FORM NRC-313 I (3-80) 10 CFR 30

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE
INDUSTRIAL

See attached instructions for details.

Completed applications are filed in duplicate with the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety, and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 or applications may be filed in person at the Commission's office at 1717 H Street, NW, Washington, D. C. or 7915 Eastern Avenue, Silver Spring, Maryland.

1. APPLICATION FOR: *(Check and/or complete as appropriate)*

	a. NEW LICENSE
X	b. AMENDMENT TO LICENSE NUMBER 20-06799-02
	c. RENEWAL OF LICENSE NUMBER

2. APPLICANT'S NAME *(Institution, firm, person, etc.)*
CAMBRIDGE MEDICAL DIAGNOSTICS, INC.
TELEPHONE NUMBER: AREA CODE – NUMBER EXTENSION
617-935-4050

3. NAME AND TITLE OF PERSON TO BE CONTACTED REGARDING THIS APPLICATION
Edward G. Fitzgerald Pres.
TELEPHONE NUMBER: AREA CODE – NUMBER EXTENSION
617-935-4050 ex. 10

4. APPLICANT'S MAILING ADDRESS *(Include Zip Code)*
(Address to which NRC correspondence, notices, bulletins, etc., should be sent.)
P.O. Box 88
575 Middlesex Turnpike
Billerica, Mass. 01865

5. STREET ADDRESS WHERE LICENSED MATERIAL WILL BE USED *(Include Zip Code)*
575 Middlesex Turnpike
Billerica, Mass. 01865

(IF MORE SPACE IS NEEDED FOR ANY ITEM, USE ADDITIONAL PROPERLY KEYED PAGES.)

6. INDIVIDUAL(S) WHO WILL USE OR DIRECTLY SUPERVISE THE USE OF LICENSED MATERIAL
(See Items 16 and 17 for required training and experience of each individual named below)

FULL NAME
a. See Attachment A
b.
c.

RECEIVED BY LFMB
Date 4/22/85
Log April 10 I
By Brown
Orig. To
Action Compl.

Applicant TITLE
Check No. 3808 4/20/85
Amount Fee Category
Type of Fee Amendment
Date Check Rec'd 4/22/85
Received By Brown

7. RADIATION PROTECTION OFFICER
Stephen R. Szczepanik
Sandra Fan

Attach a resume of person's training and experience as outlined in Items 16 and 17 and describe his responsibilities under Item 15.
See Attachment B

8. LICENSED MATERIAL

LINE NO.	A ELEMENT AND MASS NUMBER	B CHEMICAL AND/OR PHYSICAL FORM	C NAME OF MANUFACTURER AND MODEL NUMBER *(If Sealed Source)*	D MAXIMUM NUMBER OF MILLICURIES AND/OR SEALED SOURCES AND MAXIMUM ACTIVITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME
(1)	See Attachment C			
(2)				
(3)				
(4)				

	E DESCRIBE USE OF LICENSED MATERIAL
(1)	See Attachment C
(2)	
(3)	
(4)	

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APR 16 1985

9. STORAGE OF SEALED SOURCES

LINE NO.	CONTAINER AND/OR DEVICE IN WHICH EACH SEALED SOURCE WILL BE STORED OR USED. A.	NAME OF MANUFACTURER B.	MODEL NUMBER C.
(1)	Auto-Gamma Counter	Searle Analytic	1190
(2)	Auto-Gamma Counter	Tracor	1285
(3)	Auto-Gamma Counter	Micro-Medic	
(4)	Multichannel Analyser	Nuclear-Data Inc.	ND-60

10. RADIATION DETECTION INSTRUMENTS

LINE NO.	TYPE OF INSTRUMENT A	MANUFACTURER'S NAME B	MODEL NUMBER C	NUMBER AVAILABLE D	RADIATION DETECTED (alpha, beta, gamma, neutron) E	SENSITIVITY RANGE (milliroentgens/hour or counts/minute) F
(1)	See Attachment D					
(2)						
(3)						
(4)						

11. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10

☒ a. CALIBRATED BY SERVICE COMPANY

NAME, ADDRESS, AND FREQUENCY
Nuclear Instrument Company
45 Grove Street
Rockland, Mass. 02370 6 Months

☐ b. CALIBRATED BY APPLICANT

Attach a separate sheet describing method, frequency and standards used for calibrating instruments.

12. PERSONNEL MONITORING DEVICES

TYPE (Check and/or complete as appropriate.) A	SUPPLIER (Service Company) B	EXCHANGE FREQUENCY C
☐ (1) FILM BADGE ☒ (2) THERMOLUMINESCENCE DOSIMETER (TLD) ☐ (3) OTHER (Specify): _____	Eberline Instrument Corp. P.O. Box 2108 Santa Fe, N.M. 87501	☐ MONTHLY ☒ QUARTERLY ☐ OTHER (Specify): _____

13. FACILITIES AND EQUIPMENT (Check were appropriate and attach annotated sketch(es) and description(s).

☒ a. LABORATORY FACILITIES, PLANT FACILITIES, FUME HOODS (Include filtration, if any), ETC.
☒ b. STORAGE FACILITIES, CONTAINERS, SPECIAL SHIELDING (fixed and/or temporary), ETC.
☐ c. REMOTE HANDLING TOOLS OR EQUIPMENT, ETC.
☒ d. RESPIRATORY PROTECTIVE EQUIPMENT, ETC. See Attachment E

14. WASTE DISPOSAL

a. NAME OF COMMERCIAL WASTE DISPOSAL SERVICE EMPLOYED
Interex Corp.

b. IF COMMERCIAL WASTE DISPOSAL SERVICE IS NOT EMPLOYED, SUBMIT A DETAILED DESCRIPTION OF METHODS WHICH WILL BE USED FOR DISPOSING OF RADIOACTIVE WASTES AND ESTIMATES OF THE TYPE AND AMOUNT OF ACTIVITY INVOLVED. IF THE APPLICATION IS FOR SEALED SOURCES AND DEVICES AND THEY WILL BE RETURNED TO THE MANUFACTURER, SO STATE.

INFORMATION REQUIRED FOR ITEMS 15, 16 AND 17

Describe in detail the information required for Items 15, 16 and 17. Begin each item on a separate page and key to the application as follows:

15. RADIATION PROTECTION PROGRAM. Describe the radiation protection program as appropriate for the material to be used including the duties and responsibilities of the Radiation Protection Officer, control measures, bioassay procedures *(if needed)*, day-to-day general safety instruction to be followed, etc. If the application is for sealed source's also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.

16. FORMAL TRAINING IN RADIATION SAFETY. Attach a resume for each individual named in Items 6 and 7. Describe individual's formal training in the following areas where applicable. Include the name of person or institution providing the training, duration of training, when training was received, etc.

    a. Principles and practices of radiation protection.

    b. Radioactivity measurement standardization and monitoring techniques and instruments.

    c. Mathematics and calculations basic to the use and measurement of radioactivity.

    d. Biological effects of radiation.

17. EXPERIENCE. Attach a resume for each individual named in Items 6 and 7. Describe individual's work experience with radiation, including where experience was obtained. Work experience or on-the-job training should be commensurate with the proposed use. Include list of radioisotopes and maximum activity of each used.

18. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 2, certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Part 30, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our 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.

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)* $120.00	b. CERTIFYING OFFICIAL *(Signature)*
	c. NAME *(Type or print)* Stephen H. Szczepanik
(1) LICENSE FEE CATEGORY: Amendment 10 CFR 170.31 3B	d. TITLE Radiation Safety Officer
(2) LICENSE FEE ENCLOSED: $ 120.00	e. DATE

FORM NRC-313 I (3-80)

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: Cambridge Medical Diagnostics, Inc.

Application Dated: 4/4/85

Control No.: 03679

License No.: 20-06799-02

2. FEE ATTACHED

Amount: $120.00

Check No.: 3805

3. COMMENTS

Signed Brenda Platchek

Date 4/17/85

03 ✓ 1/90 03214

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 3B #120

2. Correct Fee Paid. Application may be processed for:

Amendment ✓

Renewal _____

License _____

Signed Maureen Brown

Date 4/22/85 4/25/85

REGION I FORM 213
(MARCH 1983)

CAMBRIDGE
Medical Diagnostics, Inc.

CAMBRIDGE MEDICAL DIAGNOSTICS, INC.

Billerica, Massachusetts

AMENDMENT TO BYPRODUCT MATERIAL LICENSE

Number 20-06799-02

March 1985

575 Middlesex Turnpike • Billerica, MA 01865 • (617) 935-4050 • TWX: 710-347-1849 • (800)-225-0850

ATTACHMENT A

Individuals who will use or directly supervise the use of licensed material

Name	Title
Edward G. Fitzgerald	President
Stephen H. Szczepanik	Radiation Safety Officer
Sandra L. Fan	Radiation Safety Officer
Carole L. Varanelli	Operations Manager
Alan J. Weiss	Research & Development Manager
Maureen M. McLaughlin	QC Supervisor
Judith A. Amelotte	Antibody Supervisor
Susan J. Monahan	Production Technologist
Jonathan R. Kava	Production Technologist
Susan A. Farbotko	Product Support Supervisor
Susan W. Savoie	Antibody Production
Judith A. Davis	QC Technologist
Carole A. Gifford	QC Technologist
Pamela F. Williams	QC Technologist
Shelley R. Barnicle	R&D Technologist
Marie A. Chiaramida	Lab Support Supervisor
Micheal E. Theberge	Production Technologist

Information of personnel supplied on Attachment B including resumes.

16. FORMAL TRAINING IN RADIATION SAFETY

ATTACHMENT B

Personnel Training and Experience

ATTACHMENT B

Formal Training in Radiation Safety

Name	Type of Training*	Where	Duration	Job	Course
Edward G. Fitzgerald	a-b-c-d	University of Lowell	1½ years	Yes	Yes
	a-b-c-d	Cambridge Medical	11 years	Yes	Yes
Stephen H. Szczepanik					
	a-b-c-d	New England Nuclear	3 months	Yes	No
	a-b-c-d	Cambridge Medical	4½ years	Yes	No
	a-b-c-d	Univ. of Lowell	2 weeks	No	Yes
Sandra L. Fan	a-c-d	Yankee Atomic Environmental Lab	6 months	Yes	No
Carole L. Varanelli	a-b-c-d	Worc. Found. Exp. Bio.	2½ years	Yes	No
	a-b-c-d	McLean Hospital	3 years	Yes	Yes
	a-b-c-d	Clin-chem Labs	3 years	Yes	No
	a-b-c-d	Cambridge Medical	3½ years	Yes	No
Alan J. Weiss	a-b-c-d	Interlab Associates	1 year	Yes	No
	a-b-c-d	Cambridge Nuclear Corp	4 years	Yes	No
	a-b-c-d	Bioran	2 years	Yes	No
	a-b-c-d	Cambridge Medical	2 years	Yes	No
Judith A. Amelotte	a-b-c-d	McLean Hospital-Harvard	6 years		Yes
		McLean Hospital-Harvard	10 years	Yes	No
	a-b-c-d	Cambridge Medical	3 years	Yes	No
Maureen M. McLaughlin					
	a-b-c-d	Cambridge Medical	2 years	Yes	No
Shelley R. Barnicle	a-b-d	New England Med. Labs	3½ years	Yes	No
	a-b-c-d	Cambridge Medical	2 years	Yes	No
Marie A. Chiaramida	a-b-c-d	Cambridge Medical	3 years	Yes	No
Susan A. Farbotko	a-b-c-d	Cambridge Medical	1 year	Yes	No
Susan J. Monahan	a-b-c-d	Cambridge Medical	1 year	Yes	No
Jonathan R. Kava	a-b-c-d	Cambridge Medical	1 year	Yes	No
Judith A. Davis	a-b-c-d	Cambridge Medical	1 year	Yes	No
Carol A. Gifford	a-b-c-d	Cambridge Medical	1 year	Yes	No
Pamela F. Williams	a-b-c-d	Cambridge Medical	2 months	Yes	No
Susan W. Savoie	a-b-c-d	Cambridge Medical	2 months	Yes	No

*Type of Training

a). Principle and Practices of Radiation Protection

b). Radioactivity measurement standardization and monitoring techniques and instruments.

c). Mathematics and calculations basic to the use and measurement of radioactivity.

d). Biological effects of radiation.

17. EXPERIENCE

Edward G. Fitzgerald

Education:

Boston College, Chestnut Hill, MA. - BS Physics 1975
(Minors: Math and Biology)
Lowell University, Lowell, MA.- MS Applied Physics 1977
(Recipient of a full scholarship)
(Concentration on Health Medical and Nuclear Physics)

Experience:

Equipment - Multichannel Analyzer, Single Channel Analyzer, Auto Gamma Spectrometer, Radiochromatographic Scanner, Scintillation Detectors, Solid State Detectors, Van de Graaff Accelerator, Laminar Flow Hood, Centrifuge, All Nuclear Detection Instrumentation and Lyophilization.

Product - Responsible for production of In-Vitro kits for DTPA, HSA, MAA and Microspheres and formulating IND's for FDA approval. Conducted research and development on iodination procedures and RIA on peptide hormones. These hormones include: PTH, Glucagon, TSH, FSH, LH, HGH, Gastrin, Prolactin, HCG_B, HCG, HPL, T_3 and T_4. Initiated and directed an 8 month study on the lyophilization of biologicals used in RIA kits.

Work - Cambridge Nuclear Corporation, Billerica, Massachusetts

June'72-Dec.'76 Technician: Work performed during this time was on a part-time basis. Responsibilities included Health Physics and packaging of radiopharmaceutical products.

