NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 09

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

OFFICIAL RECORD COPY

Licensee	
1. Du Pont Merck Pharmaceutical Company	In accordance with the application dated October 29, 1996,
2. 331 Treble Cove Road North Billerica, Massachusetts 01862	3. License Number 20-28598-01 is amended in its entirety to read as follows:
	4. Expiration Date March 31, 2007
	5. Docket or Reference No. 030-32013

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material with atomic numbers 1 through 83	A. Any	A. Not to exceed 200 curies per radionuclide and 5,000 curies total
B. Any byproduct material with atomic numbers 84 through 94	B. Any	B. Not to exceed 60 millicuries per radionuclide and 5 curies total
C. Hydrogen 3	C. Any	C. 50,000 curies
D. Carbon 14	D. Any	D. 1,000 curies
E. Phosphorus 32	E. Any	E. 400 curies
F. Sulfur 35	F. Any	F. 1,000 curies
G. Nickel 63	G. Any	G. 1,000 curies
H. Krypton 85	H. Any	H. 10,000 curies
I. Strontium 90	I. Any	I. 500 curies
J. Molybdenum 99/ Technetium 99m	J. Any	J. 10,000 curies
K. Xenon 133	K. Any	K. 1,500 curies
L. Cesium 137	L. Any	L. 500 curies
M. Samarium 153	M. Any	M. 2000 curies
N. Americium 241	N. Any	N. 350 curies
O. Uranium (depleted in the isotope Uranium 235)	O. Metal	O. 550 kilograms
P. Any byproduct material listed in Schedule B of 10 CFR 30.71	P. Any	P. Not to exceed limits specified in Schedule B of 10 CFR 30.71

9. Authorized use

030001

A. through N. (1) Research and development as defined in 10 CFR 30.4; animal studies.
(2) Manufacture of radiochemicals, radiopharmaceuticals and sealed sources. Packaging and distribution of manufactured radiochemicals, radiopharmaceuticals, and sealed sources to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission or any Agreement State.

NL 10

(3) Calibration of analytical instruments.
(4) Storage as radioactive wastes.
(5) Return of sealed sources to the Du Pont Merck Pharmaceutical Company, Billerica Site for the purpose of refurbishment or disposal.
(6) Waste from the E.I. Du Pont Boston facility prior to disposal.

O. Shielding for Mo99/Tc99m generators and sealed sources and shipping containers.

P. Demonstration by sales persons.

CONDITIONS

10. A. Licensed material may be used only at the licensee's facilities located at 331 Treble Cove Road, North Billerica, Massachusetts, Buildings 110, 150, 200, 250, 300, 325, 375, 400, 500 and 600.

B. Licensed material in Item 6.P. may be used at temporary job sites of the licensee anywhere in the United States where the U. S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.

11. A. Licensed material shall be used by, or under the supervision of individuals designated in writing by the Radiation Safety Committee, Peter Holton, Chairperson.

B. The Radiation Safety Officer for this license is Dennis Dumas.

12. This license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31 or equivalent regulations of any Agreement State or to persons exempt from licensing pursuant to 10 CFR 30.14 through 30.20 inclusive, or equivalent regulations of any Agreement State.

13. Licensed material shall not be used in or on human beings.

14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

15. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

16. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

17. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.

18. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.

B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

19. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.

20. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

E. Sealed sources and detector cells need not be leak tested if:

(i) they contain only hydrogen-3; or

(ii) they contain only a radioactive gas; or

(iii) the half-life of the isotope is 30 days or less; or

(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

21. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

22. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:

A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

23. Radioactive waste generated under this license shall be stored in accordance with the statements, representations, and procedures included with licensee's waste storage plan described in the licensee's application dated November 14, 1990 and letter dated May 3, 1993.

24. The licensee may possess up to 10 curies of iodine-125 waste in any building without installation of radiation detection systems and alarms to continuously monitor possible effluent releases from associated ventilation systems, provided the material is stored as waste in non-combustible drums and the drums are provided with sprinkler protection.

25. The licensee shall make no change in the emergency plan submitted pursuant to 10 CFR 30.32(i), 40.31(j), or 70.22(i), that would decrease the effectiveness of the plan without prior Commission approval. The licensee may make changes to its Emergency Plan without prior Commission approval if the changes do not decrease the effectiveness of the plan. The licensee shall maintain records of changes that are made to the plan without prior approval for a period of three years from the date of the changes and shall provide the U.S. Nuclear Regulatory Commission, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406 a report, within six months after the change is made, containing a description of each change.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 20-28598-01

Docket or Reference Number 030-32013

Amendment No. 09

26. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated October 29, 1996
B. Letter dated February 14, 1997

For the U.S. Nuclear Regulatory Commission

Date MAR - 7 1997

By Original Signed By:
Keith D. Brown, Ph.D

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

MAR - 7 1997

License No. 29-28538-01
Docket No. 030-32013
Control No. 123852

Dennis Dumas
Associate Director
Safety and Environmental Engineering
DuPont Merck Pharmaceutical Company
331 Treble Cove Road
North Billerica, MA 01862

Dear Mr. Dumas:

This refers to your license renewal request. Enclosed with this letter is the renewed license.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Until your license is terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. when the Radiation Safety Officer or Chairman of the Radiation Safety Committee, permanently discontinues performance of duties under the license or has a name change; or

   b. when the mailing address on the license changes (no fee is required if the location of byproduct material remains the same).

OFFICIAL RECORD COPY

IML 10

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. change Radiation Safety Officer or Chairman of the Radiation Safety Committee;

   b. order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   c. add or change the address or addresses of use identified in the license application or on the license; or

   d. change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than the Radiation Safety Officer or a consultant.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement actions will be

taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Thank you for your cooperation.

Sincerely,

ORIGINAL SIGNED BY:

Keith D. Brown, Ph.D.
Division of Nuclear Materials Safety

License No. 20-28598-01
Docket No. 030-32013
Control No. 123852

Enclosures:
1. Amendment No. 09
2. 10 CFR Parts 2, 19, 20, 30, 170, and 171
3. NRC Forms 3 and 313

DOCUMENT NAME: R:\WPS\MLTR\L2028598.01
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Brown/kdb							
DATE	03/03/97		03/ /97		03/ /97		03/ /97	

OFFICIAL RECORD COPY

DU PONT
MERCK

RADIOPHARMACEUTICALS

331 Treble Cove Road
N. Billerica, MA 01862
Phone: (800) 362-2668
Fax: (508) 671-8149

February 14, 1997

M516
Q-7

U.S. Nuclear Regulatory Commission
ATTN.: Keith Brown
Region I
475 Allendale Road
King of Prussia, PA 19406

Reference: Material's License #20-28598-01
Mail Control #123852

Dear Mr. Brown:

This is written in response to your verbal request for additional information concerning our license renewal application.

1. A complete radioactive material inventory for all Billerica site operations is maintained and will continue to be maintained by the site Radiation Protection Office. As a large manufacturing site with some research and development activities, inventories of radioactive material are routinely obtained through computerized manufacturing/order entry/warehousing/distribution databases. In addition, the site Environmental Engineering group maintains a computerized radioactive material inventory for all site radioactive waste activities.

   Annually all the previously obtained radioactive material inventory information is compiled into one large computer file where it is compared with the licensed quantities. The results of this comparison is provided to the Radiation Safety Officer and the site Radioisotope Committee for review.

   It is important to note that our Broad Scope license allows for very large quantities of various radioisotopes plus all radioactive material operations require preapproval by the Radioisotope Committee. In this way it is assured that no license limits have the potential to be exceeded at any time within the year.

2. As you can see in our license application, we currently have a formal system of authorization and approval for Radiation Workers that is coordinated by the Radiation Protection Office. This process involves registration with the Radiation Protection Office, the successful completion of radiation safety training, the implementation of dosimetry requirements and completion of on-the-job training.

   With regards to the management of the Radiation Workers and their operations, the site Radioisotope Committee reviews the credentials and will authorize individuals as Supervisors or Managers of the licensed operational programs. These individuals have overall management responsibility for the licensed operations and are approved by the Radioisotope Committee based on their past work experience and training relevant to the operations involving the use of radioactive material.

123852

OFFICIAL RECORD COPY ML 10

FEB 20 1997

FAX REC'D FEB 17 1997

DUPONT
MERCK

In consideration of the discussions between my staff and yourself, we will introduce a new category of worker called an "Authorized User". While this person is required to be an approved Radiation Worker, this person is more specifically responsible for the day to day activities in the licensed restricted areas. In other words the "Authorized User" will be able to make specific decisions and notifications to management affecting radiological safety in their area of responsibility. In essence they will oversee the radiological safety operations of the Radiation W. kers in the area. The designation as "Authorized User" will be granted by the Radioisotope Committee based on previous work experience and the completion of more advanced radiological safety training.

This three tier system of authorization to work with radioactive materials will be implemented by the beginning of the second quarter of 1997. The Radioisotope Committee will develop the required credentials for an "Authorized User" based on the nature of the licensed operations. A standard operating procedure will then be entered into the existing document control system.

3. A program is in place for the auditing of the Radiation Protection Program. As you may know my staff conducts routine radiological compliance surveys of each area in accordance with our licensed program. These surveys are conducted either weekly or monthly and at other times that a non-routine assessment is needed. These surveys consist of not only monitoring area radiation levels and potential levels of radiological contamination but also include assessments of postings, the use of personal protective equipment and the use of the required dosimetry.

   In addition, on an annual basis, an administrative review of the overall Radiation Protection Program is conducted by the Radiation Protection Office. On an on-going basis, these programs assess the quality of the radiological safety program as authorized by our license.

4. As you discussed with my staff, we will continue to need the Materials License #20-00320-19 for the three remote Distribution Centers in the NRC states. It is our understanding that this license will continue to be administered by NRC Region I after Massachusetts has obtained Agreement State status. As you may know this license is a limited scope possession license that is separate from our Broad Scope manufacturing/distribution license #20-28598-01 and separate from our radiopharmaceutical distribution license #20-00320-16MD. It is our understanding these latter two licenses will be transferred to the state of Massachusetts once they become an Agreement State. With regards to the issue of the handling of radioactive material at remote job sites throughout the U.S., beyond the three Distribution centers listed on the "-19" license, we will utilize the "reciprocity" regulatory requirements established by the NRC and as adopted by Massachusetts when they become an Agreement State.

I trust this information will be useful in your further processing of our renewal application. Please contact me at 508-671-8669 if you require any additional information.

Sincerely,

Dennis Dumas

Dennis Dumas
Associate Director
Safety and Environmental engineering.

TELEPHONE CONVERSATION RECORD	Date: January 15, 1997	Time: 9:30 a.m.
Mail Control No.: 123852	**License:** 20-28598-01	**Docket No.:** 030-32013
Person Called: Francis (Skip) Roy	**Organization:** Du Pont Merck Pharmaceutical Co.	**Telephone Number:** (508) 671-8242
Person Calling: Keith D. Brown		
Subject: Renewal Request		
Summary: I requested the following information in support of their renewal application 1. Commitment to have a method for tracking inventory and a description of the system they currently use. 2. Criteria RSC will use for users in each area. That is, how will the RSC ensure that in each area of use there will be individuals with sufficient expertise to safely handle material and deal with any emergencies that arise. 3. More detailed description of routine audits including frequency and functions performed (e.g. contamination surveys, review for compliance with requirements, etc.).		
Action Required/Taken: MS15		
Signature: Keith D Brown	**Date:** January 15, 1997	

MAIL 10

NOV - 7 1996

Roger C. Heison, E.D OPS
Du Pont Merck Pharmaceutical Co.
331 Treble Cover Road
North Billerica, MA 01862

SUBJECT: LICENSE RENEWAL APPLICATION

Dear Mr. Heison:

This is to acknowledge receipt of your application for renewal of materials(s) license identified below. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Any correspondence regarding the renewal application should reference the control number specified below.

Sincerely,

Original Signed By:

Sheryl Villar
Licensing Administrative Specialist
Division of Nuclear Materials Safety

License No. 20-28598-01
Docket No. 030-32013
Control No. 123852

DOCUMENT NAME: R:\WPS\MISC\2028598.01
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Brown/gxc RJBrown		Villar					
DATE	11/06/96		11/7/96		11/ /96		11/ /96	

OFFICIAL RECORD COPY ML 10

The Du Pont Merck Pharmaceutical Company
Radiopharmaceutical Division
331 Treble Cove Road
No. Billerica, MA 01862
(508) 667 9531

030-32013

October 29, 1996

U.S. Nuclear Regulatory Commission
ATTN.: Elizabeth Ullrich
DNMS Region I
475 Allendale Road
King of Prussia, PA 19406

DU PONT
MERCK

Reference: Materials License #20-28598-01
Program Code #03211

Dear Ms. Ullrich:

This is an application for renewal of the above-referenced Materials License.

We have chosen to select the alternative procedure described in the instructions for preparation of an application for license renewal. Instead of submitting a new application in its entirety we are providing the previously submitted documents that still describe our current program. However, we have included new editions of our site Handbook for Radiation Protection, the site Radiological Emergency Contingency Plan and the Decommissioning Plan.

The following documents are enclosed for your consideration in the processing of our renewal application.

1. Application dated November 14, 1990 with Section M Handbook of Radiation Protection, Section N Radiological Emergency Contingency Plan and Section B of the Radiological Decommissioning Funding Plan removed.
2. Letter dated May 15, 1991
3. Letter dated August 16, 1991
4. Letter dated May 3, 1993
5. Letter dated November 8, 1993
6. Letter dated November 3, 1994
7. Letter dated January 9, 1995
8. Letter dated December 5, 1995
9. Letter dated March 29, 1996
10. Letter dated April 19, 1996
11. The Billerica Site Handbook of Radiation Protection, Required Rules and Procedures; revised April 1994.
12. The Radiological Emergency Contingency Plan for the Billerica Site, revised August 1996.
13. A copy of the Standby Trust Agreement between CitiBank and the DuPont Merck Pharmaceutical Company authorizing a $9.6 MM regulatory assurance for the Billerica Site.
14. A new Decommissioning Cost Estimate for the Billerica Site prepared by Scientific Ecology Group, August 1996.

123852

OCT 30 1996

DUPONT

OFFICIAL RECORD COPY ML 10

DU PONT
MERCK

October 29, 1996

U.S. Nuclear Regulatory Commission
ATTN.: Elizabeth Ullrich
DNMS Region I
475 Allendale Road
King of Prussia, PA 19406

With this renewal application a new Decommissioning Funding Plan is being submitted for your review. You will note that the cost estimate report breaks out the cost for decommissioning the DuPont Merck operations from the DuPont NEN leased operations at the Billerica site. The existing Standby Letter of Credit in the amount of $9.6MM has been renewed for another year effective July 30, 1996. The total cost estimate for decommissioning the entire Billerica site, DuPont Merck operations plus DuPont NEN leased operations, amounts to $8.1MM. Prior to July 30, 1997 we plan to reduce the DuPont Merck Billerica Site Standby Letter of Credit to the amount described in this new decommissioning cost estimate report for $6.3MM. DuPont NEN will be responsible for the remaining decommissioning cost in a separate funding plan.

Please contact me if you require any additional information.

