant Manager, the duties of the Safety Officer are divided into three sections: Radiation Safety, General Safety and Hazardous Waste Management.

RESPONSIBILITIES:

Radiation Safety

1. Designs and implements the Radiation Safety and Health Physics program for B-D operations at the Orangeburg facility to insure that releases and exposures are kept as low as reasonably achievable (ALARA concept).

2. Insures compliance with applicable federal, state and local regulations pertaining to procurement, possession, use, sale and disposal of radioactive materials, including discharge to the environment.

3. Provides liaison between the Company and regulatory agencies.

4. Revises, updates and maintains the Radiation Safety and Health Physics Manual to insure applicability to current operations.

5. Trains new and current employees, and procures or prepares such training aids as appropriate.

6. Maintains personnel monitoring equipment and assures its proper calibration.

7. Implements and directs such programs for personnel and environmental radiation monitoring as are required and/or appropriate.

8. Maintains personnel exposure records; informs individuals and their superiors of unacceptable exposure levels, investigates cause of overexposure and takes appropriate corrective action.

9. Supervises decontamination in case of an accident; investigates all incidents and implements safeguards and corrective actions to prevent recurrence.

10. Assists in the design of equipment or devices which will aid in the safe handling and containment of radioactive material within the facility.

11. Monitors and reviews production and test procedures to ensure safe handling of radioactive materials.

12. Maintains inventory records of radioactive material to insure compliance with licensed possession limits.

13. Develops and maintains procedures and equipment for the safe and effective storage and disposal of radioactive waste and supervises the program.

14. Provides technical expertise on matters relating to radiological safety and radiochemical technology.

15. Serves on the Radiation Safety Committee and maintains the minutes of all meetings.

16. Reviews customer or shipper complaints involving radioactive material.

17. Orders and maintains supplies of protective apparel (i.e. - shoe covers, gloves, masks, etc.) used when working with radioactive material.

18. Maintains good housekeeping in the Waste Room, Waste Processing areas, Health Physics Laboratory, and Health Physics supply area.

19. Supervises and directs the Radiochemical Waste Technician(s) in the performance of their duties.

General Safety

1. Provides liaison between the B-D operations at the Orangeburg facility and Division and Corporate on safety matters.

2. Provides liaison between the Company and regulatory agencies.

3. Maintains log of hours worked without a lost-time accident and the plant-wide posting of such hours.

4. Prepares the monthly/quarterly Summary of Industrial Injuries Report sent to Corporate

5. Serves on the Safety Committee.

6. Schedules at least two fire drills yearly.

7. Assists in the design and implementation of the safety program for B-D operations at the Orangeburg facility.

8. Assists in the development and maintenance of procedures and equipment for the safe storage of chemical supplies.

9. Assists in the training of new and current employees, including the procurement and utilization of outside resources such as pamphlets and guest speakers. This may include monthly safety movies/talks before the entire B-D Orangeburg work force.

10. Maintains the Supervisor's Accident Investigation Reports file and plays a key role in prompt accident investigation and follow-up, including physical changes and improvements where necessary.

11. Orders and maintains an appropriate supply of safety apparel (i.e. safety glasses, gloves, etc.) as needed.

12. Maintains a core of individuals certified in cardiopulmonary resuscitation (CPR) and basic first-aid.

13. Maintains first aid room and first air supplies. Dispenses such supplies when needed.

14. Maintains all fire team evacuation lists current.

Hazardous Waste Management

1. Coordinates the collection and storage of all hazardous waste materials.

2. Insures the segregation of all non-compatible waste in storage.

3. Insures compliance with hazardous waste labeling requirements.

4. Ships hazardous wastes within 90 days of entry to the storage area or accumulation of 55 gallons in any area that may be designated a satellite accumulation area.

5. Inspects the Hazardous Waste Storage area at least weekly when waste is in residence.

6. Assists in the identification of waste hazard, if any, as determined by current regulations.

7. Maintains a Material Safety Data Sheet for all materials that may become hazardous waste.

8. Signs and insures the accurate preparation of Hazardous Waste Manifests.

9. Insures the return of the manifest copy showing final disposal at the designated facility within current regulatory time frames.

10. Acts as liaison with local Fire, Police and other emergency response units.

11. Updates the Facility Contingency Plan as required to keep emergency coordinator and equipment lists current.

12. Attends a formal Compliance Management Course on the applicable regulations regarding the safe disposal of hazardous wastes on a bi-annual basis with certification to be kept on file in Human Resources.

13. Annual review of the initial training will occur as permitted in-house by:

    a. Subscribe to the Bureau of National Affairs Chemical Substances and Control updating service.

    b. Reviews at least on a bi-annual basis, alternate with the bi-annual course attendance, the Contingency Plan, EPA and N.Y.S. DEC regulations. A signed statement indicating review dates will be kept on file in Human Resources.

14. Trains designated facility personnel in-house as required.

POSITION REQUIREMENTS

A. Knowledge and Experience

B.S. or M.S. in the physical or biological sciences or in safety engineering or health physics, plus three years experience working with radionuclides.

B. Supervision

Directly supervises 1-2 Radiochemical Waste Technicians

C. Training

Any new individual assigned the responsibility for hazardous waste management will not work unsupervised until formal training has been received. Formal training is to take place within six months of responsibility assignment.

ACCOUNTABILITY

A. Compliance of the Orangeburg site to environmental regulations.

B. Implementation of location safety programs.

PREPARED BY: _____ DATE: 7/13/88

APPROVED BY: _____ DATE: 7/17/88