Jan.'77-Present Manager: Operations Manager - responsibilities include the management of production, quality control, health physics and research and development.

Vice President of Cambridge Nuclear Corporation and Vice President of Cambridge Nuclear Radiopharmaceutical Corp. since 1978.

Executive Vice President of Cambridge Nuclear Corporation and Executive Vice President of Cambridge Medical Diagnostic, Inc. since 1980.

Publications:

"A Proton-Recoil Telescope Utilizing a 900mm^2 Silicon Surface Barrier Detector and Tubular Collimators" --- March 1977

(A paper was presented on the experimental portion of this work at the Spring 1977 meeting of the American Physical Society).

Stephen Henry Szczepanik

Education:

University of Massachusetts, Amherst
Bachelor of Science in Zoology, Class of 1979
Magna Cum Laude G.P.A. 3.54 out of 4.00
Departmental Honors in Zoology

Graduate Level Courses at the University of Lowell
Radiological Sciences and Protection
Biological Sciences

Phillips Academy, Andover, Massachusetts
Graduating Class of 1975

Experience:

1978 to 1979 — Honors thesis research at the University of Massachusetts
Analysis of ribosomal temperature adaptation using tritiated amino acids

6/79 to 8/79 — Laboratory Technologist
New England Nuclear, Billerica, Massachusetts
Processing Gallium and Thallium in a "hot cell".

9/79 to 6/80 — High school biology/physiology teacher
Keith Hall, Lowell, Massachusetts

8/80 to 6/82 — Laboratory Technologist
Cambridge Nuclear Corporation, Billerica, Massachusetts

6/82 to 12/83 — Radiation Safety Officer
Cambridge Medical Diagnostics, Billerica, Massachusetts

1/84 to Present — Radiation Safety Officer/Production Supervisor
Cambridge Medical Diagnostics, Billerica, Massachusetts

Carole C. Varanelli

Education:

September, 1966 - January, 1970
B.A. Zoology
University of Maine
Orono, Maine

January, 1970 - January, 1972
M.S. Zoology
University of Maine

Thesis Title: Locomotor Activity of Atlantic Salmon Parr (*Salmo salar* L.) in Various Light Conditions and in Weak Magnetic Fields.

Stipend Awards: National Science Foundation Research Assistant 1970-1972

Honorary Societies: Phi Beta Kappa
Phi Kappa Phi
Neai Methetai

Experience:

July 1981 to Present — Cambridge Nuclear Corporation, Billerica, Massachusetts
RIA/R&D Supervisor
Manager of Quality Assurance

Oct. 1978 to July 1981 — Clin-Chem Laboratories, Boston, Massachusetts
Asst. Supervisor Radioassay Laboratory

May 1975 to Oct. 1978 — McLean Hospital, Belmont, Massachusetts
Senior Research Assistant - under Dr. James Ellingboe
Alcohol and Drug Abuse Research Center

Oct. 1972 to May 1975 — Worcester Foundation for Experimental Biology, Shrewsbury, MA.
Research Assistant - under Dr. Sumner Burstein

Jan. 1970 to March 1972 — University of Maine, Orono, Maine
Research Assistant - under Dr. James McCleave
Department of Zoology

Alan Joseph Weiss

Education:

PhD Candidate - Boston University School of Medicine
Biochemistry Boston, Massachusetts

September 1979 to present
Expected date of completion: January 1984

Bachelor of Science - University of Miami
Biology Coral Gables, Florida

Departmental Honors, Cum Laude 1975

Bachelor of Science - University of Miami
Coral Gables, Florida

Cum Laude, 1975

Experience:

Jan. 1982 to Present — Cambridge Medical Diagnostics, Billerica, Massachusetts
(Part Time) Research and Development Assistant
Development of RIA kits and components.

9/1980 - 1/1982 — Bioran, Cambridge, Massachusetts
(Part Time) Clinical Laboratory Technologist
Clinical analysis of laboratory specimens by RIA and CPB.

9/1979 to 9/1980 — Cambridge Nuclear Corporation, Billerica, Massachusetts
(Part Time) Research and Development Assistant
Development of RIA kits and components.

7/1976 - 9/1979 — Cambridge Nuclear Corporation, Billerica, Massachusetts
RIA Supervisor
Development and production of RIA kits and components.

5/1975 - 7/1976 — Interlab Associates, Miami, Florida
Laboratory Technologist
Clinical analysis of laboratory specimens by RIA and CPB.

Judith Ann Amelotte

Education:	Boston University - Bachelor of Arts in Biology
Experience:	Cambridge Medical Diagnostics, Inc., Billerica, Massachusetts
1/1982 - 7/1982	Laboratory Technologist
7/1982 - Present	Immuno Technologist (Antibody R&D) Responsibilities consist of supervising maintenance of animal facilities; providing health care for the animals; antiserum production, immunization, harvesting of blood and processing of serum; antiserum characterization; preparation of antiserum for distribution; antserum inventory control.
1977 to Present	Star Graphics (personally owned business) Graphic and scientific illustrations for professional presentation or publication.
1974 - 1981	Dr. Alfred Pope, Director Ralph Lowell Laboratories McLean Hospital, Belmont, Massachusetts For the Lowell Laboratories: Responsible for maintaining general supply inventory; maintaining equipment in good repair; trouble shooting breakdowns; and training technicians and fellows in proper equipment usage. Safety Officer 1976 to 1981, responsible for biannual safety inspections and advising personnel in safe laboratory practices. For Dr. Pope: Responsible for organizing the design, execution and analysis of experiments in enzyme analysis of neurological material; familiar with histological techniques as applied to neuropathology, photomicroscopy, ion exchange and thin layer chromatography, some gel electrophoresis and elementary glass blowing.
1973 to 1974	Dr. James Ellingboe Alcohol and Drug Abuse Research Center McLean Hospital and Harvard Medical School, Belmont, Mass. Responsible for the radioimmunoassay of testosterone, cortisol and morphine; including collaboration in the development of the morphine assay as used in the laboratory.
1968 - 1973	Dr. Larry J. Embree
1971 - 1973	Harvard Medical School, Boston, Massachusetts
1968 - 1971	Biological Research Laboratory, McLean Hospital, Belmont, MA. Responsible for the micro-biochemical quantitative analysis of neurological material, including the complete processing of tissue for the following methods: RNA, DNA, gangliosides, cerebrosides, cholesterol, phospholipids, proteolipid protein and total protein as well as enzyme (ATPase) determinations. Assisted in developing microadaptions of the following methods: Hexosamine, hexose, resorcinol-HCl for sialic acid, fluorodinitrobenzene method for sphingosine.

Shelley R. Barnicle

Education:	Lasell Junior College - Associates Degree in Science A.S.C.P. Certification - February 1982
Experience:	Cambridge Medical Diagnostics, Inc., Billerica, Massachusetts
2/1983 to Present	Research & Development Technologist Development of RIA kits and procedures.
5/1980 - 1983	Laboratory Technician - New England Medical Laboratories Troubleshooting and evaluation of RIA kits. Radioactive waste control and urinalysis.
1977 - 1980	Physical Science Aide - U.S. Natick Army Laboratories Researching food products for the armed forces.
Summer 1976	Nurses Aide - Walden House Health Care

Maureen A. McLaughlin

Education:	Boston College 1981 - Bachelor of Science in Biology/English
Experience:	Cambridge Medical Diagnostics, Inc., Billerica, Massachusetts
1/1983 to Present	Laboratory Technologist
	Iodination of antigens for research and diagnostic kits. Production of components for RIA kits.
1980 - 1981	Day Camp Director
	Supervision of camp staff
1977 - 1980	Chemistry Assistant
	Work/study in chemistry department at Boston College
Summer 1980	Clinical Research Center Aide
	Childrens Hospital Medical Center, Boston, MA. Medical research aide.

Marie Chiaramida

Education:	Fitchburg State College, Fitchburg, Massachusetts Bachelor of Science in Biology, May 1981
Experience:	
Sept. 1981 to Present	Cambridge Nuclear Corporation, Billerica, Massachusetts Laboratory Technician
Sept.-May 1981	Nashua River Watershed Association, Fitchburg, Mass. Environmental Science Internship Compiled a recreational land use and topographic inventory of major segments of the Nashua River and its tributaries. Major responsibilities included surveying segments of the Nashua River, propose recreational facilities, diagram proposals, and develop charts.
June-July 1979	Bon Secour Hospital, Methuen, Massachusetts Volunteer in Histology Laboratory - Duties included secretarial work in laboratory office and assistant to Medical Technician in Histology lab in which responsibilities entailed preparing and filing tissue slides.
July-Aug. 1980	Recreation Department, Town of Methuen, Methuen, Mass. Playground supervisor that required the ability for leadership and disciplinary action.
Extracurricular Activities	Chairperson of Townhouse Board of Governors Vice-President of Biology Club Member of Student Government Association Member of Student Government Finance Committee Member of Alumni Association Nominated for Outstanding Senior Award in Biology

The following technologists are receiving on-the-job training in the use of radioisotopes. They will work under close supervision until deemed proficient in the use of radioisotopes by the Radiation Safety Officer.

Susan J. Monahan	Springfield College, Springfield, MA 1983 B.S. Biology
Susan A. Farbotko	LaSalle Jr. College 1980 Associates Degree; Medical Lab. Technician Previous experience: RIA at Harvard Community Health Services
Jonathan R. Kava	McGill University, Montreal, Quebec 1984 B.S. Biology Coursework on radiation effects
Judith A. Davis	Ithaca College, Ithaca, NY 1983 B.A. Chemistry
Carol A. Gifford	University of Lowell, Lowell, MA 1983 B.S. Biology
Pamela F. Williams	Middlesex Community College, Bedford, MA 1978 Associates Degree Medical Lab. Technician
Susan W. Savoie	University of New Hampshire, Durham, NH 1984 B.S. Animal Science
Michael E. Theberge	University of New Hampshire, Durham, NH 1984 B.S. Biology

ATTACHMENT C

Element and Mass Number	Chemical and/or Physical Form	Name of Manufacturer	Maximum Amount that Licensee May Possess at Any Time Under This License
Molybdenum-99 Metastable state Technetium-99	Any Form	Union Carbide General Electric	5000 mCi
Iodine - 131	Any Form	Union Carbide Chalk River, Amersham	5000 mCi
Iodine - 125	Any Form	Amersham Chalk River or Union Carbide	5000 mCi
Xenon - 133	Any Form	Union Carbide, Chalk River	5000 mCi
Cobalt - 60	Sealed Source	New England Nuclear	1 mCi
Cesium - 137	Sealed Source	New England Nuclear	1 mCi
Iodine - 129	Sealed Source	New England Nuclear	1 mCi

Items cited above in Attachment C (and referring to Section 8 of the license application) will be used for processing, labeling and for distribution to Authorized Recipients.

Sealed sources above will be used for instrument calibrations.

Items cited above in Attachment C (and in Section 8) will be used for production, research and development as defined in part 30 title 10 code of Federal Regulations.

ATTACHMENT D

Radiation sensitive instruments available at Cambridge Medical

Diagnostics for use in the laboratory:

TYPE	DESIGNATION	RANGE	NUMBER OF INSTRUMENTS ON HAND
Geiger	Eberline E-120	0-50 mR/hr	2
* Ionization Chamber	Cutie Pie	0-2.5 R/hr	1
Portable Ion Chamber	Eberline PIC 3	0-1000 mR/hr	1
Portable Ion Chamber	Eberline PIC 6A	0-1000 R/hr	1
Radiation Monitor MR15	Eberline (4 ranges)	0-500 KCPM (2 ranges)	1
Radiation Monitor	Eberline (4 ranges) (Plutonium Probe)	0-500 KCPM	1
Radiation Monitor MR14	Eberline (3 ranges)	0-50 KCPM	1
Area Monitor	Victoreen	0-100 mR/hr	1
Surface Monitor	TA TBM-3	0-15 mR/hr	2
Radiation Monitor	Ludlam 16	0-500 KCPM	1

* Not in use- standby only.

All of the above instruments will be calibrated on a half-year basis using standard procedures.