Sincerely,

Dennis Dumas

Dennis Dumas
Associate Director,
Safety and Environmental Engineering

NRC FORM 313 U. S. NUCLEAR REGULATORY COMMISSION

(10-94)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-96

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-6 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. 030-32013

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

X

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

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

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

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 20-28598-01

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

DuPont Merck Pharmaceutical Co.
331 Treble Cove Road
N. Billerica, MA 01862

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

(See Attached)

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dennis Dumas

TELEPHONE NUMBER
(508) 671-8669

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

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

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY N/A | AMOUNT ENCLOSED $ N/A

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

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

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

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Dennis Dumas, Assoc. Dir., Safety & Env. Eng.	Dennis Dumas	10/29/96

OCT 30 1996

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
					123852
APPROVED BY				DATE	

DU PONT DE NEMOURS & CO. (INC.).
MEDICAL PRODUCTS DEPARTMENT

FEDERAL EXPRESS 3478279813
CUSTOMER PACKAGE TRACKING NUMBER — PULL UP PURPLE TAB

Delivered 8:48 AM 11/20/90
signed by S. Lakes, USNRC

November 14, 1990

United States Nuclear Regulatory Commission
Region I
King of Prussia, PA 19406

Attn.: John D. Kinneman, Chief
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards

Reference: License No. 20-00320-21

Gentlemen:

This is an application for a new Type A broad scope manufacturing/ distribution license for a company formed by a Joint Venture between the two major corporations, Du Pont and Merck. The new company will be named the Du Pont Merck Pharmaceutical Company and will include the existing radiopharmaceuticals manufacturing/distribution business at 331 Treble Cove Road, North Billerica, MA. Both Du Pont and Merck each have a 50% interest in the new company and will maintain a strong business relationship with the Joint Venture.

The segment of this new company covered by this license request resides at 331 Treble Cove Road, North Billerica, MA, and is the Imaging Agents radiopharmaceuticals business that was previously licensed by the NRC Materials License 20-00320-21. Thus, as of January 1, 1990, the majority of operations at the Billerica site will belong to the new company.

At the Billerica site address Du Pont will continue to own and operate the remaining businesses of Research Products (known as Bionuclides, including Iodination, in Building 250), Specialty Technologies (includes the RIA kit manufacturing operation, in Building 400) and Biotechnology Systems Research and Development (in Building 500). The Du Pont operations at the Billerica site will be leasing the existing space from the Du Pont Merck Pharmaceutical Company.

This application specifies that all operations at 331 Treble Cove Road, North Billerica, Massachusetts, including the Du Pont operations, will be serviced by the Health Physics organization of the Du Pont Merck Pharmaceutical Company, in terms of licensing and regulatory requirements, at the same levels as previously authorized by your office under Materials License 20-00320-21.

November 14, 1990
John D. Kinneman
U.S.N.R.C.
Region I

It is our understanding, based on discussions with your office, the operations of the Du Pont Merck Pharmaceutical Company will be authorized, as of January 1, 1991, by Du Pont's existing NRC Materials License 20-00320-21. Initially only the name has changed, therefore this licensing approach should be valid until the Du Pont license is amended and this license application has been processed for the Joint Venture.

A check is enclosed in the amount of $1800.00 in payment of the license application processing fee specified for License Fee Category 3A in the regulations of Title 10 CFR Part 170, Section 170.31.

Please contact me if you require any additional information.

Sincerely,

Dennis O. Dumas

Dennis O. Dumas
Area Supervisor
Safety and Environmental Affairs

Telephone: (508) 671-8669

PAYMENT QUESTIONS SHOULD BE DIRECTED TO THE PURCHASING SITE

E.I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
FINANCE DEPT. - DISBURSEMENTS
WILMINGTON, DELAWARE 19898

05103847

ALWAYS REFER TO OUR P.O. NUMBER IN YOUR CORRESPONDENCE

00-000-002343820 DUPONT ACCOUNTS PAYABLE 05103847 10/10/90

VOUCHER NO.	INVOICE NO.	P.O. NUMBER	DATE	GROSS	DISCOUNT	NET
XD5392	100190	YNEN0107	10-01-90	1,800.00	.00	1,800.00
RELEASE:	000011858					
	TOTALS			1,800.00	.00	1,800.00

DU PONT

E I du Pont de Nemours & Company
INCORPORATED
FIN 01
FINANCE DEPT. - DISBURSEMENTS
WILMINGTON, DELAWARE 19898

05103847
64-1327/611

DATE	CHECK NUMBER	AMOUNT
10/10/90	05103847	$ ******1,800.00

PAY TO THE ORDER OF
US GOVT
OFFICE OF THE CONTROLLER
US NUCLEAR REGULATORY COMM
WASHINGTON DC 20555

NOT VALID AFTER 90 DAYS

E. B. Hunt

TO
FIRSTATLANTA
The First National Bank of Atlanta
Augusta, Georgia

Better Things for Better Living . . . from Du Pont

⑈05103847⑈ ⑆061113279⑆ 07 519 318⑈

NRC FORM 313
(9-88)
10 CFR 30, 32, 33, 34, 35 and 40

APPLICATION FOR MATERIAL LICENSE

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

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

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY, NMSS
WASHINGTON, DC 20555

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

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

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

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

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

IF YOU ARE LOCATED IN:

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

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

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

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

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

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

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

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

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

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

DuPont Merck Pharmaceutical Company
331 Treble Cove Road
North Billerica, MA 01862

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

331 Treble Cove Road
North Billerica, MA 01862

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION: Dennis Dumas — TELEPHONE NUMBER: (508) 671-8669

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

5. RADIOACTIVE MATERIAL. a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9. FACILITIES AND EQUIPMENT.	10. RADIATION SAFETY PROGRAM.
11. WASTE MANAGEMENT.	12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*: FEE CATEGORY: 3A — AMOUNT ENCLOSED: $ 1800.00

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

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

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

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Dennis Dumas	Dennis Dumas	Area Supervisor, Safety and Environmental Affairs	11/14/90

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS

AMOUNT RECEIVED	CHECK NUMBER

APPROVED BY	DATE

Du Pont Merck Pharmaceutical Company

Billerica, Massachusetts

USNRC LICENSE APPLICATION

TABLE OF CONTENTS

ITEM 2 NAME AND MAILING ADDRESS OF APPLICANT

The Du Pont Merck Pharmaceutical Company Billerica site operations will consist primarily of the manufacturing, distribution and research of medical radiopharmaceutical products. These operations are an integral part of the company's Imaging Agents business.

At the Billerica site address the Du Pont company will continue to own and operate the remaining businesses of Research Products (known as Bionuclides, including Iodination, in Building 250), Specialty Technologies (includes the RIA kit manufacturing operation, in Building 400) and Biotechnology Systems Research and Development (in Building 500). The Du Pont operations at the Billerica site will be leasing the existing space from the Du Pont Merck Pharmaceutical Company.

This application specifies that all operations at 331 Treble Cove Road, North Billerica, Massachusetts, including the Du Pont operations, will be serviced by the Health Physics and Environmental Engineering (Waste Management) organization of the Du Pont Merck Pharmaceutical Company

The Du Pont Merck Pharmaceutical Company will consist of management and employees that previously were a part of the Du Pont safety culture. The safety commitment from Du Pont that includes the basic philosophy that "safety is a condition of employment" will carry over to the new company. Safety will continue to be the responsibility of each employee, including a commitment to safety throughout the line management organization.

ITEM 3 ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

a. Licensed material will be used at the Billerica Facility; at 331 Treble Cove Road, N. Billerica, Massachusetts, 01862.

The Du Pont Merck Pharmaceutical Company will have operations in the following buildings.

110 Office, Warehouse and Receiving Area

150 Environmental Engineering Facility (Radioactive Waste Shipping)

200 Imaging Agents Operations (Radiopharmaceutical Manufacturing)

250 Imaging Agents Operations (Cyclotron Operations)

Note: The Du Pont Bionuclides operations (e.g. Iodination) will continue to operate in this building.

300 Administration and Services

325 Environmental Engineering Building (Radioactive Waste Storage)

350 Storage Building (General equipment, non-radioactive)

375 Storage Building (General Equipment, non-radioactive)

500 Biomedical Research Laboratory (Animal Facility, Imaging Agents Research)

Note: Du Pont's Biotechnology Systems Research and Development operations will continue in this building.

600 Customer Service Center

Note: Building 400 will continue to be used for the Du Pont Specialty Technology operations (i.e. RIA kit manufacturing)

d. Licensed material may be used at temporary job sites for demonstration by sales persons at customers facilities.

ITEM 5 RADIOACTIVE MATERIAL

a. Element and Mass Number	b. Chemical and/or physical form.	d. Maximum quantity of activity which will be possessed at any one time.
A. Any byproduct material with atomic numbers 1 to 83	A. Any	A. 200 Curies of each radionuclide atomic numbers 1 to 83 with a total possession limit of 5,000 Curies
B. Krypton-85	B. Any	B. 10,000 Curies
C. Molybdenum-99	C. Any	C. 8,000 Curies
D. Americium-241	D. Any	D. 350 Curies
E. Xenon-133	E. Any	E. 1,500 Curies
F. Nickel-63	F. Any	F. 1,000 Curies
G. Sulfur-35	G. Any	G. 800 Curies
H. Carbon-14	H. Any	H. 1,000 Curies
I. Cesium-137	I. Any	I. 500 Curies
J. Phosphorus-32	J. Any	J. 200 Curies
K. Strontium-90	K. Any	K. 500 Curies
L. Hydrogen-3	L. Any	L. 50,000 Curies
M. Any byproduct material with atomic numbers 84-94.	H. Any	H. 60 Millicuries each radionuclide with atomic numbers 84-94.
N. Any byproduct material listed in Schedule B 10CFR30.71	I. Any	I. Not to exceed limits specified in Schedule B 10CFR30.71.

ITEM 6 PURPOSES FOR WHICH LICENSED MATERIAL WILL BE USED

A through M

1. Research and Development as defined in Section 30.4(q) of 10CFR30.

2. For possession, use and processing incident to manufacture of radiochemicals, radiopharmaceuticals, and sealed sources.

3. For storage prior to distribution of manufactured radiochemicals, radiopharmaceuticals and sealed sources.

4. For packaging and distribution of manufactured radiochemicals, radiopharmaceuticals and sealed sources to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the Nuclear Regulatory Commission or Agreement States.

5. For use in calibration of Du Pont Merck Pharmaceutical Company instruments at the Billerica site.

6. For storage as radioactive wastes.

N. For demonstration by sales persons at customers facilities, anywhere in the United States where the Nuclear Regulatory Commission has jurisdiction.

A through M

Sealed sources can be returned to the Billerica Site for the purpose of refurbishment or disposal. All such return shipments will be handled in compliance with the conditions of the appropriate Du Pont Merck Pharmaceutical Company USNRC Materials License, as well as applicable DOT regulations.

A through M

This application requests that the Du Pont Merck Pharmaceutical Company Materials License authorize the return of components of DOT containers of radioactive material that previously contained radioactive material. These components that could be returned to the Billerica site for reuse, recycling or disposal would include packing material such as "styrofoam" inserts, lead shields, and the primary containment used for the radioactive material such as the glass/plastic vials.

ITEM 7 INDIVIDUAL RESPONSIBLE FOR RADIATION SAFETY PROGRAM, TRAINING AND EXPERIENCE

a. The Du Pont Merck Pharmaceutical Company Billerica Site Radiation Protection Officer will be Dennis Dumas

DENNIS DUMAS: HEALTH PHYSICIST

EDUCATION

Lowell Technological Institute, Lowell, Massachusetts. Graduated 1971. Degree: Associate of Science in Radiological Health.

Lowell Technological Institute, Lowell, Massachusetts. Graduated 1974. Degree: Bachelor of Science in Radiological Health.

Rivier College, Nashua, New Hampshire. Graduated 1978. Degree: Master of Business Administration.

EXPERIENCE

During school at Lowell Technological Institute, performed as a technologist part-time in radiation and contamination control.

1971 - 1973: Lead Radiation Specialist, New England Nuclear Corporation. Responsible for the performance of several Health Physics Technologists and reported directly to the Radiation Protection Officer. Monitored all functions required of the Radiation Protection Program, such as in-plant radiological monitoring, personnel monitoring (both internal and external), environmental monitoring, radioactive waste disposal, State and Federal regulatory agency compliance accountability, etc.

1973 - 1978: Radiation Protection Officer, New England Nuclear Corporation, Billerica, Massachusetts operations. On license as responsible for all regulatory compliance monitoring and analyses. Supervised 20 people in their completion of all surveys, analyses and procedural reviews required in the Radiation Protection Program in order to provide quality assurance of techniques used to determine date and complete documentation for the various regulatory agencies.

1978 - Present: From 1978 to 1981 served as Corporate Director of Radiation Protection, New England Nuclear Corporation and from 1981 to present as Area Supervisor of Safety and Environmental Affairs. Radiation Protection Officer on all N.R.C. licenses and responsible for directing the various functions of the Radiation Safety Program, such as Technical Development, Operational Radiation Protection and Radioactive Waste Engineering to ensure maximum safety of employees from radioactive materials and to demonstrate control of these radioactive materials to all regulatory agencies. Advise management at all levels as necessary on situations which may result in personnel exposure or releases of radioactivity to the environment above established guidelines, to ensure management awareness of radiation safety issues requiring its attention. Coordinate all inspections by Federal and State agencies as required. Direct training programs for new and old employees to ensure that all employees are adequately trained and informed about radiation protection principles. The Safety and Environmental Affairs organization currently consists of approximately 40 people at various professional levels, with an operating budget of about $5.5 million.

PROFESSIONAL ORGANIZATIONS

International CHCM. Position: Certified Hazard Control Manager, Master Level; Plenary Member.

New England Chapter of the Health Physics Society. Position: President 1980 - 1981.

Health Physics Society. Position: Plenary Member.

New England Chapter of American Industrial Hygiene Association. Position: Plenary Member.

American Nuclear Society, New England Section. Position: Plenary Member.

American Association for the Advancement of Science. Position: Plenary Member.

ITEM 8 TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

1. Initial training in the fundamentals of radiation protection will be given to each new employee by the Safety Office.

   Topics covered include:

   a. Radiation and Radioactivity

      - Radioisotopes
      - Radioactive Decay
      - Types of Radiation
      - Quantities of Radiation

   b. Measurement of Radiation

      - External Personnel Dosimetry
      - Internal Dosimetry
      - Survey Equipment

   c. Biological Effects of Ionizing Radiation

      - Natural Radiation
      - Low Level Radiation Risks
      - Regulatory Exposure Limits
      - ALARA

   d. Control of Radiation Exposure

      - Time
      - Distance
      - Shielding
      - Contamination Control

   e. Standards of Radiation Protection

      - Company Standards
      - State and Federal Rules and Regulations

   An exam is administered after the above training is completed.

2. Refresher training sessions are given through-out the year to personnel working in Restricted Areas. In addition, ancillary personnel will be retrained when their job assignments are in an area where radioactive material is handled.

   A brief review is given of the topics listed in section H.1. above. Additional issues of concern to the personnel are discussed.

3. Radioactive materials are to be used by, or under the supervision of individuals designated by the Radioisotope Committee.