In addition:

1) Auto gamma counters with teletype
   a. Searle analytic
   b. Micromedic
2) Radioisotopic Calibrator Capintec
3) Spectrophotometer Bausch & Lomb
4) Single Channel Analyser Hamner
5) Single Channel Analyser Ludlam
6) Thyroid Cannon
7) Multi Channel Analyser
8) Auto gamma counter Traycor

ATTACHMENT E

13.0 Facilities and Equipment

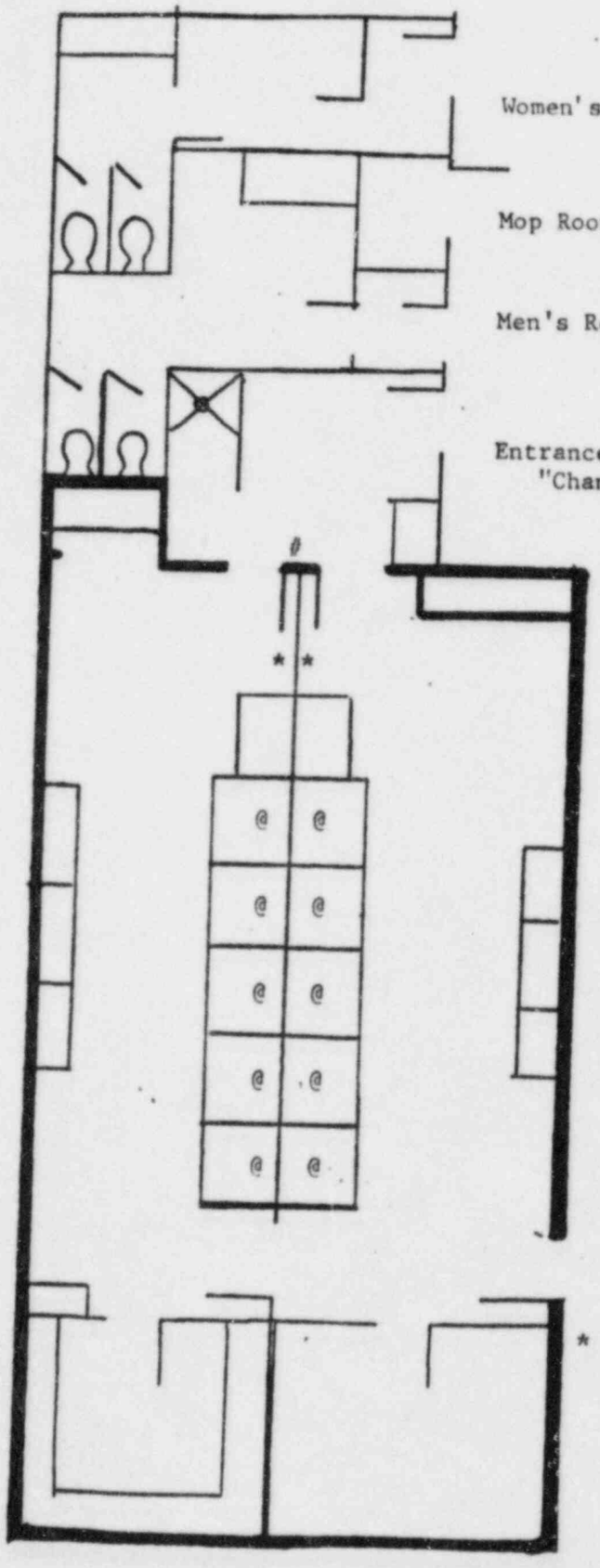
13(a) Laboratory Facilities and Hoods

13(b) Effluent Systems and Storage Facilities

13(c) Respiratory Protective Equipment

ATTACHMENT E (13a)

Red Zone and Change Area



ATTACHMENT E 13(b)

Effluent Systems and Storage Facilities

Ventilation:

The required air-flow pattern in the building has been so designed to coincide with the radiation and contamination control area. The air-flow pattern is established so that the Green or unrestricted area is the most positive and the Red or restricted area is the least positive with respect to air pressure (i.e., Green Zone air flow, to Yellow to Red; Red Zone air is exhausted). Thus, any air flow into the building is exhausted primarily through the hoods and plenums which comprise the radioactive effluent exhaust, and partially through chemical fume exhaust. The animal room is provided with its own air-handling system to prevent any animal odors from intruding into the rest of the building. Air-flow measurements are made daily with a velometer at the interfaces of the Green-Yellow Zone and Yellow-Red Zone. A colored thin paper strip is continuously visible at each of these barriers and magnahelic gauges are located at the Green-Yellow Zone barrier and at the Yellow-Red Zone barrier. All employees have been instructed to inform the Health Physicist if any of the air flow is not proper. Each employee has been informed of the proper air flow. In addition, if the air flow system fails, a light indicator will go on at the RSO or Health Physics office to indicate a problem in the ventilation system.

Radioactive Effluent Exhaust System:

a. Iodine System:

The radioactive effluent exhaust system consists of the following components: fume hoods, glove boxes, pre-filters, absolute particulate filters, and activated charcoal filters. The pre-filters, absolute filters and charcoal filters are housed in a stainless steel caisson on the roof of the building. The system is equipped with two blowers, each capable of 6400 CFM. One blower is for normal operation, the second provides 100 percent, automatic backup. Alarming devices signal the system status.

b. Filter Performance Monitoring:

The exhaust system is equipped with an isokinetic air sampling device and activated charcoal filters to continuously monitor the stack filter

performance. Sampling is normally continuous. In the event of equipment failure, sufficient parts are available so that sampling will not be interrupted for more than 8 hours during the normal work week.

Liquid Waste:

All contaminated liquids shall be absorbed in the appropriate absorbant material, packaged and transferred to Health Physics for proper disposal with contaminated waste.

Solid Waste Storage Area:

The solid waste storage area is located in a separate building behind the main building. The area consists of a cement-block building surrounded by a chain-link fence. There is a double door entry into the building which is provided with lead shielding on the interior surface of the inner door to prevent radiation streaming when radioactive waste is in storage. The building has a capacity to provide approximately 6 months accumulation of solid waste at the present operating levels. The building entry and fence are both supplied with locks and the area is posted as a restricted area.

ATTACHMENT E 13(c)

RESPIRATORY PROTECTIVE EQUIPMENT

1. RaDeco Large Volume Air Filter
   Charcoal disc filters

2. M.S.A. Respirators
   Vapor & particulate filter

3. M.S.A. Personal Air Monitors
   Charcoal disc filters

15. RADIATION PROTECTION PROGRAM

The Radiation Protection Program of Cambridge Medical Diagnostics, Inc. is descibed in the Radiation Safety Manual which is included in this License Renewal Application as item number 15.

CAMBRIDGE MEDICAL DIAGNOSTICS, INC.

Billerica, Massachusetts

RADIATION SAFETY MANUAL

Eighth Revision

February 1985

First Edition - 1967
First Revision - October 1969
Second Revision - September 1974
Third Revision - September 1976
Fourth Revision - September 1980
Fifth Revision - July 1981
Sixth Revision - June 1982
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Chairman, Radioisotope Committee

PREFACE

This Radiation Safety Manual sets forth rules and recommended procedures relative to Radiation Safety and Radioisotope Control at Cambridge Medical Diagnostics, Inc. Laboratories. The rules and procedures were promulgated so as to be consistent with the applicable requirements of the Byproduct Materials License which is issued by the U. S. Nuclear Regulatory Commission. Since adherence to the above license requirements does not necessarily insure an adequate radiation safety program, additional requirements are also specified in order to limit both external and internal radiation exposures to desirable levels. Therefore, all personnel must become thoroughly familiar with and adhere to the manual's requirements.

The contents of this manual are approved by the CMD Radiation Safety Committee and any proposed changes must be approved by this Committee before adoption.

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CMD RADIATION SAFETY MANUAL

SECTION I - INTRODUCTION

A. POLICY

The basic responsibility for radiation safety and for adherence to applicable Federal and State regulations and requirements lies with the General Manager. However, it is a fundamental policy at CMD that this responsibility be shared directly with all supervisory personnel. Therefore, each supervisor is responsible for administering his work effort to insure that personnel under his jurisdiction are thoroughly familiar with and adhere to the requirements of this manual and that applicable Federal and State regulations and requirements are complied with. Another fundamental policy at CMD is that personal safety must be a first consideration at all times and the requirements of meeting schedules or deadlines will not be allowed to override safety considerations.

As an adjunct to the NRC Byproduct Materials License, a CMD Radiation Safety Committee has been established to provide a continuing review of the radiation safety program and provide recommendations for improvement where necessary. In addition to this Committee, a Health Physics Department is provided to assist supervisory personnel in fulfilling their above responsibilities and to give advice and make recommendations regarding radiological protection. A more detailed discussion of these two groups follows.

B. RADIATION SAFETY COMMITTEE

The CMD Radiation Safety Committee as appointed by the President of CMD is composed of the following members:

President of CMD	- Chairman
General Manager	- Member
Radiation Safety Officer	- Secretary
Member-at-Large	

A primary responsibility of this Committee is to provide a continuing review of the adequacy of the CMD radiation safety program and to provide recommendations for improvement where indicated. In addition, the Committee shall also investigate any abnormal radiation incidents or exposures and see to the preparation of a report of the results of

such investigations. The Committee also is responsible for certain specific radiation control functions. These functions and the methods by which they are normally carried out are:

1. Radioisotope Procurement and Disposal:

The procurement of all radioactive materials on the CMD site, as well as the disposal of such materials, requires the approval by the Radiation Safety Committee. Normally, the Committee authorizes the Radiation Safety Officer to review and approve on behalf of the Committee all such requests.

2. Committee Meetings:

The Radioisotope Committee meets as often as necessary in order to fulfill its responsibilities and a permanent written record of proceedings is maintained by the Secretary.

C. HEALTH PHYSICS

The Health Physics Department provides technical assistance, training in radiation protection practices, makes recommendations regarding radiological protection, and executes a radiological monitoring program. Most of the routine authority of the Health Physics section is delegated by the President of CMD to the Radiation Safety Officer. The person functioning in this capacity is authorized by the President to order the modification or cessation of any activity involving the handling of radioactive materials which threatens to produce or is producing a significant radiological hazard. He also has the authority to suspend persons willfully violating either U.S. Nuclear Regulatory Commission or CMD radiological protection regulations. In the event of the latter, a Radiation Safety Committee meeting must be convened as soon as possible to review the circumstances and determine the course of action to be taken with the violator.

SECTION II - GENERAL PERSONNEL REQUIREMENTS

A. AUTHORIZATION TO USE RADIOISOTOPES:

1. General

In accordance with the CMD Byproduct Materials License, radioactive materials shall be used only by, or under the supervision of individuals identified by the license. Therefore, all persons who work with radioactive materials at CMD must perform their work under the supervision of someone who is identified by the license. This requirement applied to all permanently employed personnel, temporarily assigned personnel, short-termed visitors or other persons who will directly handle radioactive materials.

2. Radioisotope Processing

Because of the hazards involved in the processing of large quantities of radioisotopes such processing must be done under the supervision of an individual identified under the license.

Processing is defined as consisting of any of the following:

i. General
   - a. dispensing
   - b. sterilization
   - c. calibration of dispensed items

ii. Chemical Processing
   - a. pH adjustment
   - b. synthesis (Technetium products, iodinated proteins, etc.)

B. INSTRUCTIONS FOR RADIOISOTOPE WORKERS

All persons who work with radioactive materials at CMD must receive instructions relative to the safety problems involved in working with radioactive materials and to the precautions or procedures which shall be taken to minimize exposures. In addition, radioisotope workers must be instructed in the provisions of the Federal and State licenses and regulations and be advised of reports of radiation which they may request. The Health Physics office maintains a complete file of Federal and State licenses and regulations which are readily available for examination.

Each new individual who is employed to work at CMD must receive a brief radiation safety indoctrination by Health Physics whether classified as a radioisotope worker or not. This indoctrination should be scheduled with Health Physics by the individual's supervisor as soon as practical after the individual reports for work.

C. PERSONNEL MONITORING REQUIREMENTS:

1. TLD Badges:

a. Permanently Employed Personnel

All personnel who are permanently employed by CMD and who have occasion to enter the radiation areas shall be provided TLD badges which shall normally be worn at all times on the CMD site. These badges will be clipped to badge boards located in the Health Physics Office. Badges should be picked up on entering the building, and must be clipped back on the board when leaving the site.

b. Working Visitors

All individuals who visit CMD to perform work in a radiation area shall be issued a TLD monitoring badge on a daily basis. This badge is obtained from the Health Physics office on starting work and must be returned to this office on conclusion of each working day. Pocket dosimeters are assigned with each working visitor's TLD badge. TLD badges previously assigned to short-term visitors may be re-issued to other visitors if the pocket dosimeter indicates an exposure of less than 10 mR was received by the previous wearer. All above individuals are instructed in Safety and emergency procedures including the use of emergency switches.

c. Non-Working Visitors

Persons who visit CMD for periods of less than one day and who do not enter a radiation area will not be assigned personnel monitoring devices. Persons who visit CMD for less than one day and who may enter a radiation area but will not perform work with radioactive materials, will be assigned a TLD badge and a pocket reading dosimeter by Health Physics. These monitoring devices must be returned to Health Physics when the visitor leaves the site. Health Physics may reissue such badges whenever the dosimeter worn by the visitor indicates an exposure of less than 10 mR.

2. Pocket Dosimeters:

All permanently employed personnel who work in the Red Zone Radiation Area should wear a pocket dosimeter. These dosimeters are available on the badge board. At the end of each work period the dosimeters should be placed in the slots provided in the badge board. The radiation exposure recorded by these dosimeters is determined at the end of each day to provide a day-to-day record of exposure to gamma radiation.

3. Special Monitoring Devices:

Special monitoring devices such as finger rings, wrist badges, etc., are available in the Health Physics office and should be utilized whenever handling radioactive materials in a manner that significant radiation exposures may be reached by specific sections of the body wherein the regular film badge could not be expected to reflect this exposure. The Radiation Safety Officer may specify that special personnel monitoring devices must be worn for some types of work.

4. Investigation of External Exposures Which Exceed Administrative Control Limits (See Section V):

a. Pocket Dosimeters

An informal investigation will be conducted by the Health Physics section whenever pocket dosimeters reflect an unscheduled radiation exposure which exceeds 100 mR per day. A Health Physics investigation will be conducted whenever it appears that an individual's daily exposure exceeded the maximum which can be recorded by the dosimeters (200 mR). The TLD badge will be processed immediately whenever this investigation indicates that the pocket dosimeter reading is valid, or unless the exposure was planned on and Health Physics is completely cognizant of the approximate exposure magnitude.

b. TLD Badges

Health Physics will conduct an investigation whenever a TLD badge indicates that the wearer received a radiation exposure in excess of a pro-rated Administrative Control limit. A formal Radiation Safety Committee meeting is held whenever an individual's exposure exceeds a Maximum Permissible Exposure limit.

5. Loss of Personnel Monitoring Devices:

a. The loss of any personnel monitoring device should be reported immediately to the Health Physics Department by the individual to whom it was issued so that a replacement device can be provided.

b. Health Physics will conduct an investigation whenever a TLD badge is lost or damaged so that an estimate of the wearer's radiation exposure can be obtained for the period during which the badge was worn.

D. MEDICAL & BIOASSAY REQUIREMENTS

1. Physical Examinations

Any individual who is employed to work at CMD on a regu-

lar and permanent basis and whose assignment requires work with radioactive materials or in radiation fields significantly above background levels, is classified as a radioisotope worker. In addition, any temporary or part-time individual is also classified as a radioisotope worker if his assignment work can reasonably be anticipated to cause a whole body radiation exposure, in excess of 300 mRem during any thirteen-week interval.

All radioisotope workers must receive a pre-employment physical examination before being permitted to work with radioactive materials. All radioisotope workers are required to receive a complete physical examination before termination of employment at CMD.

2. Thyroid Scans:

Any radioisotope worker handling in excess of 100 mCi of I-131 or I-125 per week shall submit to a thyroid scan to determine possible uptake of radioactive iodine. All radioisotope workers will be subject to a quarterly thyroid scan. Thyroid scan scheduling shall be determined by the Radiation Safety Officer.

SECTION III-FACILITIES DESCRIPTION

A. FACILITIES:

1. Zones:

The Billerica laboratory has been subdivided into three zones. The subdivisions were made on the basis of the radioactivity usage for the purpose of radiation and contamination control throughout the facility (See Figure 2). The designation and definition of each area is as follows:

a. Green Zone designates a clean zone, i.e., an unrestricted area, as defined in 10 CFR 20. This area consists of the Corporate and Administrative offices, lunch room, library and conference room.

b. Yellow Zone designates an area, portions of which may be restricted at times depending upon usage. This area encompasses the animal room, shipping room, antibody production labs, coated tube labs, R&D labs, stock rooms, workshop, cold rooms, walk-in freezers, lyophilization lab, dispensing lab, change room, and the main lab.

c. Red Zone is a restricted area in which the uncontained material is processed. This area comprises the main production laboratory complex where radioactive materials are handled or stored. Personnel entrance or egress from the area is only through the change area.

2. Ventilation:

The required air-flow pattern in the building has been so designed to coincide with the radiation and contamination control area. The air-flow pattern is established so that the Green or unrestricted area is the most positive and the Red or restricted area is the least positive with respect to air pressure (i.e., Green zone air flow, to Yellow to Red; Red zone air is exhausted). Thus, any air flow into the building is exhausted primarily through the hoods and plenums which comprise the radioactive effluent exhaust, and partially through chemical fume exhaust. The animal room is provided with its own air-handling system to prevent any animal odors from intruding into the rest of the building. Air-flow measurements are made daily with a velometer at the interfaces of the Green-Yellow Zone and Yellow-Red Zone. A colored thin paper strip is continuously visible at each of these barriers and magnahelic gauges are located at the Green-Yellow Zone barrier and at the Yellow-Red Zone barrier. All employees have been instructed to inform the Health Physicist if any

of the air flow is not proper. Each employee has been informed of the proper air flow. In addition, if the air flow system fails, a light indicator will go on at the RSO or Health Physics office to indicate a problem in the ventilation system.

3. Radioactive Effluent Exhaust System:

   a. Iodine System:

      The radioactive effluent exhaust system consists of the following components: fume hoods, glove boxes, pre-filters, absolute particulate filters, and activated charcoal filters. The pre-filters, absolute filters and charcoal filters are housed in a stainless steel caisson on the roof of the building. The system is equipped with two blowers, each capable of 6400 CFM. One blower is for normal operation, the second provides 100 percent, automatic backup. Alarming devices signal the system status.

   b. Filter Performance Monitoring:

      The exhaust system is equipped with an isokinetic air sampling device and activated charcoal filters to continuously monitor the stack filter performance. Sampling is normally continuous. In the event of equipment failure, sufficient parts are available so that sampling will not be interrupted for more than 8 hours during the normal work week.

4. Liquid Waste:

   All contaminated liquids shall be absorbed in the appropriate absorbant material, packaged and transferred to Health Physics for proper disposal with contaminated waste.

5. Solid Waste Storage Area:

   The solid waste storage area is located in a separate building behind the main building. The area consists of a cement-block building surrounded by a chain-link fence. There is a double door entry into the building which is provided with lead shielding on the interior surface of the inner door to prevent radiation streaming when radioactive waste is in storage. The building has a capacity to provide approximately 6 months accumulation of solid waste at the present operating levels. The building entry and fence are both supplied with locks and the area is posted as a restricted area.

6. Laboratories:

   The laboratories wherein radioactive materials are handled and/or stored and their zone locations are as follows:

SUMMARY OF LABORATORY OPERATIONS

(See attached floor plan for Red and Yellow Zones)

LOCATION	ISOTOPE	NORMAL QUANTITY USED	NORMAL OPERATION
Iodination Labs (R)	I-125	600 mCi	Labeling, dispensing, storage
Waste Room (R)	I-125	250 mCi	Waste packaging
Animal Room (Y)	I-125	0	Antibody production
Antibody Labs (Y)	I-125	50 uCi	Assay
Cold Room 1 (Y)	I-125	5 mCi	Storage
Cold Room 2 (Y)	I-125	100 uCi	Assay Support
R&D Labs (Y)	I-125	100 uCi	Assay
Coated Tube Lab (Y)	I-125	0	Coated Tube Prep.
Shipping Area (Y)	I-125	0 uCi to 50mCi	Packaging
Dispensing	I-125	0	Cold component Packaging
Freezer 1 and 2	I-125	0	Cold component Storage
H.P. Office	I-125	10 uCi	Calibration
Main Lab	I-125	250 uCi	Assay

The iodiation labs are equipped with appropriate hoods for safe handling and storage of radioisotopes.

A change area is provided at the entry to the Red Zone. Normal entry into the Red Zone is via the change area.

SECTION IV - RADIOISOTOPE CONTROL

A. PROCUREMENT

The administrative procedure authorizing the procurement of radioisotopes used in the production of radiopharmaceuticals is through a purchase requisition approved by the Radiation Safety Officer.

B. RADIOISOTOPE RECEIPT

Upon receipt of a radioisotope shipment, the receiving/shipping department initiates a Radioisotope Process Log and submits the HP copy to Health Physics together with the packing slip. The shipment and Radioisotope Process Logs are then turned over to the production department for processing.

C. DISPOSAL

The Health Physics department is responsible for packaging and disposal of radioactive waste. Notification is given to Health Physics when a particular stock is to be retired (unusable) and all Radioisotope Process Log sheets routed via Health Physics to Quality Control for filing. The retired stock is then packaged in a waste disposal drum and the drum appropriately marked. All off-site disposals must be packaged and handled in accordance with DOT regulations.

D. INVENTORY OF RADIOACTIVE MATERIALS

The Health Physics department is responsible for maintaining an inventory of all radioisotopes on hand at CMD. This will normally be accomplished through comparison of written records obtained from receiving and packing slips and from records of the Radioisotope Processing Log.

The Health Physics department is responsible for maintaining records of all non-exempt sealed sources at CMD and for scheduling leak tests on such sources within the appropriate time interval.

E. LABELLING REQUIREMENTS FOR RADIOACTIVE MATERIALS

Federal regulations contain specific requirements for labelling of containers in which radioactive material is either transported, stored or used. These requirements must be adhered to. In general, it is good radiological practice to label a container which holds radioactive material with the kind and quantity of radioactive materials within. A supply of such labels can be obtained from the shipping and Health Physics departments. It is equally important to remove and destroy such labels when they are no longer applicable.

SECTION V - EXTERNAL RADIATION CONTROL

A. EXTERNAL EXPOSURE LIMITS

1. Maximum Permissible Exposure Limits

The maximum external radiation levels permitted for routine work at CMD must not exceed the limits specified in 10 CFR, Part 20. These are as follows:

a. Whole body, gonads, active blood-forming organs, head and trunk, lens of eye --- 3 Rems per calendar quarter until a total occupational dose of 5(n-18) Rems is accumulated. ("n" is the individual's age in years at his last birthday).

b. Hands and forearms, feet and ankles --- 18 3/4 Rems per calendar quarter.

c. Skin of whole body --- 7½ Rems per calendar quarter.

2. CMD Administrative Limits

Administratively, whole body exposures should normally be limited to 2.1 Rem per calendar quarter. This administrative limit is further controlled by restricting unscheduled personnel exposures to 100 mRem or less in any one day, and 400 mRem in any bi-weekly period. Scheduled exposures greater than the quarterly level of 2.1 Rem must receive the approval of either the Radiation Safety Officer, General Manager or the Chairman of the Radiation Safety Committee.

B. RADIATION ZONE CONTROL

In order to permit personnel to assess the potential for external radiation exposure throughout the building, the following zones have been established:

1. Green (Non-Radioactive) Zone

The Green Zone includes that proportion of the facility in which no significant source of external radiation exposure is permitted. This zone normally includes the CMD lobby, Corporate and Administrative offices, conference room, library and lunchroom. Exempt sealed sources or containers with radioactive material which have been properly packaged and authorized for off-site shipment may be transported through, or temporarily stored in, this zone but must receive the prior approval of the Radiation Safety Officer.

2. Radiation Zones

Permanent radiation zones have been established in those portions of CMD where significant sources of radiation are transported, handled,

or processed.

Portions of permanent radiation areas which contain an actual radiation field in which a level of 5 mRem/hour or greater is accessible to personnel shall normally be clearly posted with "CAUTION - RADIATION AREA" signs and roped off where appropriate.

3. High Radiation Area

Any area in which the major portion of the body of an individual could receive a dose in excess of 100 mRem in any one hour must be designated as a high radiation area.

High radiation areas may be established on a temporary basis and these areas must be conspicuously posted with appropriate signs and must be barricaded if practicable.

C. SPECIAL PROTECTION REQUIREMENTS

1. Pre-Planning Non-Routine Production Work in Radiation Areas

Each supervisor has a primary responsibility to pre-plan all non-routine production work performed in radiation areas in order to insure that personnel radiation exposures are measured and recorded on appropriate personnel monitoring devices and to insure that personnel radiation exposures are restricted to administrative control limits. A basic radiological safety practice which should prevail when pre-planning non-routine production work is that all unnecessary radiation exposure should be avoided and all practicable measures should be utilized to minimize necessary exposures.

2. Radiation Survey Requirements

Any area within a radiation zone which is posted with A "CAUTION - RADIATION AREA" sign should never be entered unless a survey has been performed to measure exposure rates which exist in the area. Therefore, a standard procedure is that a survey instrument be obtained and utilized whenever entering such an area. Additionally, Health Physics routinely surveys each laboratory prior to commencing operations. The results of these surveys are posted on the door of each laboratory. Health Physics must be notified and requested to perform a radiation survey whenever an exposure rate of 5.0 mRem/hour* or greater is detected near or in an area where work is to be performed.

3. Avoid Direct Handling of Radiation Sources

Because of the inability of most survey instruments to measure the unusually high radiation levels which exist at or near the surface of small radiation sources, a required practice is to use tongs, manipula-

tors, or some other means to avoid direct handling of the source. (Note that the actual exposure rate at ~½ centimeter from a 5 millicurie radium source is about 170,000 mR/hour whereas the radiation level at two feet from the source would be only 12 mR/hour. Furthermore, a conventional cutie pie ionization chamber which is held so that the front of the chamber touches the source would reflect an exposure rate of only about 2,500 mR/hour.

4. Special Work Permit Requirement

A special work permit (see Exhibit I) issued by the Health Physics office must be prepared in advance for maintenance personnel who may be required to work in a high radiation area (radiation level exceeds 100mRem/hour). A special work permit may be required for any outside contractor personnel who may be required to work in any designated radiation area. Normally, special work permits are valid for one day but may be extended beyond this period on special request.

*PERSONNEL WHO HAVE RECEIVED SPECIFIC TRAINING IN THE USE OF SURVEY METERS AND WHO HAVE BEEN APPROVED FOR SELF MONITORING BY HEALTH PHYSICS MAY CONDUCT RADIATION SURVEYS IN CONNECTION WITH THEIR WORK.

SECTION VI INTERNAL RADIATION CONTROL

A. MAXIMUM INTERNAL EXPOSURE LIMITS - RESTRICTED AREAS

1. Exposure to Airborne Radioactive Material

No person shall knowingly be exposed to an atmosphere containing airborne radioactive material wherein the concentration of such material above natural background exceeds the maximum permissible concentration levels specified in 10 CFR 20, Appendix B, Table I, Column 1. These concentrations shall not knowingly be exceeded even though personnel may be required to wear a respirator or other respiratory protective devices. With reference to this maximum exposure limit, exposure concentrations may be averaged over a 40-hour work week in any period of seven consecutive days.

2. Exposure to Radioactive Materials in Water

No person shall knowingly drink or otherwise be exposed to water containing radioactive materials in concentrations above natural background which exceed those specified in 10 CFR 20, Appendix B, Table I, Column 2. With reference to this maximum exposure limit, exposure concentrations may be averaged over a 40-hour work week in any period of seven consecutive days.

B. CMD ADMINISTRATIVE CONTROL LIMITS

1. Exposure to Airborne Radioactive Material

The processing of radiopharmaceuticals at CMD presents some potential for airborne activity at each stage of manufacture. The use, however, of appropriately designed hoods and glove boxes minimizes this potential.