ITEM 9 FACILITIES AND EQUIPMENT

Information is presented according to the following format for the Billerica Facility.

The information has been listed in certain sections as follows:

A. Building Diagrams

B. Description of Laboratory Operations

C. Laboratory Descriptions (General)

1. Change Areas
2. Hoods
3. Containment Boxes
4. Hot Cells
5. Storage Areas, Containers, Special Shielding
6. Remote Handling Tools
7. Respiratory Protection Equipment

D. Environmental Monitoring

E. Site Security and/or Access Control to Buildings

ITEM 9 BILLERICA OPERATIONS

A. Building Diagrams

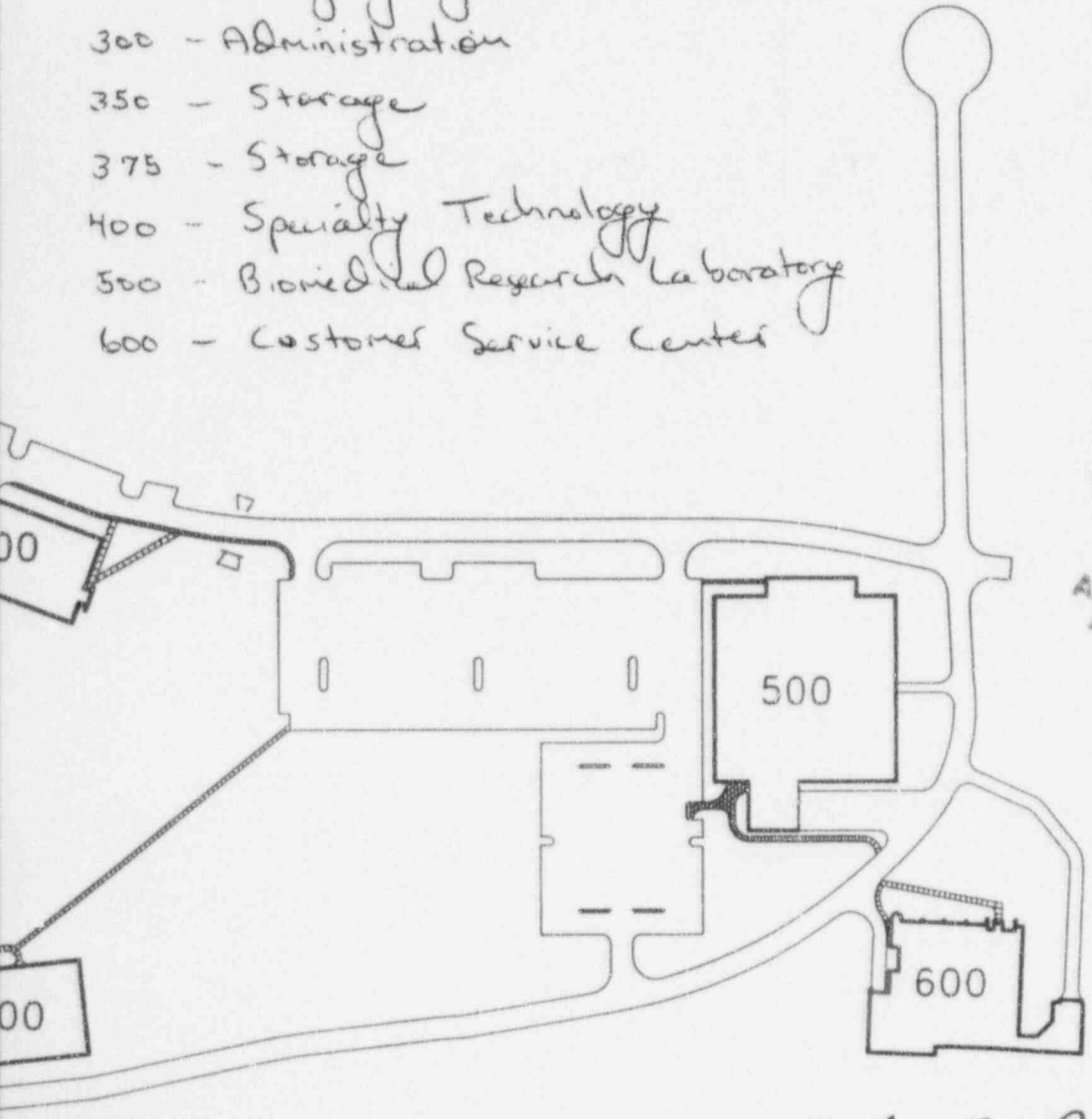
and

B. Description of Laboratory Operations


110
150
200
250
325
TEL
375
350

Building

110 - Warehouse
150 - Environmental Engineering
200 - Imaging Agents
250 - Imaging Agents and Bionuclides
300 - Administration
350 - Storage
375 - Storage
400 - Specialty Technology
500 - Biomedical Research Laboratory
600 - Customer Service Center



9707070178-01

DUPONT **Medical Products**

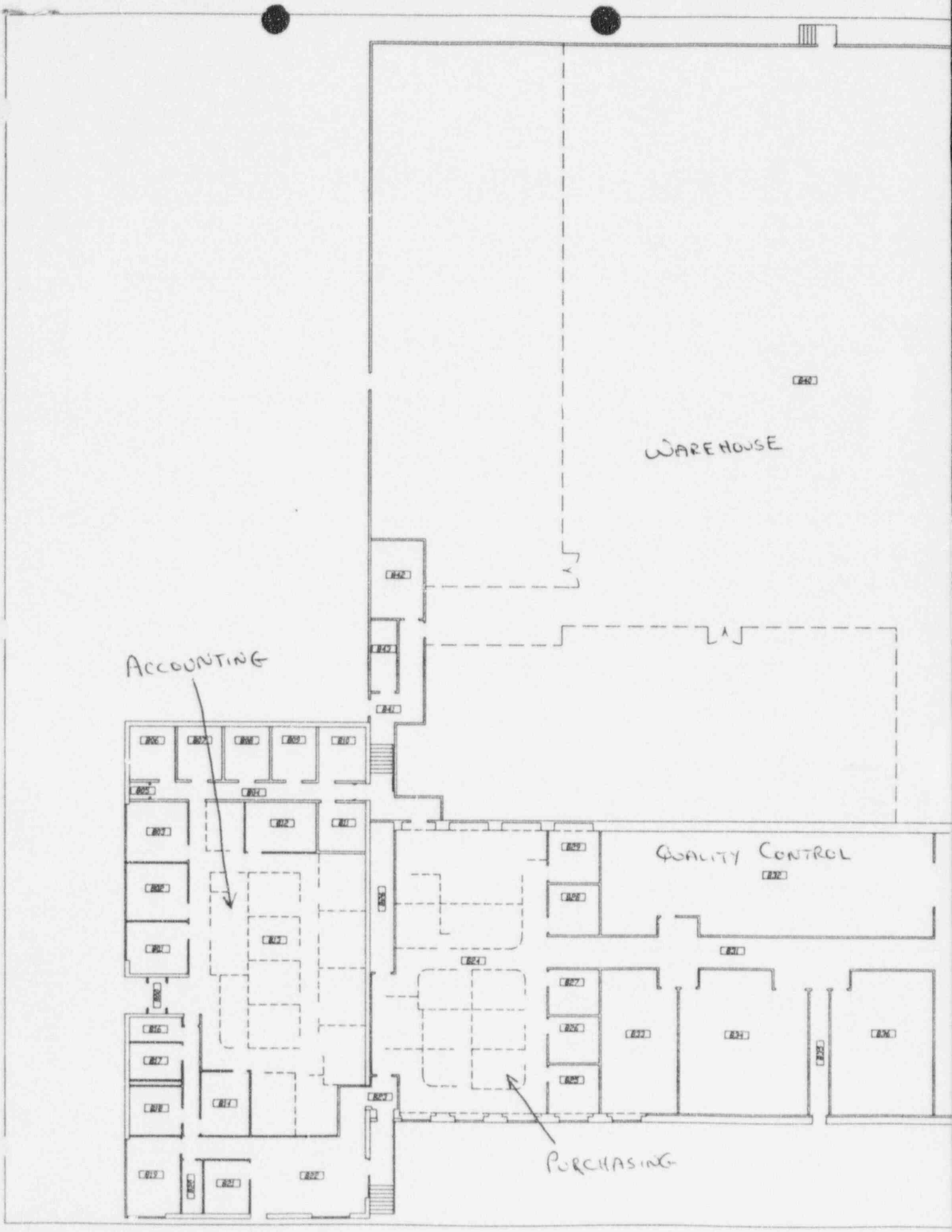
BOSTON AREA SITE
BILLERICA
FACILITY

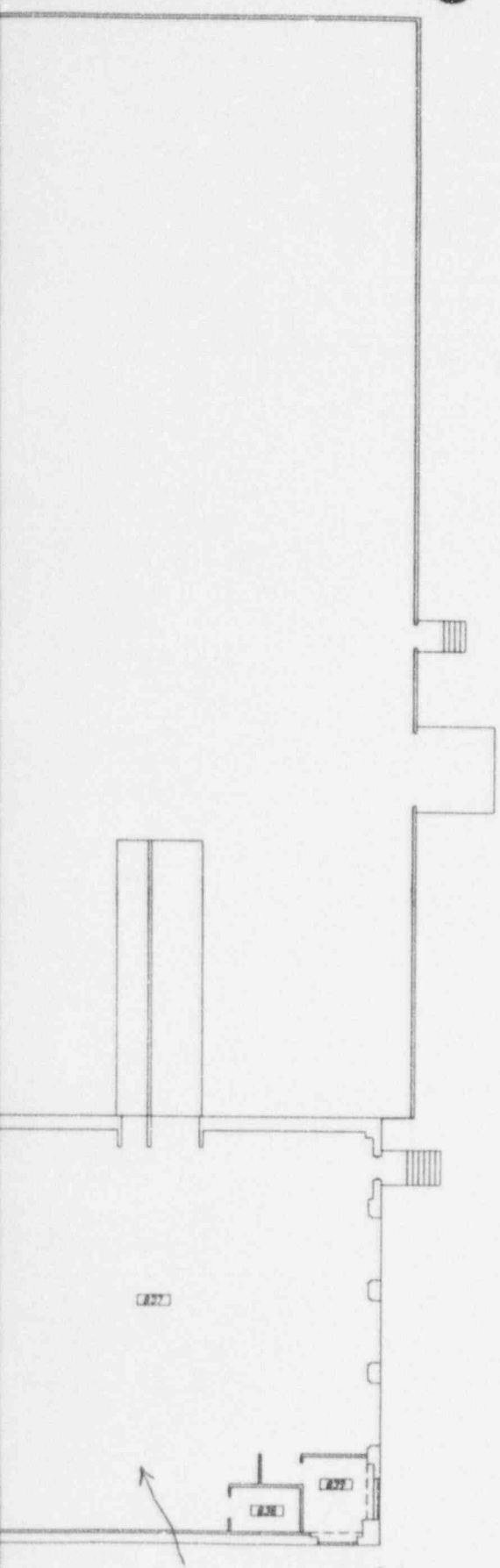
123852

Building #110, Office, Warehouse and Receiving Area

This building houses an office area, receiving dock area and warehouse operation.

The dock area is used for receipt of radioactive material. Packages are monitored and placed into a secure holding area until delivery to site areas.