Either room air sampling or the wearing of a portable air sampler is required for those operations with the greatest potential for airborne activity.

In general, Health Physics is responsible for specifying and providing the type of air sampling and/or other protective equipment to be used.

2. Exposure to Radioactive Materials in Water

No one should drink any water which contains any radioactive materials other than those which naturally exist.

3. Maximum Permissible Burdens of Radioactivity in Total Body

As noted in the above maximum exposure limits, Federal regulations attempt to control internal exposures by limiting exposure to concentrations of radioactive material in air and water. However, there are other routes

through which radioactive materials may enter the body which are of equal if not more important. These include direct absorption of radioactive materials through the skin or by accidental injection directly into the body through a cut or a wound. In addition, radioactive materials may also enter the body through ingestion or by direct transfer of contamination into the mouth. Therefore, in recognition of these additional routes of entry, routine personnel exposures to radioactive materials must be administratively controlled to insure that the total amount of radioactive material taken into the body does not exceed the equivalent of one MPB (maximum permissible burden). Specific values for MPB's for most isotopes are specified by the ICRP and NCRP and the most current conservative values must be utilized with regard to this administrative control.

C. AIRBORNE RADIOACTIVITY ZONE CONTROL

All laboratories in which radioactive materials may become airborne periodically or in which it can reasonably be anticipated that radioactive materials may become airborne must be permanently labelled "CAUTION - AIRBORNE RADIOACTIVITY AREA".

D. SPECIAL PRECAUTIONS

1. Eating, Drinking and Smoking Limitations

No beverages, food or smoking are permitted in the Red Zone. Care should be taken in the Red Zone to insure that pencils or other similar objects are not placed in the mouth.

2. Pipette Limitations

No liquid is to be pipetted by mouth.

3. Procedure for Handling Cuts or Wounds Received in a Contamination Area

Anyone receiving a cut or wound while in a contamination area must contact Health Physics immediately so that an evaluation may be performed to determine whether or not radioactive materials have entered the body.

E. ACTION LEVELS FOR POSITIVE THYROID ANALYSIS

The administrative action levels for thyroid uptake of I-125 and I-131 are based upon the maximum permissible body burden established by the ICRP and NCRP. Inasmuch as the effective half-life (T_e) for any single isotope varies greatly (1 to 7 days for I-131, for example) the true meaning of a positive bioassay result is subject to considerable interpretation.

1. Thyroid

a. Action Level 1 - Uptake is 35% to 70% MPBB

Investigation of personnel technique and process equipment will be made when individual exposure exceeds 35% of MPBB and approaches 70% of permissible uptake.

b. Action Level 2 - Uptake exceeds 70% MPBB

If uptake is 70% of the maximum permissible body burden, employee will be restricted from the specific nuclide operations until accumulated dose is less than 35% of MPBB. These action levels correspond to the following activity levels in the thyroid:

ISOTOPE	ACTIVITY (uCi)	ACTION LEVEL
I-131	0.05 to 0.10	1
	0.10 or greater	2
I-125	0.39 to 0.77	1
	0.77 or greater	2

c. Action to be Taken

ACTION LEVEL	UPTAKE OF ACTIVITY	ACTION TO BE TAKEN
1	35% to 70% MPBB	(1) Investigate personnel techniques and process equipment (2) Notify employee of exposure
2	Greater than 70% MPBB	(1) Investigate personnel techniques and process equipment (2) Notify employee of exposure (3) Restrict employee from area and operation until concentration of activity in critical organ is less than 35% MPBB

Action Levels for Positive Analysis

Notwithstanding the action levels herein described no one is authorized to expose themselves to an atmosphere containing airborne radioactive material wherein the concentration of such material above the natural background exceeds the maximum permissible concentration levels specified in 10 CFR 20, Appendix B, Table I, Column 1 nor shall any person drink or otherwise be exposed to water containing radioactive materials in concentrations above natural background which exceed those specified in 10 CFR 20, Appendix B, Table I, Column 2.

SECTION VII - CONTAMINATION CONTROL

A. CONTAMINATION ZONE CONTROL

For purposes of contamination control, the CMD building is subdivided into three separate zones. These are the Green or clean zone, the Yellow zone or control zone, and the Red or contamination zone. These areas have previously been defined in detail (see Section III A.)

Temporary contamination control zones must also be established for areas which may have a probability of contamination spread on only an occasional basis. In addition, a temporary contamination zone must be established whenever contamination greater than the control limits specified below is encountered.

B. ADMINISTRATIVE CONTAMINATION LIMITS

Permissible surface contamination depends in part on the following factors:

1. The type of radiation.
2. The degree to which the activity is fixed in the material or on the surface of the material.
3. The material contaminated and use of thereof.
4. The nature of the surface of the material contaminated.

The permissible contamination levels on various surfaces will not be permitted to exceed those values of fixed and/or unbound activity which could result in dose rates or intake concentration of activity that would exceed the maximum permissible values set forth in 10 CFR 20. In general, every effort will be made to keep the contamination levels at the lowest possible value. Administrative limits for the various zones have been set and are delineated in the sub-paragraphs which follow:

1. Green Zone

All areas which are not posted as a contamination zone are considered as a clean zone. Smear tests for gross gamma with a filter paper wipe over 100 cm^2 on any surface in the area should reflect less than 200 dpm for this zone.

2. Yellow Zone

The Yellow Zone is normally to be maintained such that loose contamination does not exceed 2½ times the limit specified above for the Green Zone. However, when contamination levels greater than 500 dpm (gross gamma) are encountered in the Yellow Zone a temporary contamination zone shall be

established and immediate steps shall be taken to reduce the contamination to meet the above Yellow Zone limit.

3. Red Zone

The Red Zone has been established as a contamination area. In order to maintain control over contamination in this zone, the following administrative limits have been established:

a. Up to 1000 dpm/100 cm^2 (gross gamma) - Acceptable in the hallway area and on laboratory floors.

b. Up to 2000 dpm/100 cm^2 (gross gamma) - Acceptable on laboratory benches.

c. Above 2000 dpm/100 cm^2 (gross gamma) - Acceptable only within the confines of hoods and glove boxes.

d. Within hoods, efforts should be made to maintain as low a level of contamination as is practical.

Smear checks are routinely performed on a weekly basis. Non-routine spot checks are made on a periodic basis as determined by Health Physics. Contamination levels which exceed the administrative limits are cleaned as soon as possible after notification of the Production Supervisor and/or persons responsible for the laboratory.

The routine smear surveys are made possible and practical because of the continuing necessity to maintain the laboratories in a clean and sanitary condition.

C. SPECIAL CONTAMINATION ZONE REQUIREMENTS

1. Protective Clothing Requirements

Red Zone shoes or shoe covers, laboratory coats and gloves should normally be worn when entering the Red Zone. Laboratory coats must be worn when entering the Red Zone for supervisory purposes or when work in the zone is such that no exposure to significant amounts of loose contamination can reasonably be anticipated. Specific clothing requirements may be posted outside of each laboratory by Health Physics should the need arise for special precautions.

2. Monitoring of Personnel and Equipment Leaving the Red Zone

It is a general CMD practice to monitor for contamination all personnel who are leaving a contamination zone and to monitor all material and equipment which is to be removed from such a zone. A suitable monitoring instrument is located in the change area.

Health Physics must be consulted whenever contamination is detected on either materials or equipment on leaving the zone. In lieu of monitoring, materials may be placed in clean plastic bags on removal from the zone and may be removed to the Health Physics office for subsequent survey. Health Physics msut be notified of fixed contamination detected on personnel and/or their street clothing which exceeds 500 cpm above background.

3. Emergency Notification:

The walk-in freezers, cold rooms, and Red Zone are equipped with alarm switches that signal the Health Physics office directly in the event of an emergency. All personnel are trained in the proper use of the emergency signal. The guidelines for use are:

1. An abnormal or high radiation level.
2. A radioactive material spill or acid spill.
3. Physical injury.
4. Presence of smoke, fire or flooding.
5. Changes in air flow.
6. A jammed or frozen door preventing exit.
7. Any true emergency that may arise.

SECTION VIII - LABORATORY WASTE DISPOSAL

A. GENERAL

As previously noted under Section V-C, Disposal, the "Radioisotope Processing Log" must be turned over to Health Physics in advance of disposal of any radioactive material. Health Physics will then take the steps necessary to insure adequate protection of the public and to conform with legal requirements in effecting disposal of the retired lot.

B. MAXIMUM CONCENTRATION LIMITS FOR DISPOSAL OF RADIOACTIVE WASTE INTO ENVIRONMENT

1. Disposal to Atmosphere

The concentration of radioisotopes released to the atmosphere must be limited so that the resulting concentration at the CMD boundary (unrestricted area), when averaged over a one-year period and corrected for dilution, does not exceed the maximum permissible concentration levels specified in 10 CFR 20, Appendix B, Table II, Column 1.

2. Disposal to Sewer System

The concentration of radioisotopes in water released to an unrestricted area must be limited so that the resulting concentration at the CMD boundary, when averaged over a one-year period, does not exceed the maximum permissible concentration levels specified in 10 CFR, Appendix B, Table II, Column 2.

C. CMD ADMINISTRATIVE CONTROL LIMITS

1. Disposal to Atmosphere

Every reasonable effort shall be made to prevent the release of radioactive materials to the atmosphere. However, for administrative purposes, disposal to the atmosphere during routine operation is limited so that the appropriately calculated MPC_a value for all radioisotopes released is not exceeded at roof top levels. In the event that the MPC value is exceeded during routine operation, an investigation will be initiated and recommendations will be made where necessary in order to control such releases to within the administrative limit.

D. ACCUMULATION AND HANDLING OF RADIOACTIVE WASTE

1. Dry Waste

Waste cans, which are labelled either contaminated waste or clean waste, are located throughout the controlled areas of the facility for the accumulation of clean and low level contaminated waste. Extreme care should be

exercised to insure that contaminated waste is not placed in a clean waste container and vice versa.

a. Handling of Contaminated Waste

The amount of waste placed in a contaminated waste container should normally be limited so that the radiation level at one foot from the container does not exceed 2mR/hour. These containers are collected periodically by Health Physics and repackaged for transfer to a commercial waste disposal firm. Whenever a sufficient amount of radioactive waste is placed in a container so that the radiation level exceeds 2 mR/hour at one foot, special arrangements should be made with Health Physics to pick up the containers. In any event, the amount of waste placed in these containers should always be limited so that the resulting radiation level from a container does not exceed 100 mR/hour at one foot. Radioactive waste which produces a radiation level in excess of this value must be considered as high level waste and should be stored in shielded containers. Special arrangements should be made with Health Physics for the disposal of any high level wastes.

b. Handling of Clean Waste

Clean waste cans are collected periodically by, and shall be monitored by, Health Physics before disposal from the controlled areas of the facility.

2. Liquid Waste

All liquid waste shall be put in appropriate containers and solidified. Health Physics shall arrange for the proper disposal of these wastes.

3. Gaseous Waste

Measures should be utilized whenever practicable to entrain or chemically absorb any radioactive gases or volitiles to avoid direct release to the atmosphere. Any operation wherein gaseous radioactive material may be released into a hood or other enclosure which eventually exhausts through a stack which is not equipped for gaseous monitoring must be approved by Health Physics in advance of the planned release so that quantitative evaluations and monitoring can be performed.

E X H I B I T S

EXHIBIT I

Work Permit

The Radiation Safety Commit ee has reviewed the training and experience of _____ and hereby authorizes him to perform _____ _____ operation involving the radionuclide _____ _____ without immediate supervision.

This authorization is given with the assumption that the standard procedure for the above operation will be utilized. Deviations from this procedure which may alter the product require immediate notification of the Production Supervisor and Quality Control. Deviations which may involve increased radiation exposure to the above named individual or to those around him require immediate notification of Health Physics and the Production Supervisor.

_____ _____
Production Supervisor Date

_____ _____
Radiation Safety Officer Date

FIGURE 1

General floor plan with emergency exits

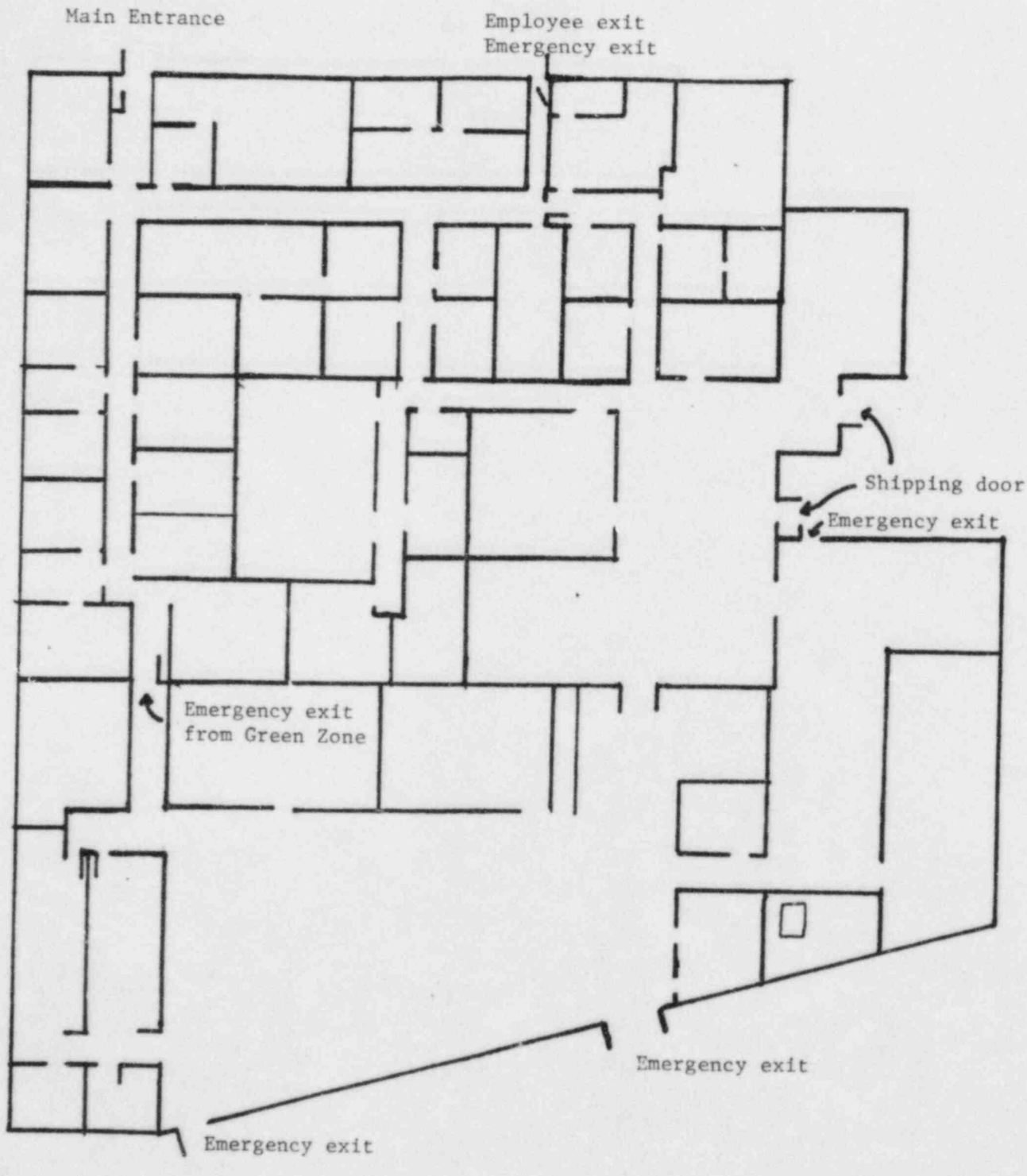


FIGURE 2

Floor plan showing separation of
Green, Yellow, and Red Zones

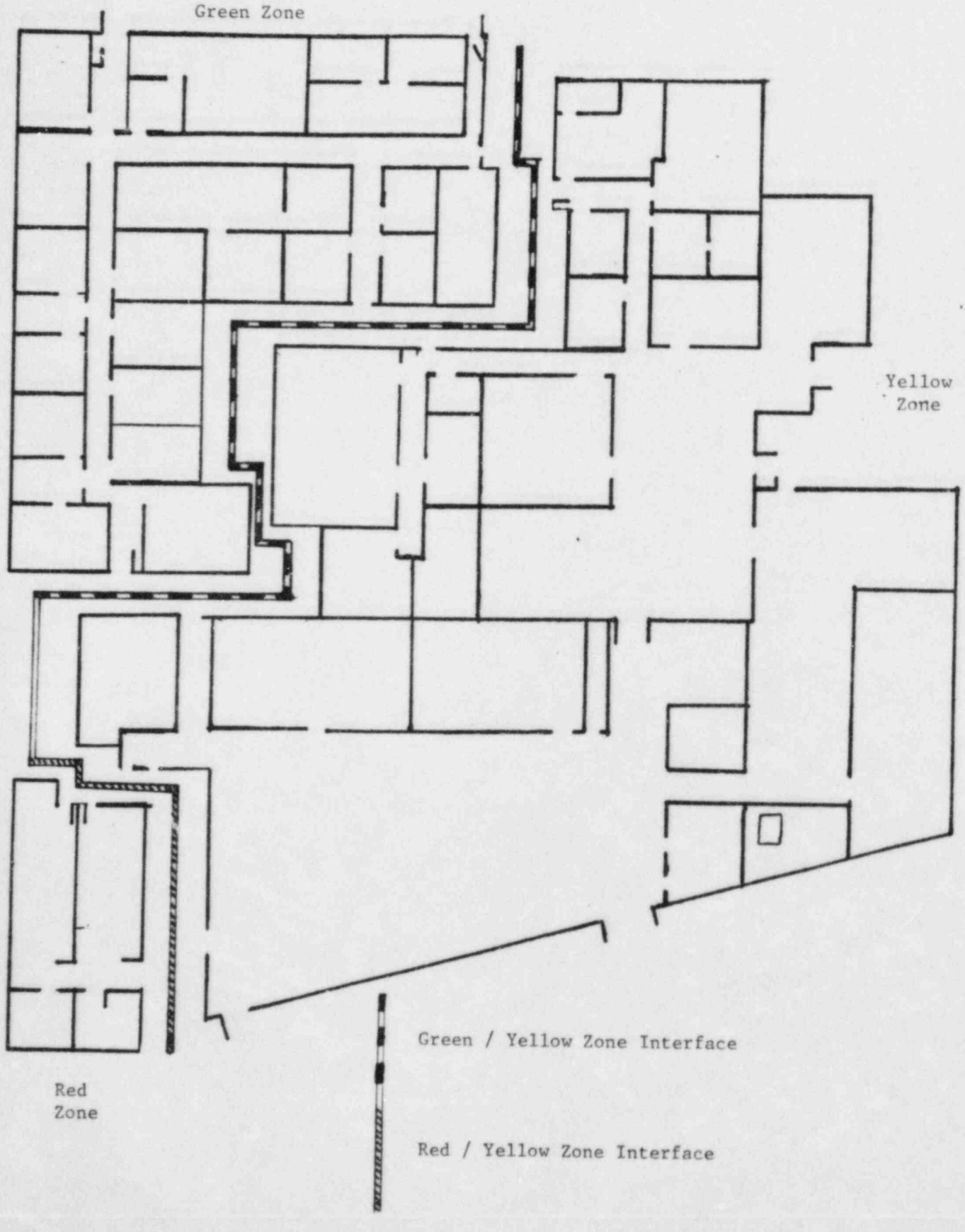


FIGURE 3

Green Zone

The Green Zone is devoted to Administative, departmental, support, and sales offices and the cafeteria. Figure 3 is a floor plan of this zone. Access is unrestricted to all Cambridge Medical employees.