9707070178 02

DUPONT **Medical Products**

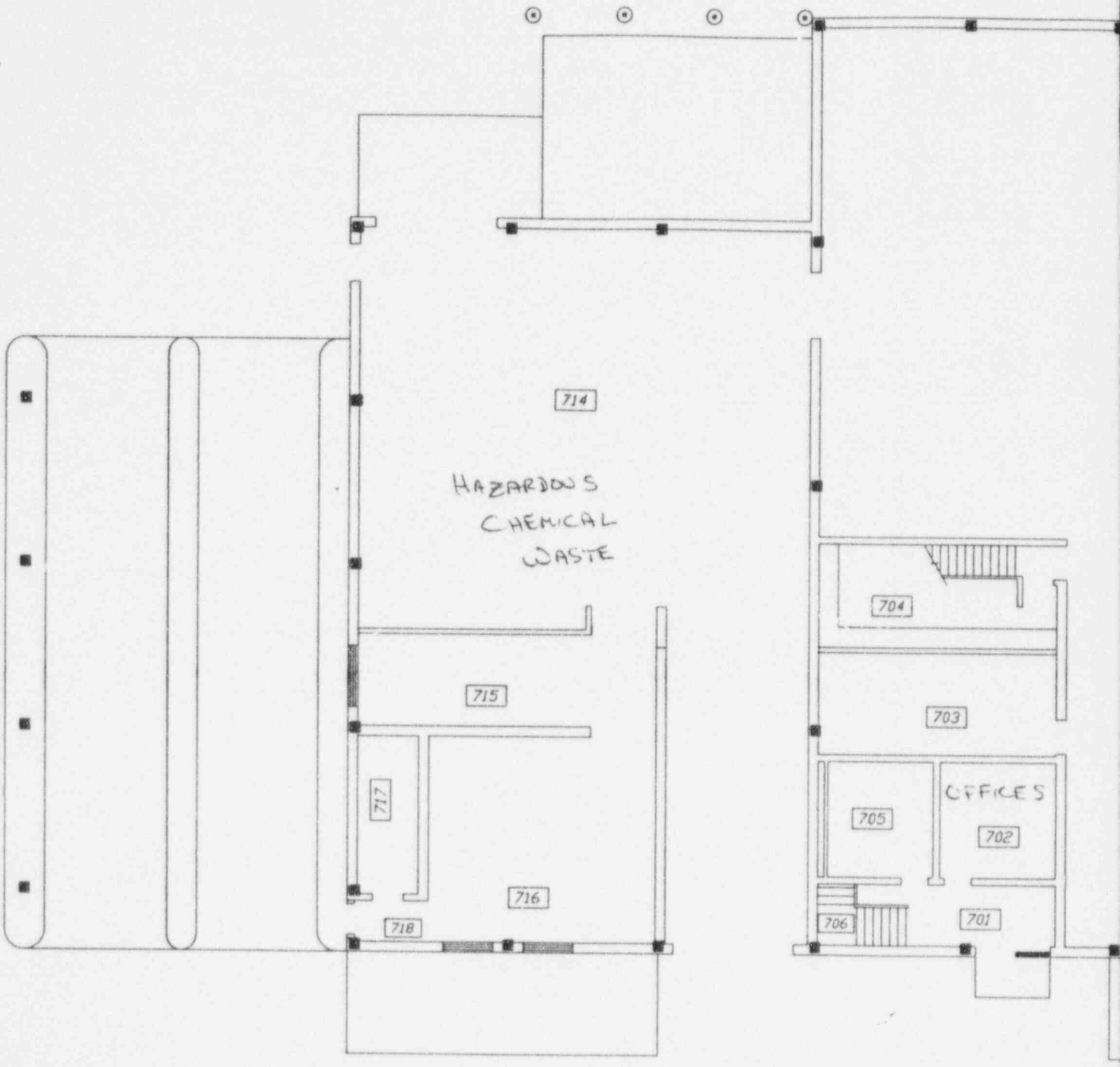
BOSTON AREA SITE
BUILDING 110
FLOOR 1

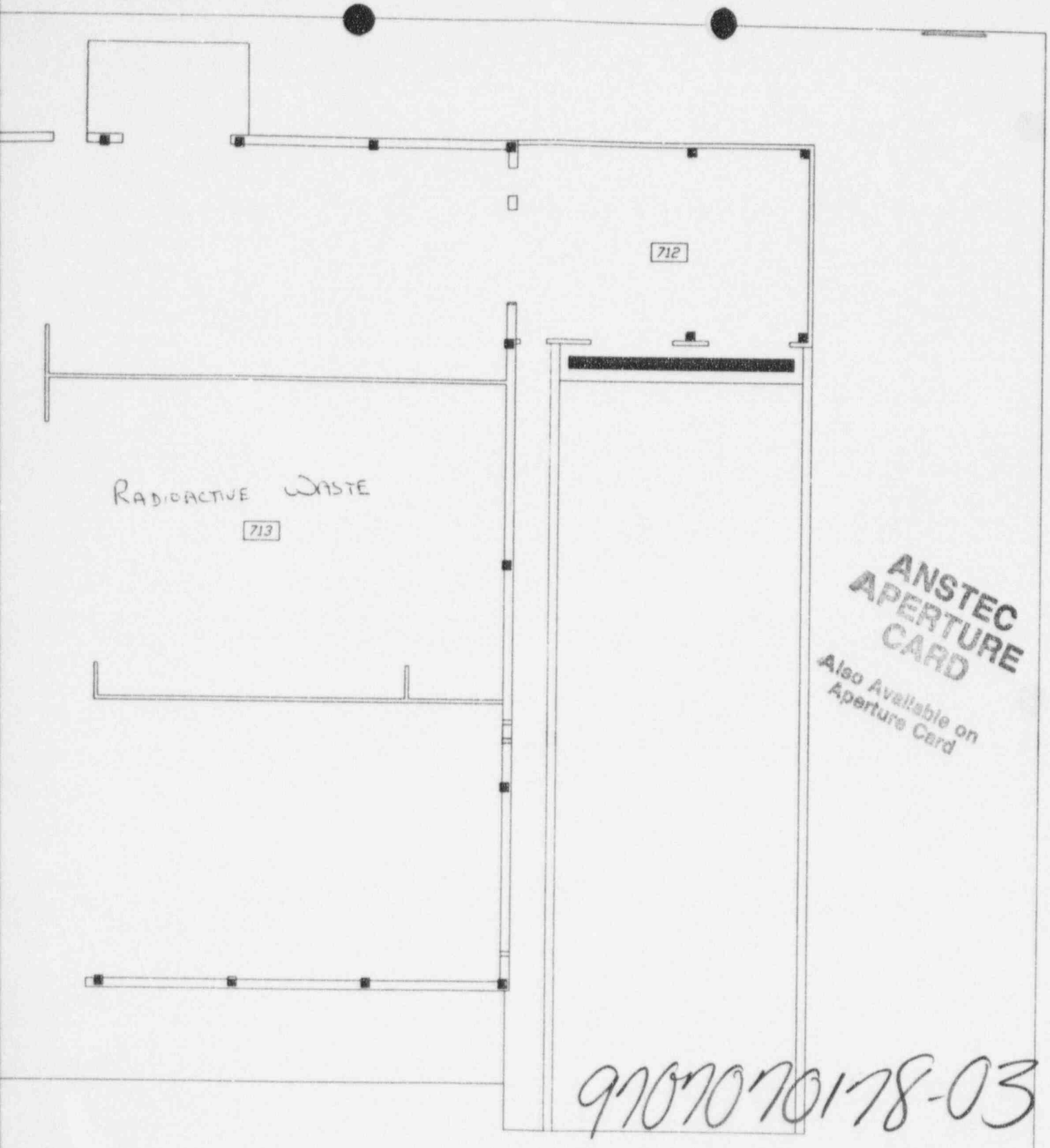
123852

Building #150, Environmental Engineering Facility

This facility is used for storage, handling and preparation for shipment of hazardous materials including radioactive waste.

All shipments of hazardous waste to authorized recipients originate from this area.


714
HAZARDOUS
CHEMICAL
WASTE
715
717
716
718
704
703
OFFICES
705
702
706
701



9707070178-03

DUPONT **Medical Products**

BOSTON AREA SITE
BUILDING 150
FLOOR 1

123852

Building #200, Imaging Agents

This building is used for production of and research and development on radiopharmaceuticals and reagent kits. Licensed products are used for the Molybdenum/Technetium generator and several associated reagent kits; Xenon gas mixtures for lung imaging; and accelerator produced Thallium and Gallium.

The Billerica Site has appropriate NRC licenses for the reagent kits and for distribution of the generators.

The building itself contains office space; sterile clean rooms; "cold" assembly areas; and many other areas to carry out various component inspections and storage required by Food and Drug Regulations.

The restricted areas are indicated on the attached map.

Production Area

Molybdenum/Technetium production is started in Room H224. The partially assembled generators are lined up in a shielded cell; the raw material is processed in the chemical cell and metered into each generator, the generators pass, assembly line fashion; along cell where final assembly is done, Q.C. samples are eluted, quantities checked, etc.

The generator is packed in its shipping container, passed to the shipping dock and into the distribution system.

Xenon-133 gas is processed in a custom designed filling hood in Room H229; the vials are placed in their shields and moved through the packaging room to the distribution system.

Thallium and Gallium are also processed in Room H229.

The other rooms in the area support the main production functions.

Entry to the area is via change areas where lab coats are put on and shoe changes made. Hand and foot counters and appropriate instruments are in place in these rooms.

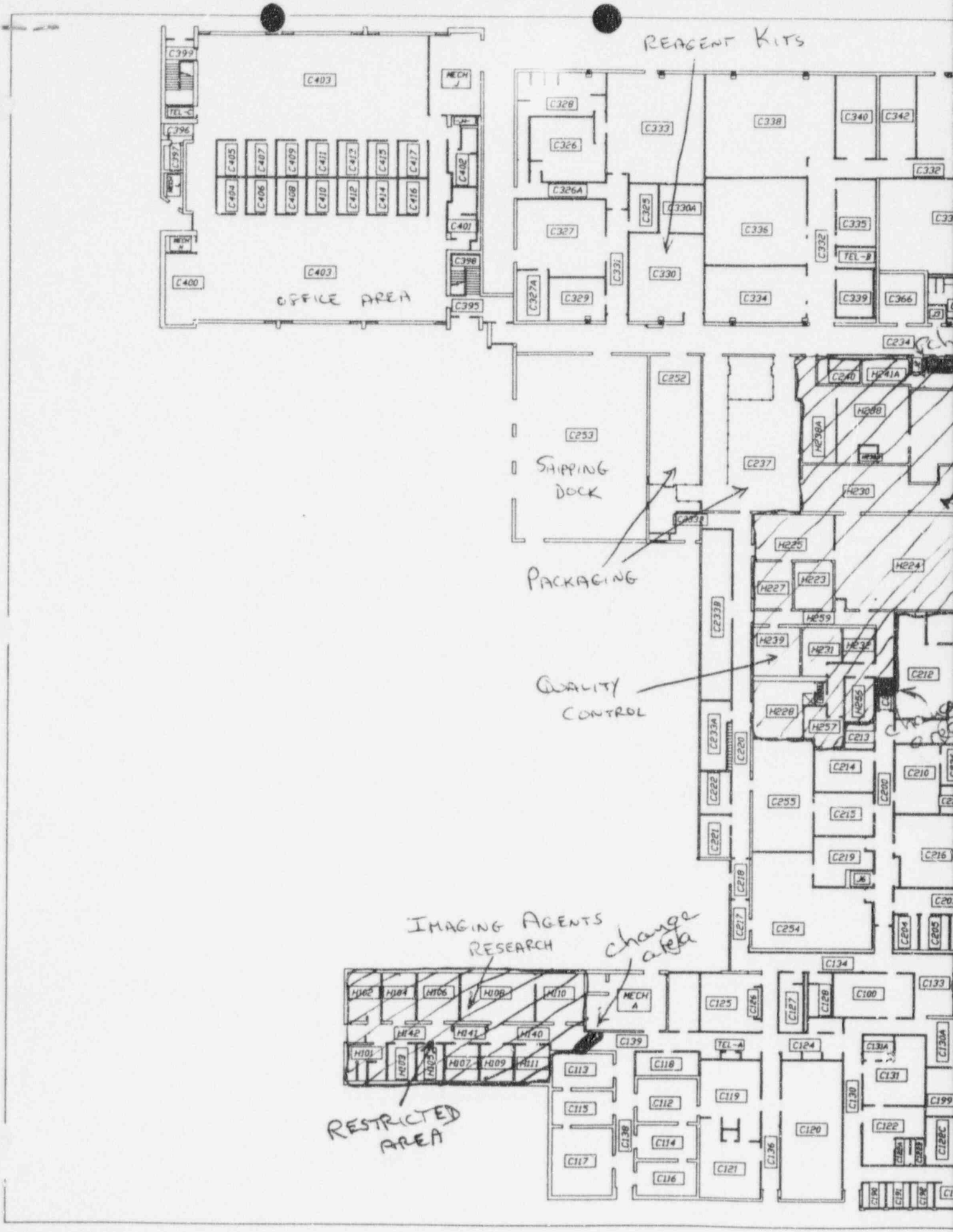
Research and Development

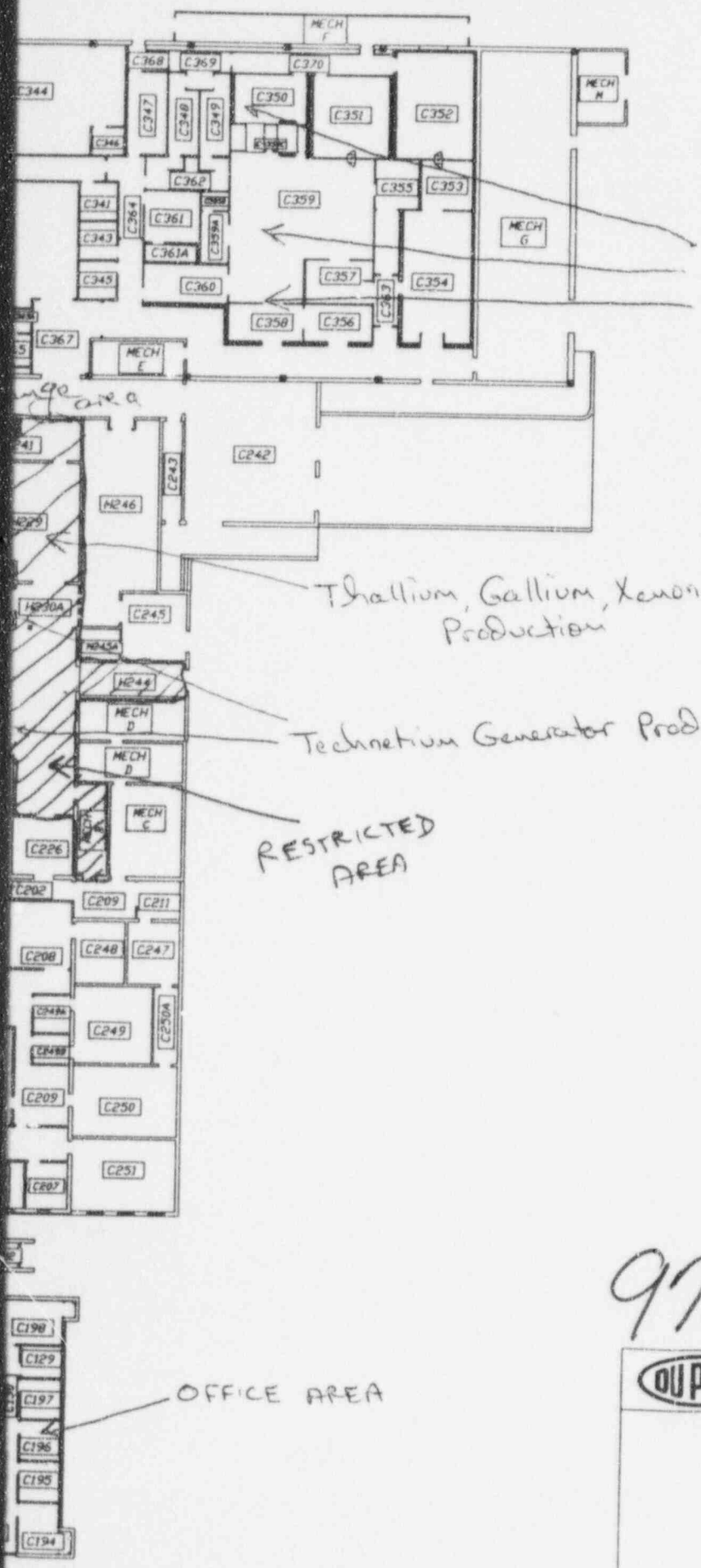
The layout of the R & D restricted area is indicated on the attached.

The activities in this area relate to testing of current products; testing of chemical components of the products and development of new products.

Relatively small amounts of radioactivity are used here; the hoods in the several laboratories are conventional laboratory hoods.

Entry to the area is through a change area where shoes are changed and lab coats donned. Instrumentation is available at the change area for workers to monitor their hands, shoes and clothing on leaving the area.


REAGENT KITS
OFFICE AREA
SHIPPING DOCK
PACKAGING
QUALITY CONTROL
IMAGING AGENTS RESEARCH
change area
RESTRICTED AREA



9707070178-04

DUPONT **Medical Products**

BOSTON AREA SITE
BUILDING 200
FLOOR 1

123852

Building #250, Imaging Agents and Bionuclides

Building #250 has two large restricted areas for the processing, handling and storage of radionuclides.

Laboratories H1 to H33

These laboratories start adjacent to Cyclotron I and go around the corner to the packaging area.

Imaging Agents operations consist of Cyclotron Production, Cyclotron Chemistry, the processing of targets from the cyclotrons, and Development, work involving medical products.

Du Pont company operations consist of Bionuclides, the processing of byproduct material as well as accelerator produced radionuclides; and Dispensing, radionuclides are dispensed for release to the shipping area to fill customer orders.

In the laboratory area all quantities of radionuclides are handled up to the license limits. The containment for these operations are performed with approximately 80 fume hoods, 20 lead cells and 10 containment boxes of which two are dedicated to iodine dispensing operations.

Laboratories H50 to H58, H70 and H71

This area houses five cyclotrons with a sixth unit under construction as of the date of this application. The laboratories listed are support operations for all aspects of the cyclotron irradiation process.

These laboratories handle primarily accelerator produced radionuclides, up to curies in quantity. Containment systems include approximately 30 fume hoods and 15 cells.

Laboratories H102 to H106

These operations are the source manufacturing processes. Kr-85 sources are produced in H102 and Ni-63 sources in H104.

The containment systems in all of these laboratories number approximately 15 fume hoods, 3 lead cells and approximately 10 containment boxes.

Laboratories H107 to H117

These laboratories consist of several operations, from the health physics lab in H107 to the nuclear medicine source lab and mossbauer source lab in H107 and H109 respectively.