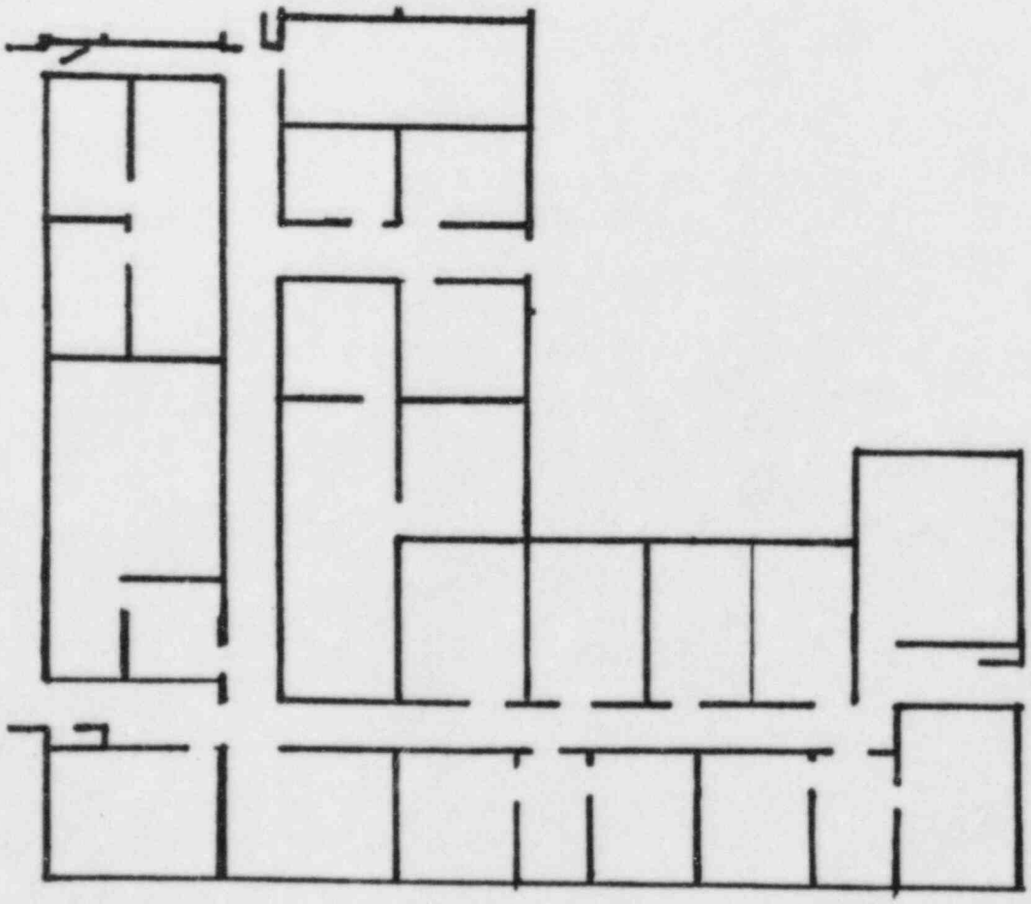


FIGURE 4

Yellow Zone

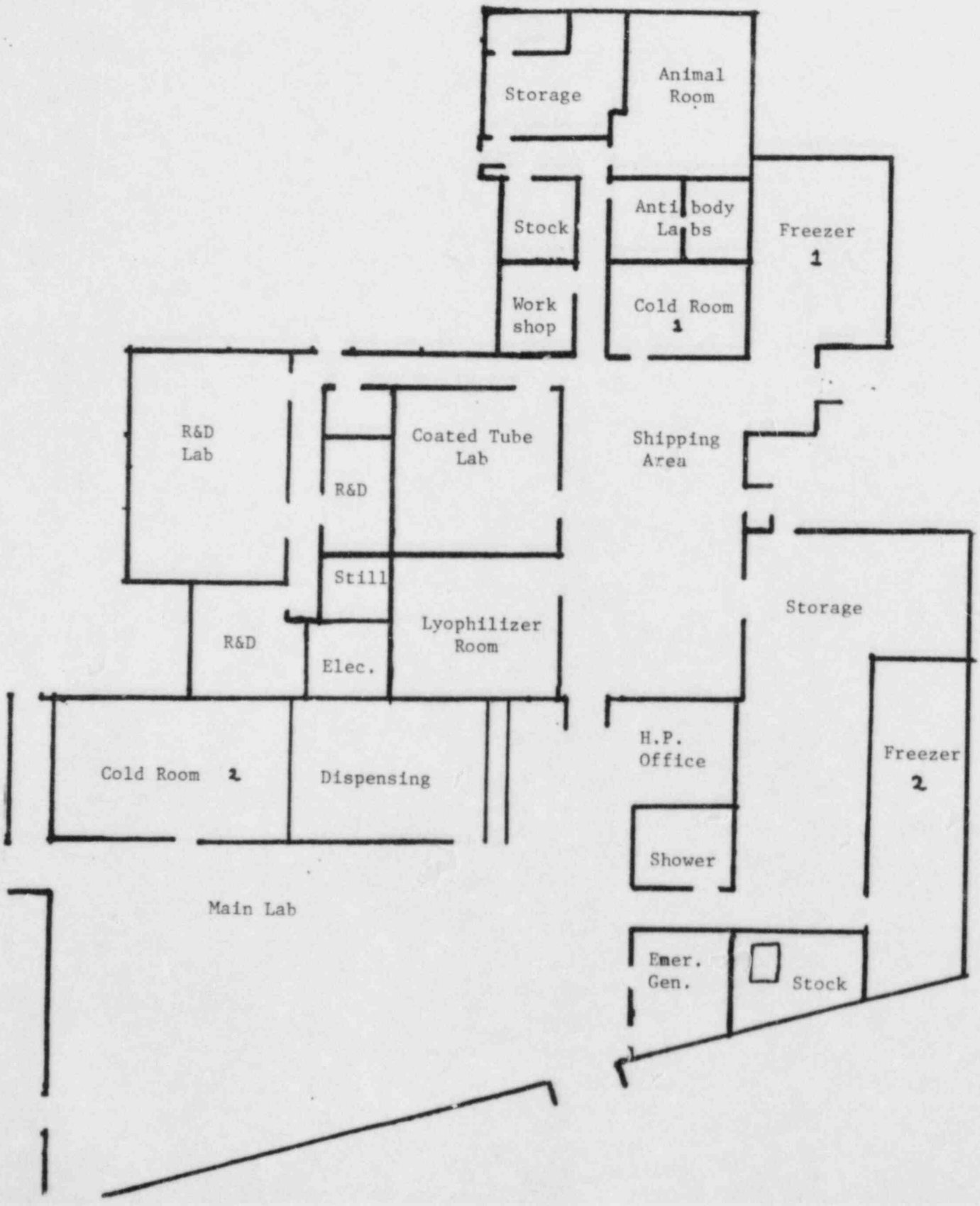


FIGURE 5

Main QC / Production Labs

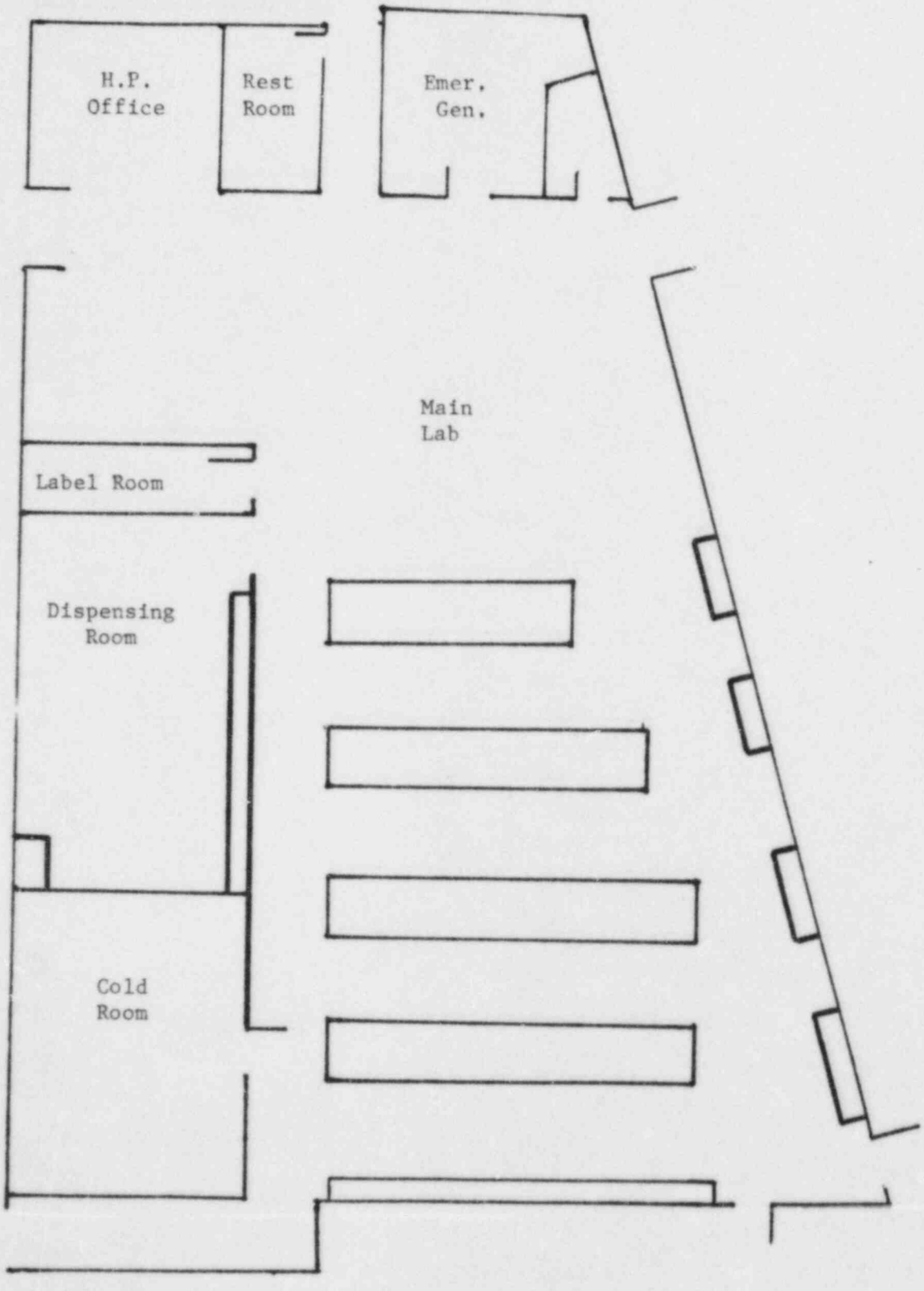
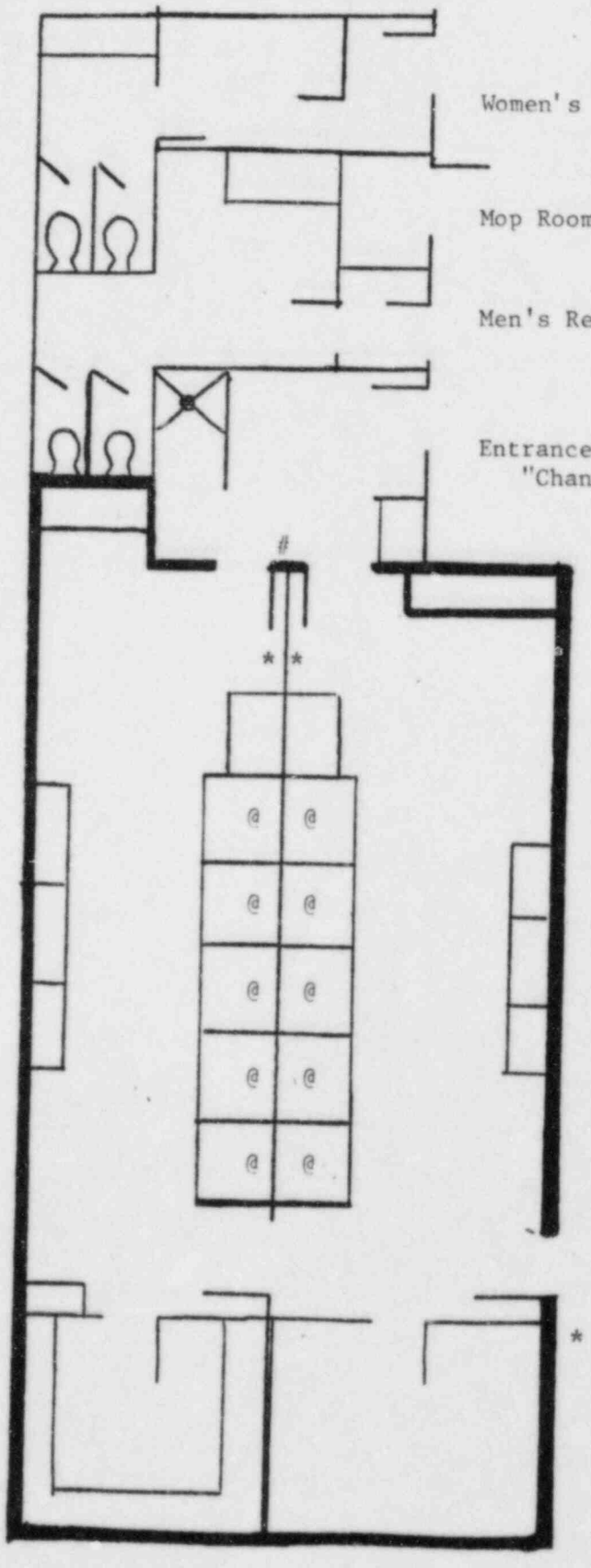


FIGURE 6

Red Zone and Change Area



A P P E N D I C E S

Foreword

The appendices which follow are for the express purpose and convenience of providing CMD's employees with additional information and general rules of practice for the laboratories. As such, these general rules are subject to change or modification as the need arises. These appendices may be separated from the Radiation Safety Manual without altering the intent thereof.

APPENDIX A

Specific Personnel Requirements

A. INTRODUCTION

The specific personnel requirements stated herein are intended to augment those stated in more general terms in the main sections of the CMD Radiation Safety Manual.

B. GENERAL RULES

1. Persons under 18 years of age shall not be permitted in radiation areas.

2. Pregnant women are not permitted in radiation areas.

3. Personnel with open wounds or cuts shall not be permitted in contamination control areas.

4. Wash hands thoroughly before eating, smoking or leaving work.

C. ALL PERSONNEL - RESPONSIBILITIES

Each individual is responsible for the following:

1. Minimizing his daily exposures through the application of accepted radiological health practices and observance of the axiom: "Any unnecessary dose is excessive".

2. Wearing appropriate radiation monitoring devices in radiation areas, specifically:

a. All supervisory personnel shall be provided with a lapel TLD badge and pocket dosimeter and shall wear same whenever in the radiation areas of the facility.

b. All personnel involved in the production or processing of isotopes or any other procedure by which significant doses might be accumulated shall be provided with lapel, wrist and ring badges and a pocket dosimeter and shall wear same at all times when in the radiation zones.

3. Checking hands, shoes and body for radioactivity and removing any contamination prior to leaving the laboratory. The maximum allowable fixed contamination without notification of Health Physics is 500 cpm above background.

4. Familiarizing himself with and utilizing survey instruments to monitor operations in progress.

5. Being basically familiar with the principles of decontamination.

6. Wearing appropriate protective clothing and using proper techniques and facilities in operations involving radioactive materials.

7. Observing the recommended procedures in regard to eating and smoking in laboratories where radioactive materials are present.

8. Promptly reporting puncture wounds, ingestion accidents, and spills to Health Physics.

9. Cleaning up contamination for which he is responsible and that created by others in spaces for which he is responsible.

10. Proper signature and handling of radioactive materials for which he is responsible.

11. Furnishing information to Health Physics concerning activities in his area, particularly alterations or proposed operations since these might lead to personnel exposures or contamination.

12. Obtaining the permission and approval of his Supervisor and Health Physics (and/or Radiation Safety Committee) prior to initiating any new procedure or prior to any deviation from an already established procedure.

D. SUPERVISORS - RESPONSIBILITIES

Supervisors are responsible for:

1. Insuring that the above individual responsibilities are discharged by those under their control.

2. Furnishing information to Health Physics concerning activities which might lead to either radiation hazards or contamination.

3. Providing such staff as is required for non-routine radiological control activities.

APPENDIX B

Airborne Concentrations in Restricted Areas

A. AIRBORNE LEVELS

This Appendix delineates the laboratories and airborne concentration limits worthy of special note by CMD employees. The values given are based upon a 40 hour week and take no credit for respiratory protection. The limits may be adjusted on a time weighted basis to account for shorter exposure periods.

Location	Isotope	Concentration uCi/cc	
		Insoluble (particulate)	Soluble (Gaseous)
Dispensing Laboratory	I-125	2×10^{-7}	5×10^{-9}
Research & Devel. Lab.	I-125	2×10^{-7}	5×10^{-9}
Protein Iodination Lab.	I-125	2×10^{-7}	5×10^{-9}

B. MONITORING REQUIREMENTS

Personnel processing iodine shall wear portable air samplers for the purpose of sampling the air in the breathing zone. All air samples thus taken will be analyzed and the results interpreted by Health Physics. Records of air sample analyses shall be kept by Health Physics in an appropriate log.

Processing of isotopes in fume hoods does not normally require the use of portable or room air samplers. However, Health Physics should be notified immediately in the event of a spill outside the hood so that appropriate air samples can be taken to access the airborne hazard involved, if any.

APPENDIX C

Decontamination Procedures

A. PERSONNEL

Thorough washing with soap and water is the best general method for decontamination of the hands and other parts of the body, regardless of the contaminant. If the contamination is localized, it is often more practical to mask off the affected area and clean with swabs, before risking the danger of spreading the contaminant by general washing.

If the exact nature of the contaminant is known, it may sometimes be more effective to immerse the hands in a suitable reagent immediately after contamination. This should be followed by thorough washing in lukewarm water with a mild soap, and thoroughly rinsing in clean water. Detergents and wetting agents may also prove useful, although sometimes a specific one may be required for a particular contamination problem in order to secure maximum cleaning efficiency. A list of detergents and wetting agents that have been used successfully to remove some contaminations is presented in NBS Handbook 48, Page 23. The skin may become sensitive following repeated application of detergents to the same area; therefore, care should be taken to avoid this practice. In any case, one must avoid the use of organic solvents that may increase the the probability of the radioactive materials penetrating through the skin barrier.

The recommended procedures for general hand-washing are as follows:

1. Wash for not less than 2 minutes, nor more than 3 minutes by the clock with a mild, pure soap in lukewarm water with a good lather, covering the entire affected area thoroughly. Give special attention to the areas between the fingers and around the finger-nails. The outer edges of the hands are readily contaminated and often neglected in the washing. Do not use highly alkaline soaps or abrasives. Rinse thoroughly and repeat, as monitoring indicates, until the desired degree of decontamination is achieved, but not to exceed three or four times.
2. If the above procedure is not sufficient to remove the contamination, scrub the hands with a soft brush using a heavy lather and lukewarm water.

This scrubbing is primarily to agitate the cleansing agent, and hence prolonged scrubbing without change of agent is of questionable value. For this reason, at least three washes, including rinses, should be made within 8 minutes, of which at least 6 minutes should be devoted to scrubbing. Only light pressure should be applied to the brush -- not sufficient to bend the bristles out of shape or to scratch or erode the skin. Rinse thoroughly and monitor.

3. Apply lanolin or hand cream to prevent chapping.

B. TOOLS AND GLASSWARE

Decontamination methods fall into two broad classifications; corrosive and non-corrosive. It is always desirable to use a non-corrosive method, yet this is seldom practical since the removal of the surface layers of material is more effective in putting ions back into solution than the very slow processes of ion exchange or desorption by non-corrosive methods.

Some of the more common decontamination procedures, involving both corrosive and non-corrosive methods are given as follows:

All glassware should be washed with a suitable cleansing agent and rinsed, as a routine procedure following use (all groups and levels of activity). All metal tools employed should be washed with a suitable cleansing agent and rinsed as a routine procedure following use. Examination of the tools for residual activity should be made to ensure that radioactive material has not undergone chemical, amalgamation, plating, etc., phenomena with the tool material.

If any of these processes have occurred, a determination by Health Physics will be made as to whether the tool should be removed from service for decay or disposal.