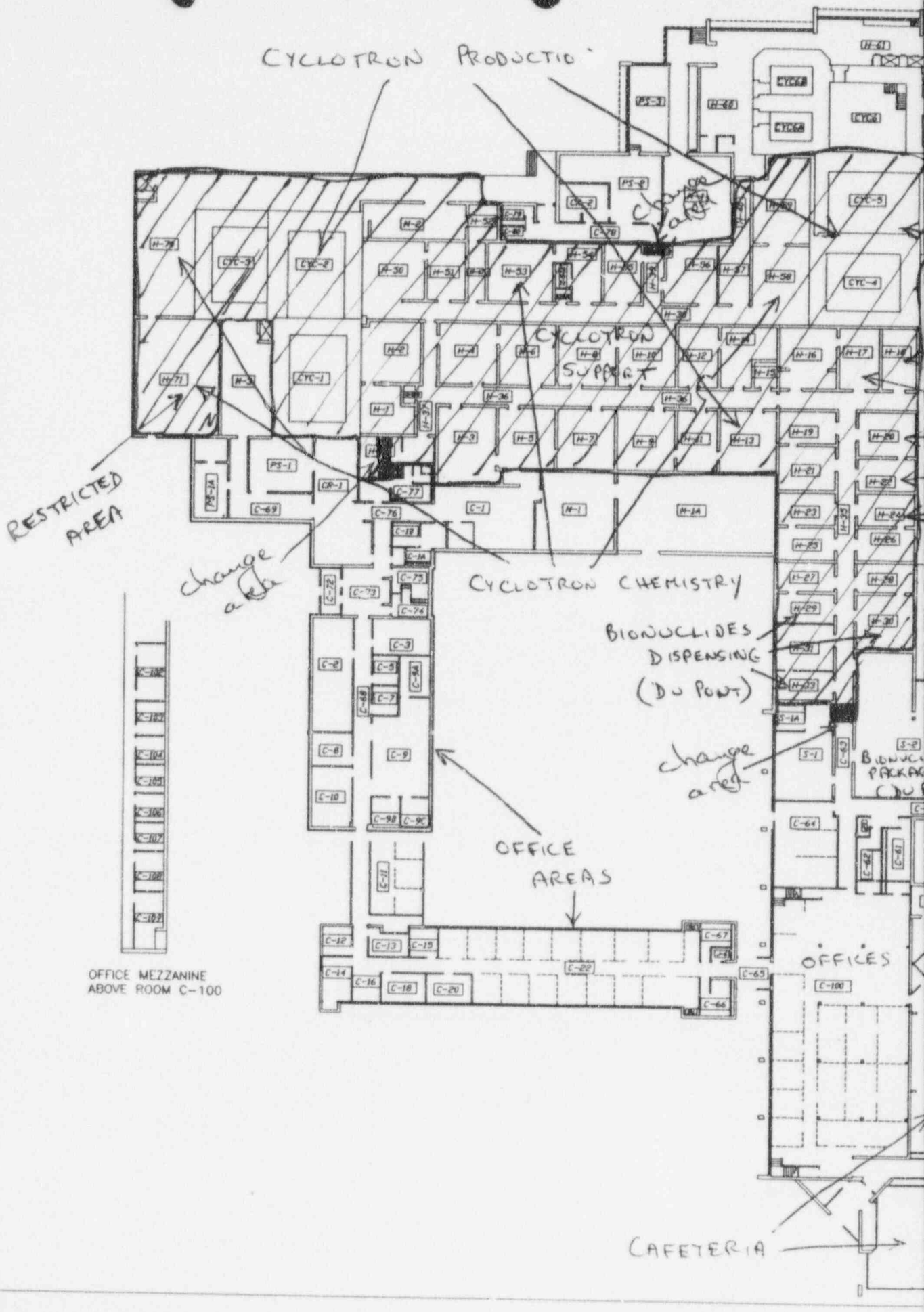
The Du Pont company's iodination laboratories are in H112 to H117 along either side of the end of the hallway beyond the source manufacturing area.

These laboratories involve primarily source manufacturing and iodination operations. The containment systems number approximately 40 fume hoods and 20 containment boxes of which eight are dedicated to iodination operations.

Laboratories H121 to H129

These laboratories house the research and development operations for Imaging Agents including the analytical counting laboratories where up to millicuries of activity are handled.

Containment systems number approximately 15 fume hoods.


CYCLOTRON PRODUCTIO
RESTRICTED AREA
change area
CYCLOTRON SUPPORT
CYCLOTRON CHEMISTRY
BIONUCLIDES DISPENSING (DU PONT)
change area
OFFICE AREAS
OFFICES
CAFETERIA
OFFICE MEZZANINE ABOVE ROOM C-100

NEW INSTALLATION
CYCLOTRON VI ; START-UP
ABOUT DEC. 1, 1990

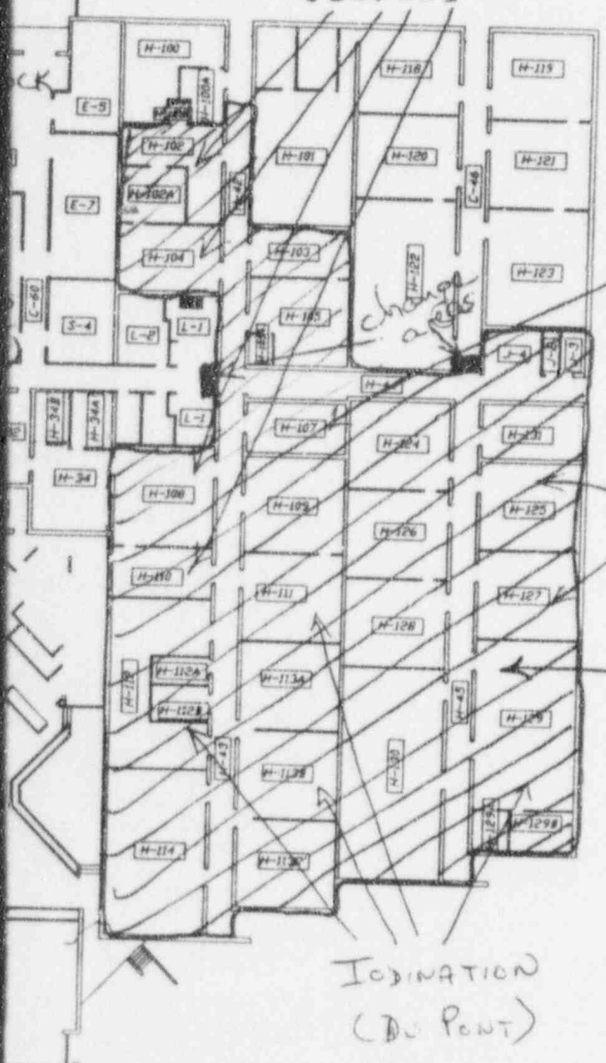
RESTRICTED AREA

ENVIRONMENTAL ENGINEERING

BIONUCLIDES (DU PONT)

P-32 AND S-35 PROCESSING

SOURCES



HEALTH PHYSICS

ANALYTICAL

RESTRICTED AREA

IODINATION (DU PONT)

9107070178-05

DUPONT **Medical Products**

BOSTON AREA SITE
BUILDING 250
FLOOR 1 & 2

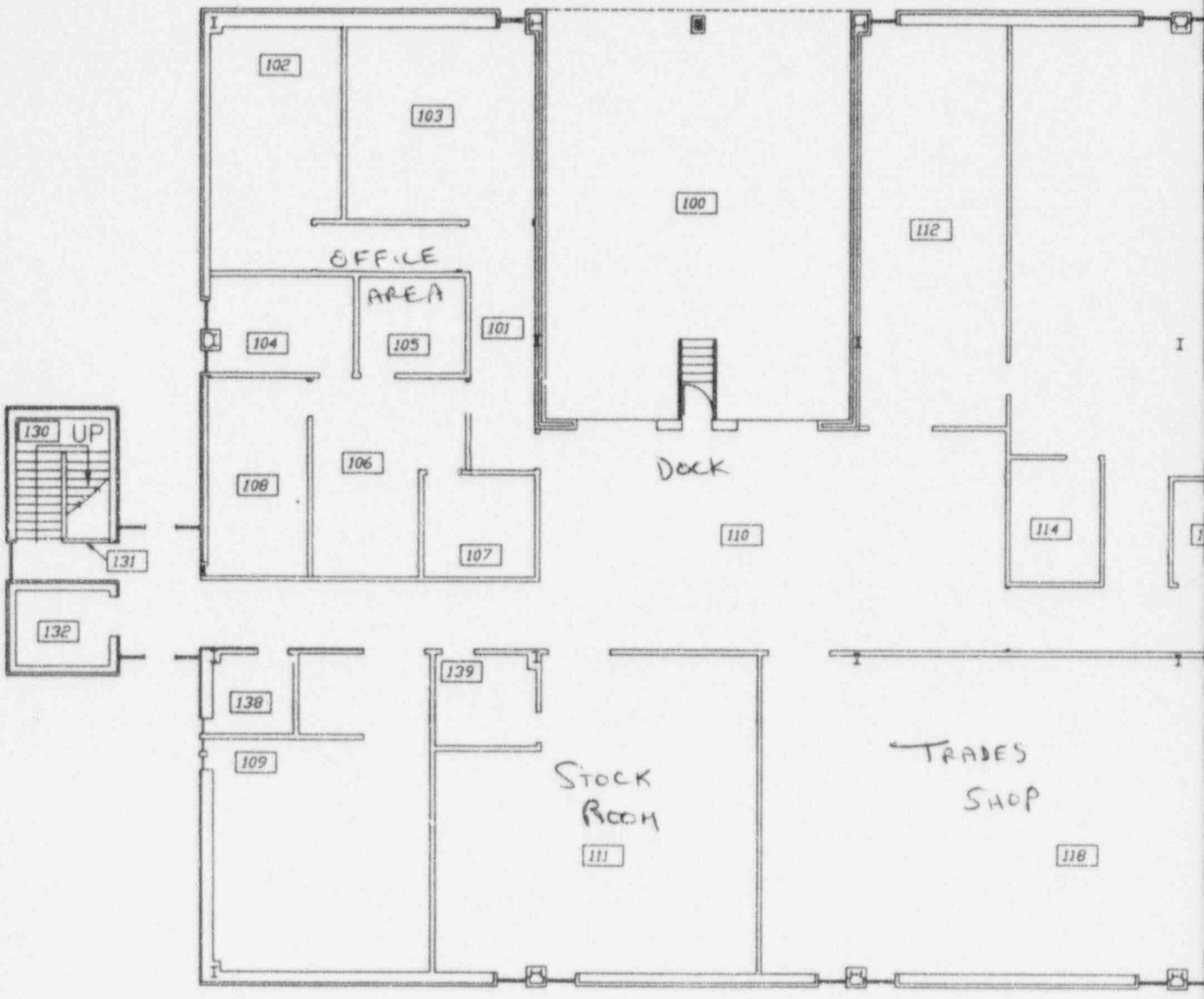
123852

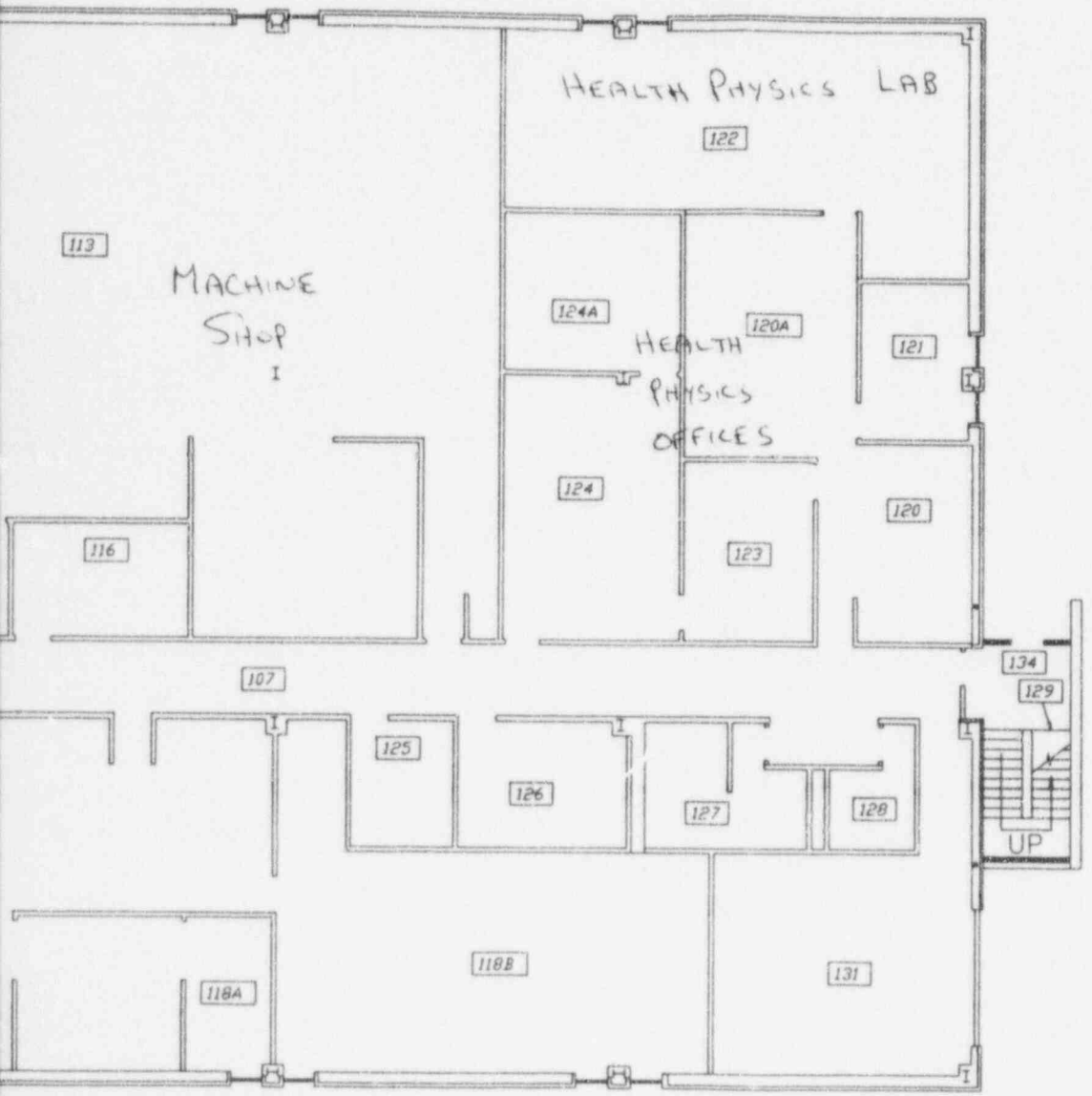
Building #300, Administration and Services

This building consists of an office area on the second floor; on the first floor are offices, trades and machine shops and health physics laboratory area.

The main health physics laboratory is on the first floor where the employee and surveillance NRC records are maintained. This laboratory also houses the dosimetry and analytical counting equipment.

Personnel offices as well as the facilities/process engineering support staff are located on the second floor of this building.


102
103
100
112
OFFICE
AREA
104
105
101
130
UP
106
108
DOCK
107
110
114
131
132
139
138
109
STOCK
ROOM
111
TRADES
SHOP
118

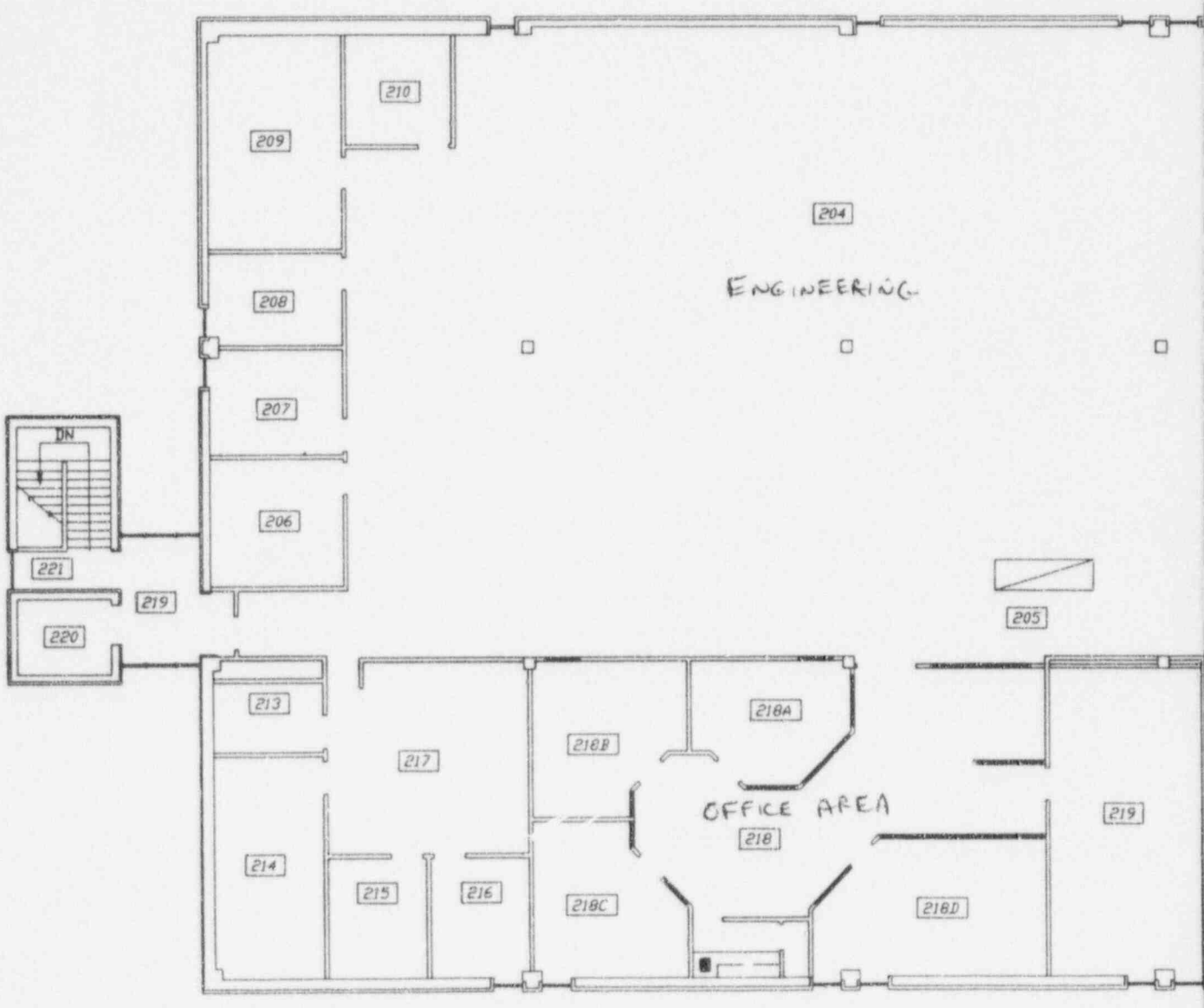


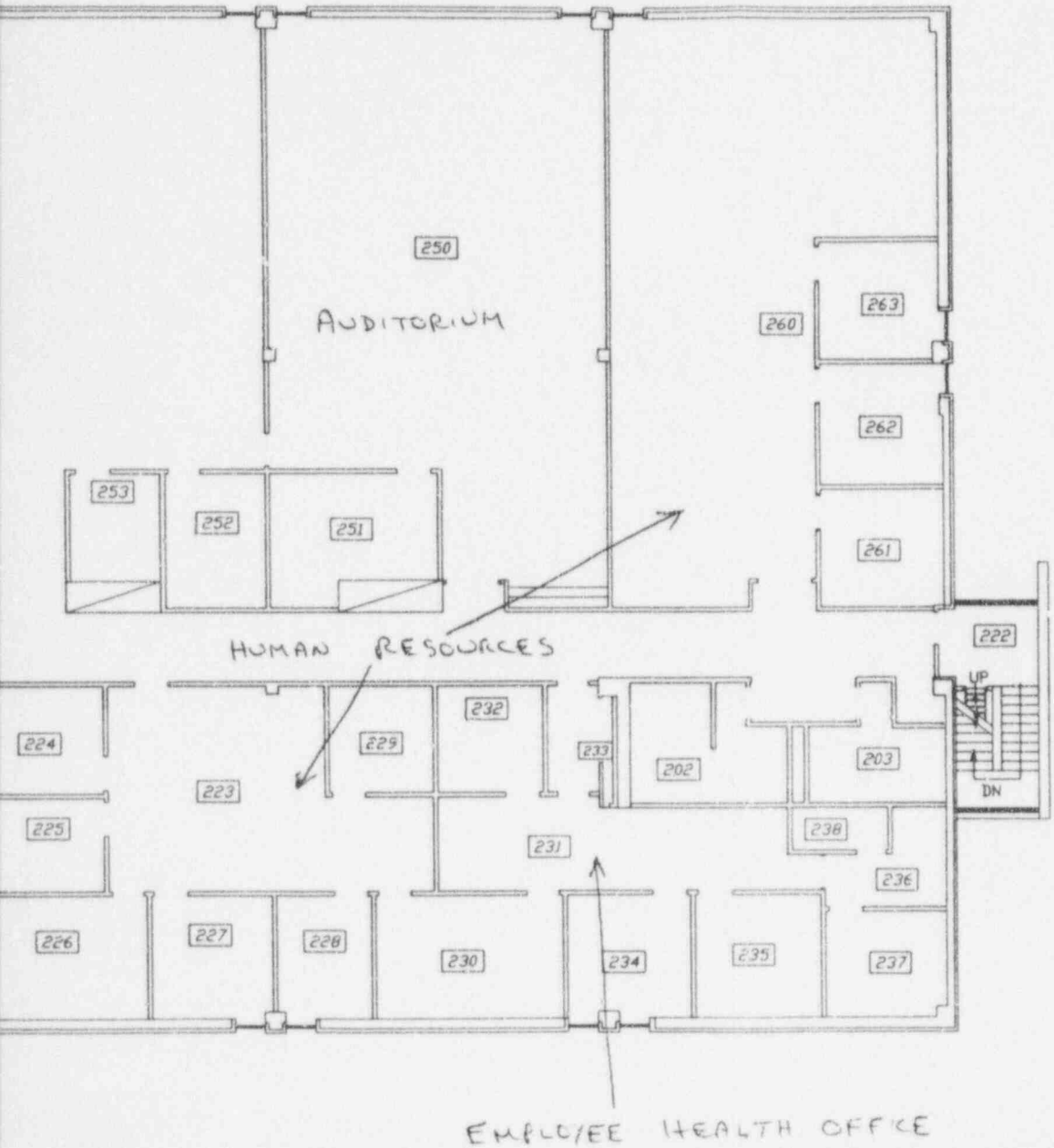
9107070178-06

DUPONT **Medical Products**

BOSTON AREA SITE
BUILDING 300
FLOOR 1

123852


210
209
204
ENGINEERING
208
207
DN
206
221
219
220
205
213
218A
218B
217
OFFICE AREA
219
218
214
215
216
218C
218D



EMPLOYEE HEALTH OFFICE

9707070178-07

DUPONT **Medical Products**

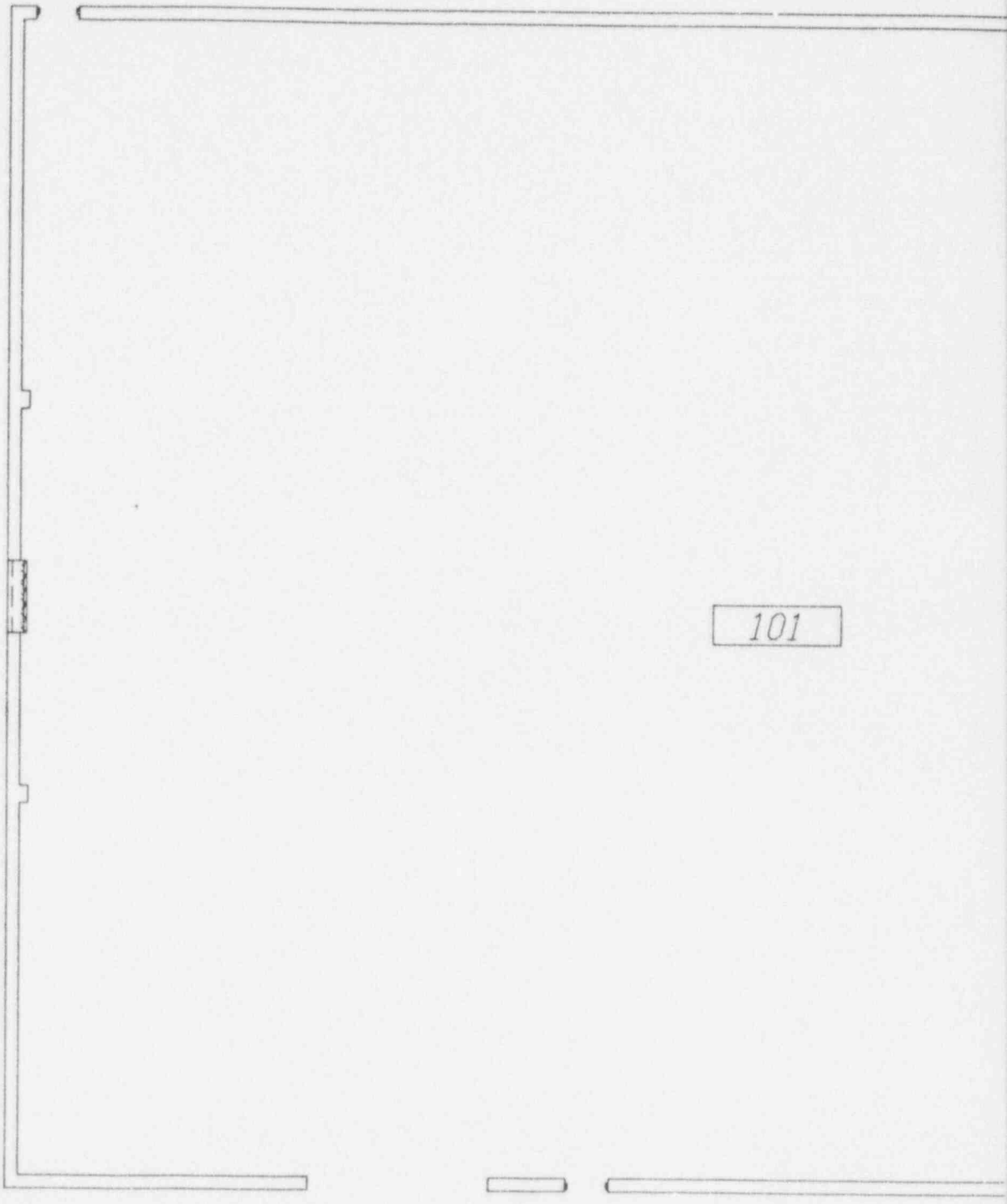
BOSTON AREA SITE
BUILDING 300
FLOOR 2

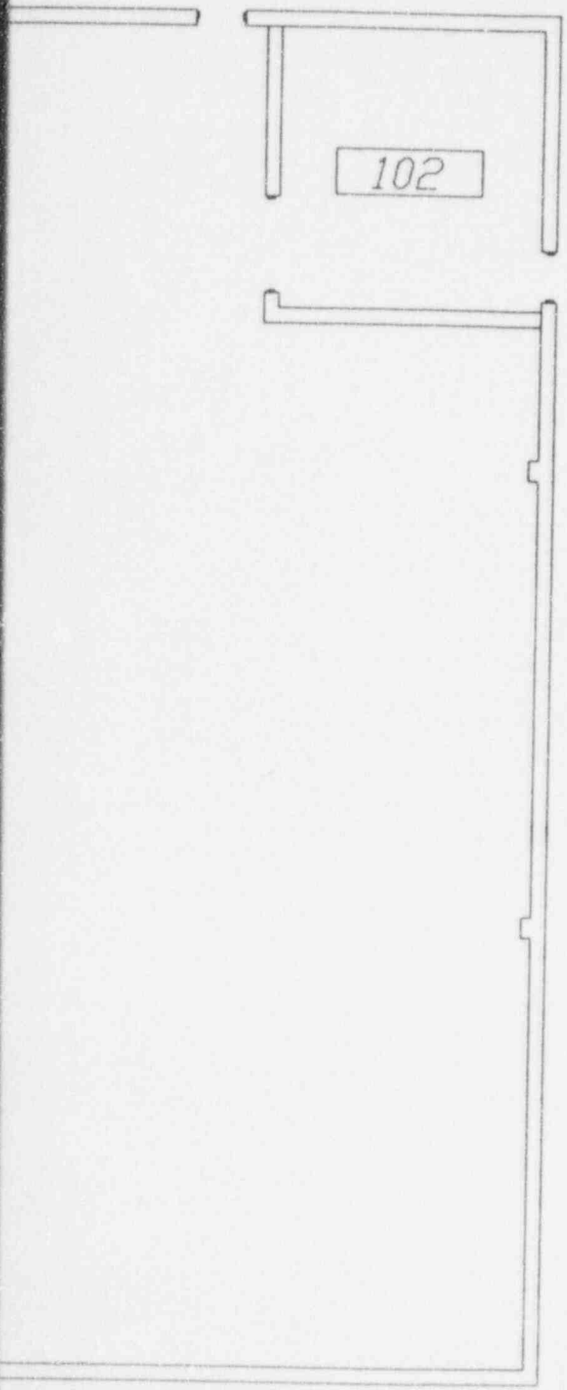
Building #325, Environmental Engineering

This building is a storage area for radioactive waste awaiting disposal.

This building is of cinder block construction with sprinkler systems. Shipments of hazardous waste destined for licensed disposal sites are staged, monitored, and documented at this area.

This building is used for the "hold-for-decay" radioactive waste storage program.


101



9701070178-08

DUPONT **Medical Products**

BOSTON AREA SITE
BUILDING 325
FLOOR 1

123852

Building #350, Storage Building

This building is currently empty. Radioactive material is not used or stored in this building.

Building #375, Storage Building

This is a warehouse of used furniture, as well as large office and laboratory equipment.

No radioactive material is present in this area.