C. FLOOR AND BENCHES

If a wet or oil mop will not remove the contamination, proceed with a method suitable for the particular surface material. Linoleum may be decontaminated by carbon tetrachloride, kerosene, ammonium citrate solution, or diluted mineral acids, care should be taken not to dissolve sealing compounds at the edges and between cracks of the linoleum. Ceramic tile may be decontaminated by the use of mineral acids, ammonium citrate, or trisodium phosphate. Paint is sometimes successfully decontaminated by carbon tetracholoride or 10 percent hydrochloric acid; however, danger of dissolution of the paint exists, and it is preferable to remove the paint and apply new coatings. With contaminated concrete no recourse is

left except to remove the surface concrete with a chisel. Similarly, contaminated wood surfaces must be planed or removed.

Detergents or wetting reagents may frequently be used as successfully as harsher reagents for the decontamination of strippable plastics on polished stainless steel, glass or other smooth impervious laboratory surfaces. However, the combination of the contaminating conditions, the surface materials and the cleansing agent are interdependent variables that often influence the decontamination process. A list of some detergents that have been found useful for some decontamination problems is given in the appendix to NBS Handbook 48.

D. TRAPS AND DRAINS

Traps and drains may sometimes be decontaminated by the following procedures:

1. Flushing thoroughly with a large volume of water.
2. Scouring with a rust remover.
3. Soaking in a solution of citric acid prepared by adding
   1 pound of acid to 1 gallon of water
4. Flushing thoroughly with a large volume of water.

E. NON-ROUTINE OR SPECIAL PROCEDURES

In any case of non-routine decontamination, the method to be used must be approved by Health Physics and Supervisor prior to initiation.

APPENDIX D

Radiation Detection Equipment

A. GENERAL

Various types of radiation sensitive instruments are available for routine use. These are listed in Table D-1 at the end of this section. Each instrument is described briefly below as well as a few of the major limitations. The theory of operations of the various instruments is adequately described in readily available literature and, therefore, will not be described here. Correct interpretation of readings is not possible without a fairly thorough understanding of the principles of operation. For this reason, frequent consultation with your supervisor and/or Health Physics is encouraged.

B. POCKET DOSIMETERS

Pocket dosimeters are available from the Radiation Safety Officer. They are pencil shaped ionization chambers which have a fairly uniform reponse to gamma radiation approximately above 150 kev. They are not a good measure of beta exposure since they are insensitive to betas below about 700 kev. These instruments are very delicate. They may be easily read at any time and therefore provide a measurement which can be followed closely when working in high radiation areas. Dosimeters are read each morning prior to commencing operations. Badges and dosimeters must be returned to the badgeboard prior to leaving the facility at the end of the workday.

C. TLD BADGES

Thermoluminescent dosimeter badges are also available from Health Physics. These badges are used to evaluate the gamma component of any radiation seen by the badge. These badges are relatively rugged and insensitive to heat or moisture. Their major disadvantage is that once the badge is read the badge is annealed and the accumulated exposure is lost and the badge cannot be reread.

1. "Cutie Pies" or CS-40A Ionization Chambers

"Cutie Pies" are pistol shaped survey instruments which have cylindrical ionization chambers as barrels. They have a flat response from about 200 kev to 2 Mev. They also serve to give qualitative information on beta doses by means of a removal shield located at the end of the chamber. The meter has three ranges which permit its use from about 1/2 mr/hr to 2500 mr/hr. These instruments are rugged and reliable. They are

fairly accurate but care should be taken to insure that the reading obtained is interpreted correctly. An example will illustrate why this is so important.

Example

When measuring the intensity of a well defined gamma beam,

$$\text{True } \frac{\text{mr}}{\text{hr}} = \text{Indicated } \frac{\text{mr}}{\text{hr}} \times \frac{\text{Volume of Chamber}}{\text{Volume of Beam in Chamber}}$$

Thus, for a well defined cylindrical beam 1/4" in diameter striking the end of the chamber perpendicularly, the true dose will be 144 times the indicated dose rate.

The CS-40A is an ionization chamber which does not have a beta shield as an integral part of the instrument. Therefore, the readings obtained with this instrument are beta/gamma readings. If it is necessary to differentiate between beta and gamma, a suitable shield must be used.

2. Geiger (G.M.) Survey Meters

G.M. Survey Meters are used primarily as "detectors" of radiation rather than quantitative dose measuring devices since they are fairly energy dependent. They are very sensitive covering the range from background to about 20 mr/hr. Various probes may be used to provide alpha, beta, gamma or beta-gamma sensitivities. In addition, removable shields permit the exclusion of alpha and beta radiation when desired.

These instruments are fairly rugged and reliable with the exception of the G.M. tube itself, especially the end window tubes which break quite easily on contact.

Correct interpretations of G.M. readings depend not only on geometrical considerations, as mentioned for Cutie Pies, but also on the energy dependence of the instrument. The following limitations also apply to G.M. instruments.

a. In very intense fields, the G.M. tube will saturate and produce a false reading.

b. Electrical equipment such as generators may cause spurious results.

c. Glass G.M. tubes become "light sensitive" if the opaque aquadag coating becomes cracked or chipped.

TABLE D - 1

Radiation sensitive instruments available at Cambridge Medical Diagnostics for use in the laboratory:

TYPE	DESIGNATION	RANGE	NUMBER OF INSTRUMENTS ON HAND
Geiger	Eberline E-120	0-50 mR/hr	2
Ionization Chamber	Cutie Pie	0-2.5 R/hr	1
Portable Ion Chamber	Eberline PIC 3	0-1000 mR/hr	1
Portable Ion Chamber	Eberline PIC 6A	0-1000 R/hr	1
Radiation Monitor MR15	Eberline (4 ranges)	0-500 KCPM (2 ranges)	1
Radiation Monitor	Eberline (4 ranges) (Plutonium Probe)	0-500 KCPM	1
Radiation Monitor MR14	Eberline (3 ranges)	0-50 KCPM	1
Area Monitor	Victoreen	0-100 mR/hr	1
Surface Monitor	TA TBM-3	0-15 mR/hr	2
Radiation Monitor	Ludlam 16	0-500 KCPM	1

All instruments will be calibrated on a half-year basis using standard procedures.

APPENDIX E

Emergency Procedures

A. MINOR SPILLS (INVOLVING NO RADIATION HAZARD TO PERSONNEL)

1. Notify all other persons in the room at once.
2. Permit only the minimum number of persons necessary to deal with the spill into the area.
3. Confine the spill immediately:

   Liquid Spills: Wear protective gloves
   Drop absorbent paper on spill

   Dry Spills: Wear protective gloves
   Dampen thoroughly, taking care not to spread the contamination.
   Drop absorbent paper on the contaminant.

4. Notify Health Physics as soon as possible.
5. Decontaminate.
6. Monitor all persons involved in the spill and cleaning.
7. Permit no person to resume work in the area until a survey is made and approval of the Radiation Safety Officer is secured.

B. MAJOR SPILLS (INVOLVING RADIATION HAZARD TO PERSONNEL)

1. Notify all persons not involved in the spill to vacate the room at once. Notify Health Physics, give information as to isotope, extent of spill, injuries, etc. Do not allow persons in immediate spill area to leave unless significant exposure will be caused by remaining.
2. If the spill is liquid and the hands are protected, right the container.
3. If the spill is on the skin, flush thoroughly using a sink intended for contaminated wastes.
4. If the spill is on clothing, discard outer or protective clothing at once and place into a plastic bag.
5. Vacate the room.
6. Take immediate steps to decontaminate personnel involved, as necessary.
7. Decontaminate the area under supervision of authorized personnel. (Personnel involved in decontamination must be adequately protected)
8. Monitor all persons involved in the spill and cleaning to determine adequacy of decontamination.

9. Permit no person to resume work in the area until a survey is made and approval of Health Physics officer is secured.

10. Prepare a complete history of the accident and subsequent activity related thereto for the laboratory records.

C. ACCIDENTS INVOLVING RADIATION DUSTS, MISTS, FUMES, ORGANIC VAPORS AND GASES

1. Notify all other persons to vacate the room immediately

2. Hold breath and close escape valves, switch off air circulating devices, etc., if time permits.

3. Vacate room, all persons involved remain nearby to minimize spread of contamination.

4. Notify Health Physics at once.

5. Ascertain that all doors giving access to the room are closed and post conspicuous warnings or guards to prevent accidental opening of doors.

6. Report at once all known or suspected inhalations of radioactive materials.

7. Evaluate the hazard and the necessary safety devices for the safe re-entry.

8. Determine the cause of contamination and rectify the condition.

9. Decontaminate the area under the supervision of an authorized person.

10. Health Physics will perform an air survey of the area before permitting work to be resumed.

11. Monitor all persons suspected of contamination.

12. Prepare a complete history of the accident and subsequent activity related thereto for the laboratory records.

D. INJURIES TO PERSONNEL INVOLVING RADIATON HAZARD

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

2. Report all radiation accidents to personnel (wounds, overexposure, ingestion, inhalation) to Health Physics as soon as possible.

3. Call a physician to treat radiation injuries at once. Treatment of injuries takes precedence over contamination control measures.

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

5. Prepare a complete history of the accident and subsequent activity related thereto for the laboratory records.

APPENDIX F

References

1. U.S. Atomic Energy Commission: Rules and Regulations Title 10, Chaper 1, Part 20: STANDARDS FOR PROTECTION AGAINST RADIATION: July 11, 1975

2. U.S. Atomic Energy Commission: Rules and Regulations Title 10, Chapter 1, Part 19: NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS, INSPECTIONS: April 30, 1975.

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5. International Commission on Radiological Protection - Permissible Dose for Internal Radiation - Reprinted 1975.

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8. International Commission on Radiological Protection - Data for Protection Against Iodinizing Radiation from External Sources (1973) - Reprinted 1975.

9. Radiological Health Handbook, U.S. Dept. of HEW - January 1970.

10. Radiological Quality of the Environment, U.S. Environmental Protection Agency, May 1976.

APPENDIX G

Definitions

For purposes of this manual the following definitions shall apply:

1. AIRBORNE RADIOACTIVE MATERIAL. This means airborne radioactive material in any form such as dusts, fumes, mists or gases.
2. ASSAY. The determination of kind and quantity of radioactive materials present by physical or chemical measurements.
3. CLEAN AREA. Any area which is to be kept free of contamination by strict preventive measures.
4. CONTAMINATION. Deposition of radioactive material in any place where it is not desired, and particularly in any place where its presence can be harmful. The harm may be in vitiating the validity of an experiment or a procedure, or in actually being a source of danger to persons.
5. CURIE. (c) A unit of radioactivity defined as the quantity of any radioactive nuclide in which the number of disintegrations per second is 3.7×10^{10}.
6. CONTROLLED AREA. Any area access to which is restricted.
7. DOSE. The amount of radiation expressed in roentgens, rads, or rems.
8. DOSE RATE. Dose per unit time.
9. HALF LIFE . Time for the activity of any particular radioisotope to be reduced to half its initial value.
10. HAZARD, RADIATION. See Radiation Hazard.
11. HEALTH PHYSICIST. A person fitted by training and experience to perform dependable radiation surveys, to oversee radiation monitoring, and to estimate the degree of radiation hazard.
12. HIGH AIRBORNE CONCENTRATION AREA. Any room, enclosure, or operating area in which airborne radioactive materials exist in excess of the maximum permissible concentrations specified in Table 1, Column 1 of 10 CFR 20.
13. HIGH RADIATION AREA. An area in which there exists a radiation level in excess of 100 millirem in any one hour.
14. MAXIMUM PERMISSIBLE DOSE. A dose of radiation that, in the light of present knowledge, is not expected to cause appreciable bodily injury to a person at any time during his lifetime.
15. MONITORING: Periodic or continuous determination of the dose rate in an occupied region or of the dose received by a person.
16. RAD. The unit of absorbed dose, which is 100 ergs/grams.

17. RADIATION. X-rays, gamma rays, alpha and beta particles, high-speed electrons, neutrons, protons, and other nuclear particles; but not sound or radio waves, or visible, infrared or ultraviolet light.

18. RADIATION AREA. Any area in which precautions against radiation exposure are required. This includes any controlled area in which there exists a radiation level over 2.5 millirem in any one hour or over 100 millirem in any seven consecutive days.

19. RADIATION HAZARD. Any condition that might result in the exposure of persons to radiation in excess of the maximum permissible dose.

20. RADIATION SURVEY. Evaluation of the radiation hazards incidental to the production, use, or presence of radioactive materials or other sources of radiation under specific set of conditions. Such evaluation customarily includes a physical survey of the disposition of materials and equipment and measurements of the dose rates of radiation that may be involved.

21. RADIOACTIVE MATERIAL. Any material, solid, liquid, or gas, that emits radiation spontaneously.

22. RELATIVE BIOLOGICAL EFFECTIVENESS (RBE). The ratio of lightly filtered x-ray dose generated at potentials of 200-300 kilovolts to the dose that is required to produce the same biological effect by the radiation in question.

23. REM. That quantity of any type of ionizing radiation (including neutrons) which when absorbed by man produces an effect equivalent to the absorption of one roentgen of x-or gamma radiation.

24. ROENTGEN (r). The quantity of x-or gamma radiation such that the associated corpuscular emission per 0.001293 grams of air produces, in air, ions carrying 1 esu of quantity of electricity of either sign.

25. SHALL. Denotes that the ensuing recommendation is necessary or essential to meet the currently accepted standards of protection.

26. SEALED SOURCE. Radioactive material enclosed in a manner which prevents the escape of any radioactive material, but at the same time permitting radiation to come out for use.

27. SHOULD . Indicates advisory recommendations that are to be applied when practicable.

28. SURVEY. See Radiation Survey.

29. UNCONTROLLED AREA. Any area access to which is not restricted.