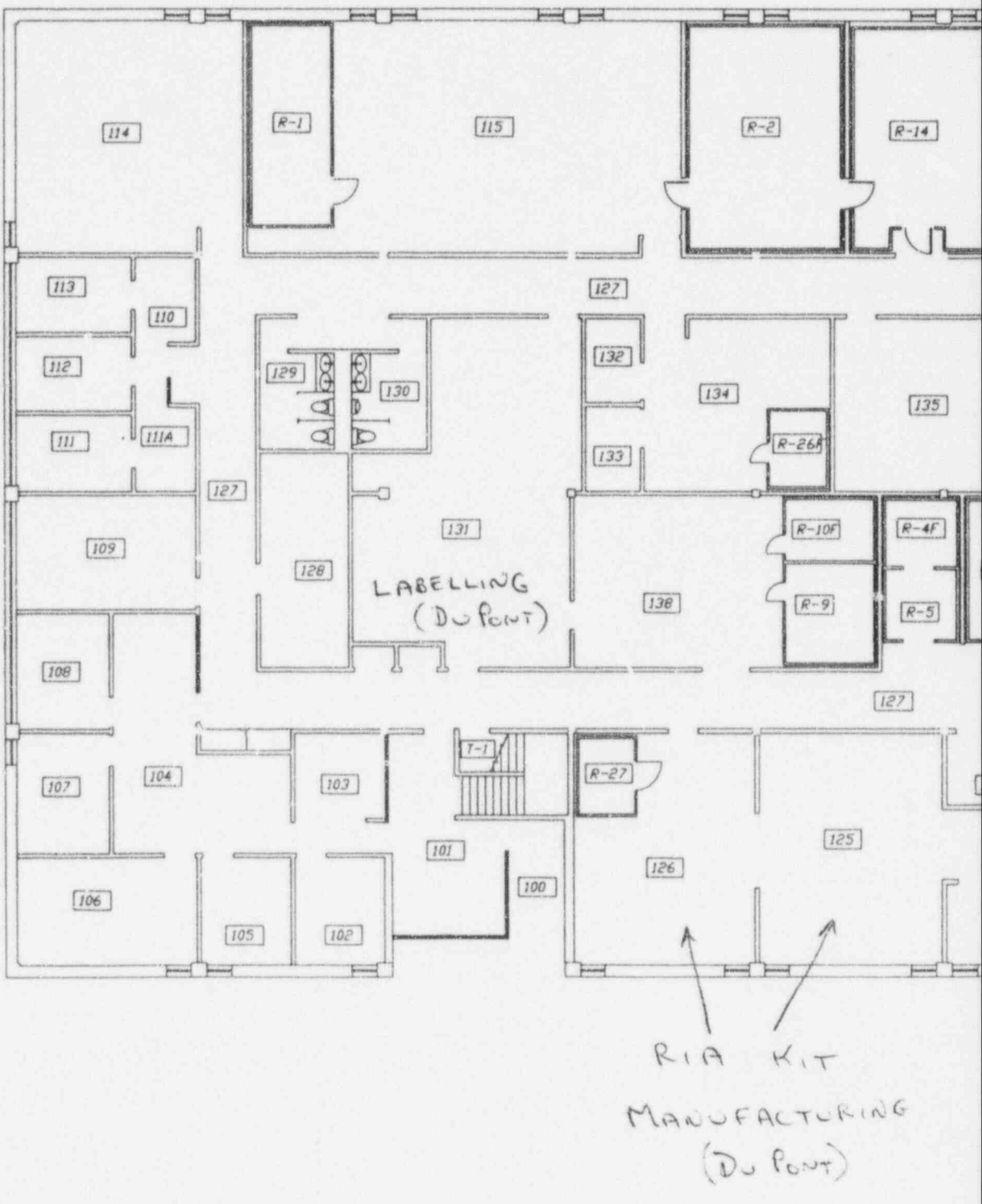
Building #400, Du Pont Specialty Technologies

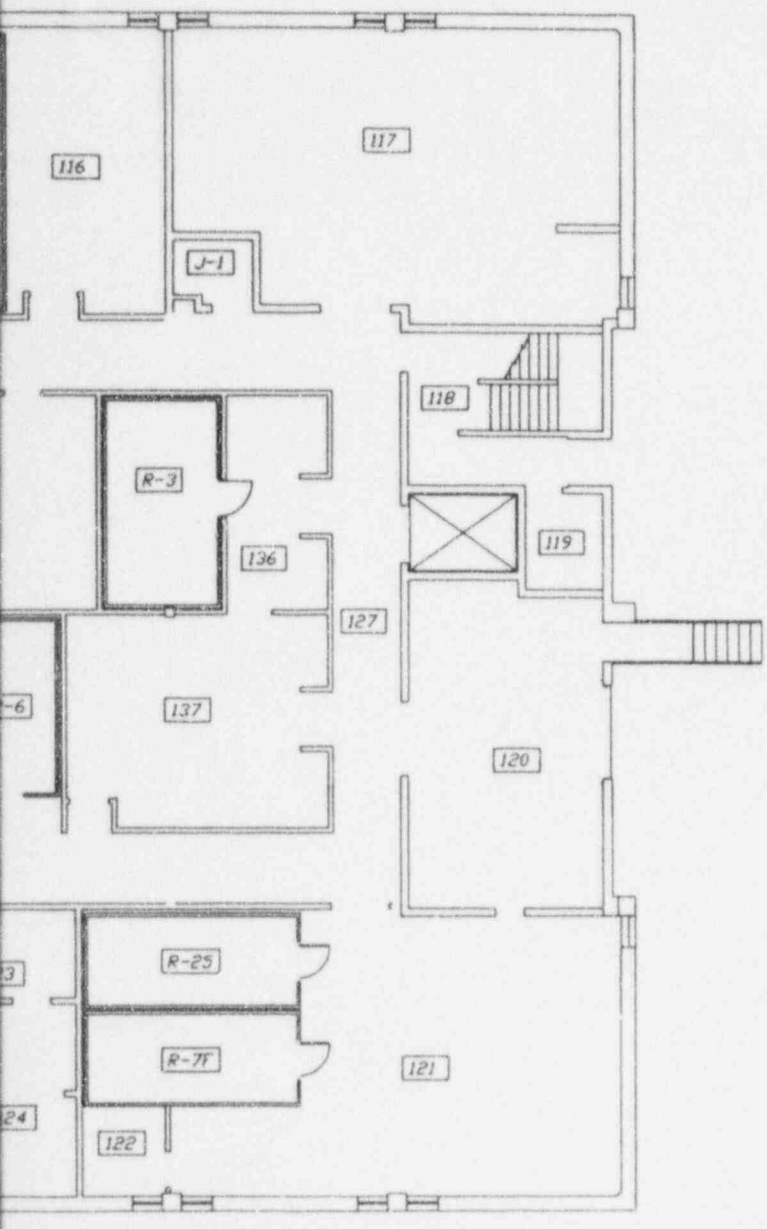
This is a two-story building that houses laboratories, assembly area, storage areas and offices.

The products of this building are several radioimmunoassay kits.

On the second floor, there is a small laboratory area that is a restricted area. This lab is used for tagging compounds that will eventually be the active component of the kits.

In this area, there is a plastic box with internal charcoal filters within a hood that is used for iodine-125 tagging.

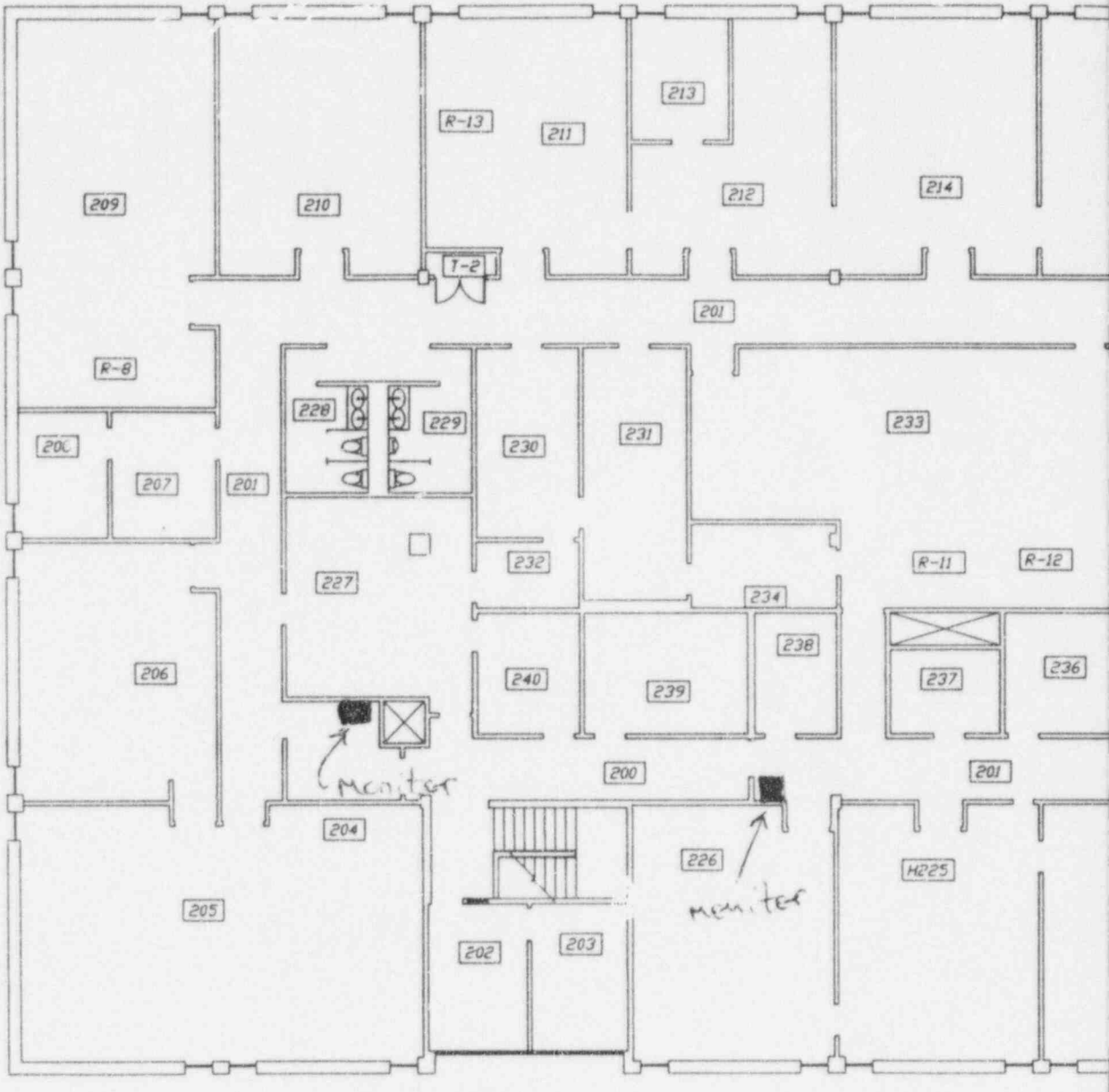

114
R-1
115
R-2
R-14
113
110
112
111
111A
127
129
130
132
134
135
133
R-26A
109
131
128
LABELLING
(DuPont)
138
R-10F
R-4F
R-9
R-5
108
127
107
104
103
T-1
R-27
101
125
126
106
100
105
102
RIA KIT
MANUFACTURING
(DuPont)

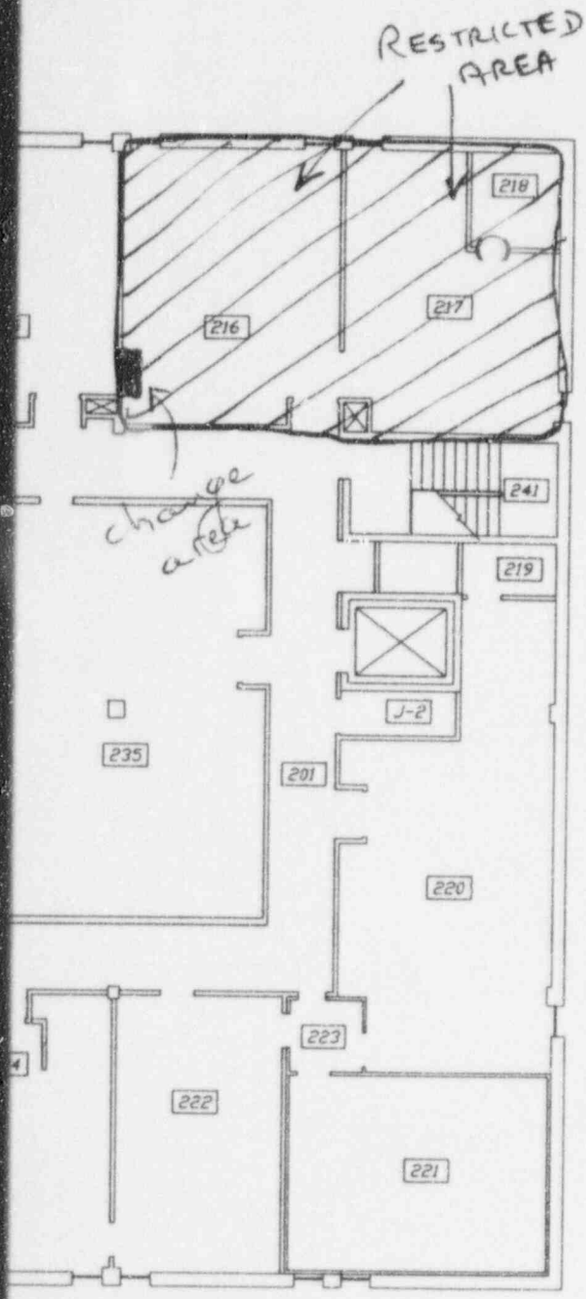


9707070178-09

DUPONT **Medical Products**

BOSTON AREA SITE
BUILDING 400
FLOOR 1


209
210
R-13
211
213
212
214
T-2
201
R-8
228
229
230
231
233
200
207
201
227
232
R-11
R-12
234
238
206
240
239
237
236
Monitor
200
201
204
226
H225
205
Monitor
202
203



ALL CONTROLLED AREA

9707070178-10

DUPONT **Medical Products**

BOSTON AREA SITE
BUILDING 400
FLOOR 2

Building #500, Biomedical Research Laboratory

This building has operations on three floors.

First Floor

The first floor operations consist of Imaging Agents Research and a large animal facility for housing and caring for a variety of species.

The entire animal facility has been designated a restricted area primarily because radionuclides are injected into the animals for research purposes with the resulting excreta and waste. Entry into the animal area requires a magnetic card key that must be inserted into a wall receptacle to gain access to the area. The authorized card holders include the animal caretakers, primary researchers, custodial and security services and the Health Physics personnel.

The research operations utilize mCi quantities of radionuclides.

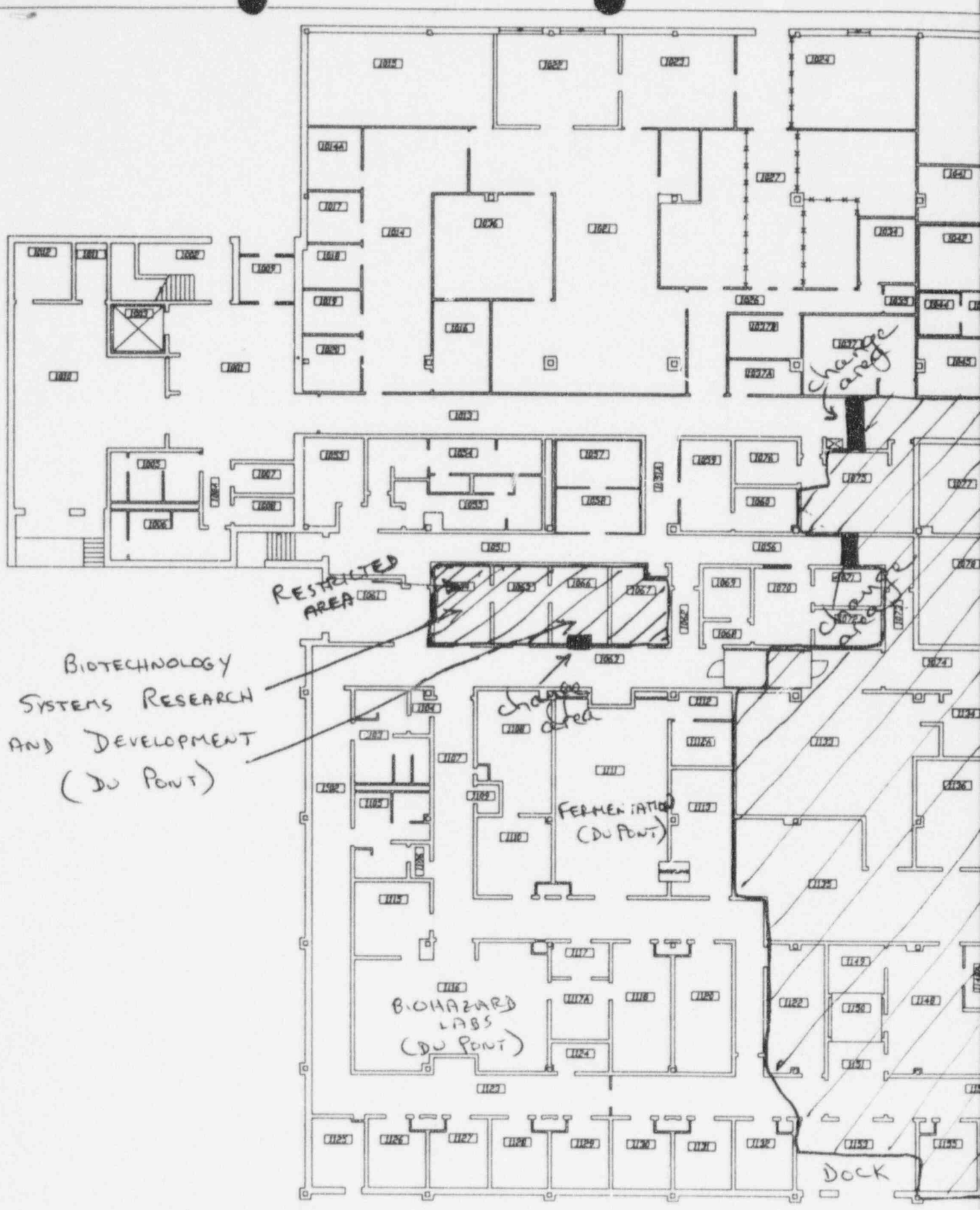
Second Floor

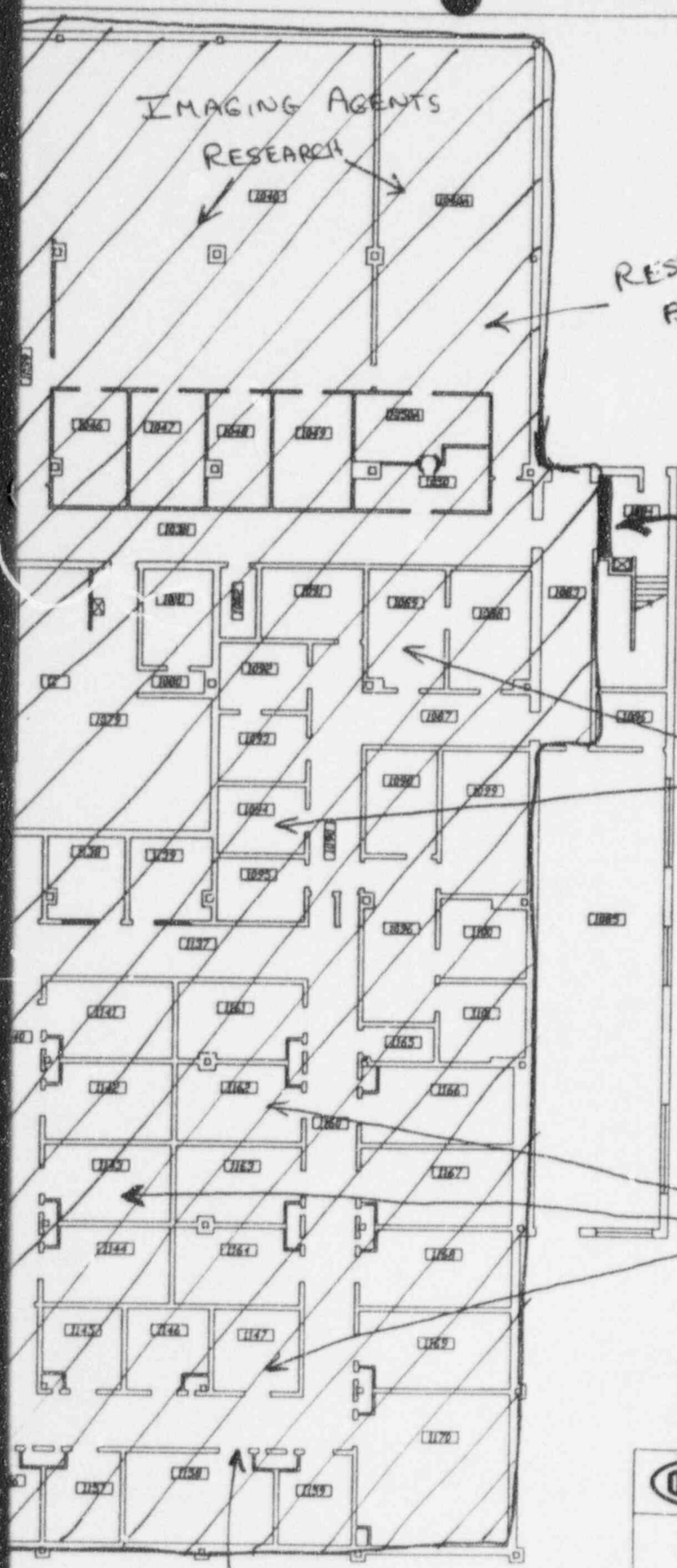
As of the date of this application there is no laboratory work being performed. The small Restricted Area is undergoing decommissioning and classification as an unrestricted area.

A library, auditorium and lunch room are located on this floor.

Third Floor

This floor consists primarily of controlled areas where µCi to mCi levels are handled for research purposes by the Du Pont company's Biotechnology Systems Research and Development operation. Monitors are set up as indicated.


RESTRICTED AREA
BIOTECHNOLOGY SYSTEMS RESEARCH AND DEVELOPMENT (DU PONT)
FERMENTATION (DU PONT)
BIOHAZARD LABS (DU PONT)
DOCK

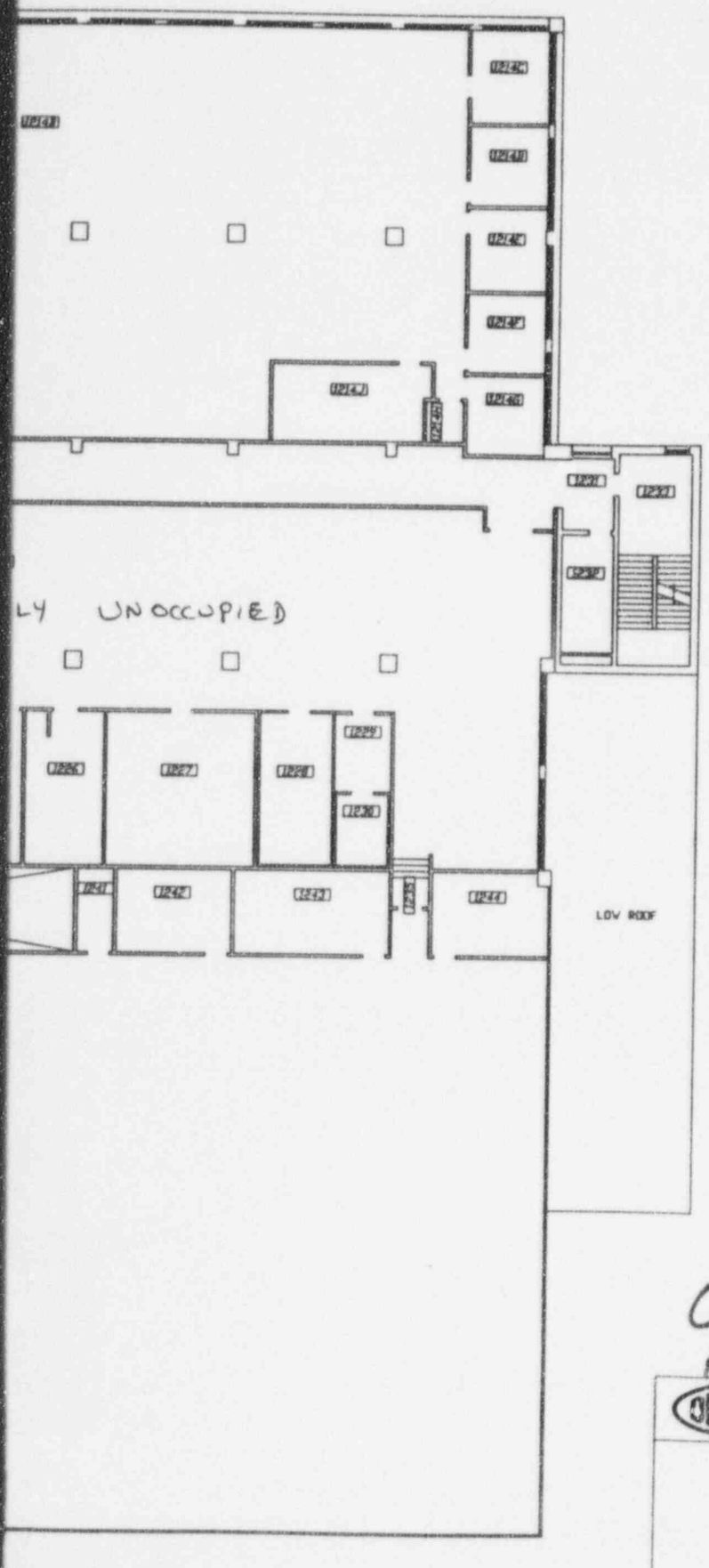


9707070178-11

DUPONT **Medical Products**

BOSTON AREA SITE
BUILDING 500
FLOOR 1

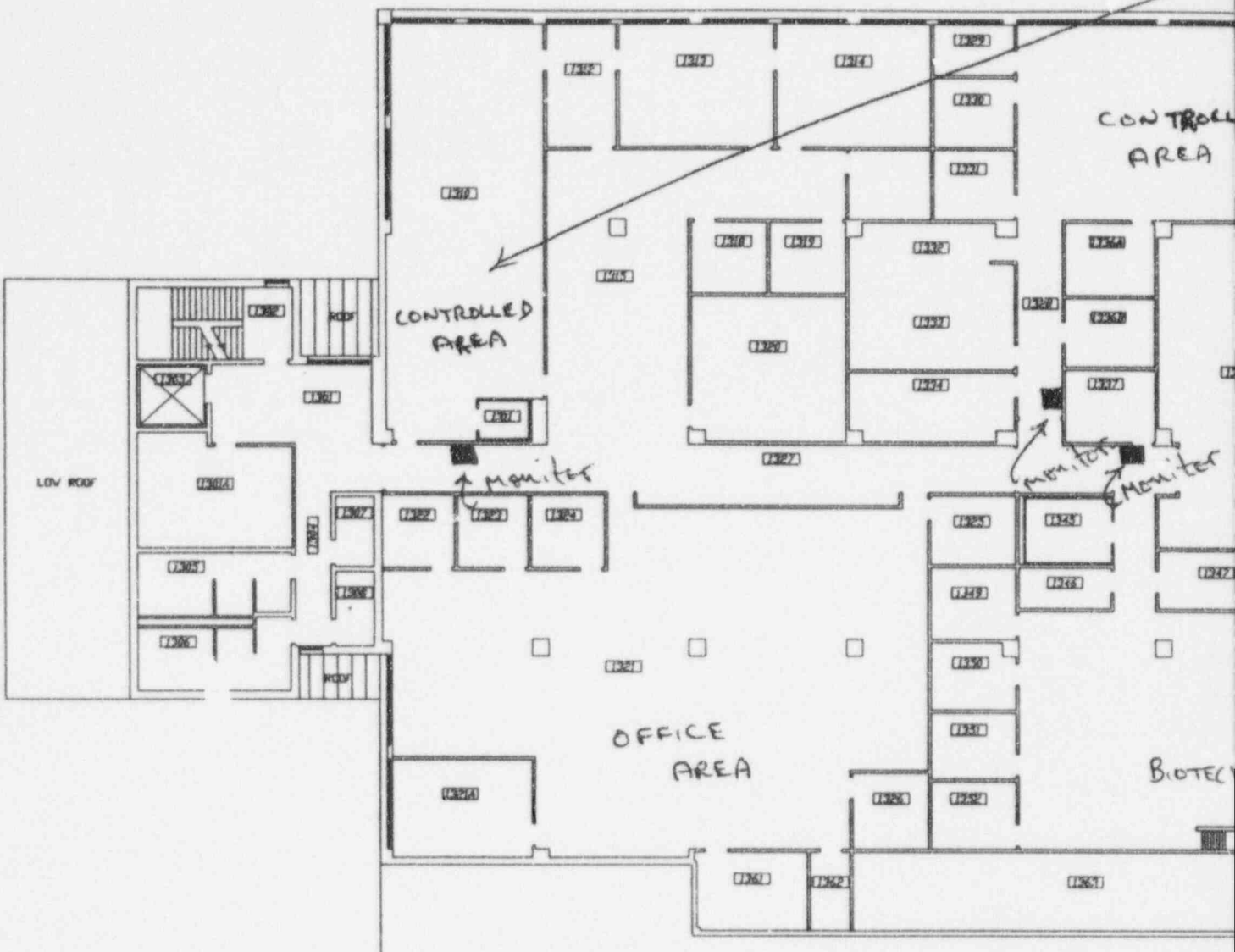

OFFICE AREA
AUDITORIUM
LUNCHROOM
LOW ROOF
ROOF
ROOF
change area
AREA
CURREN
LIBRARY
RESTRICTED AREA
(TO BE DECOMMISSIONED
TO UNRESTRICTED AREA)

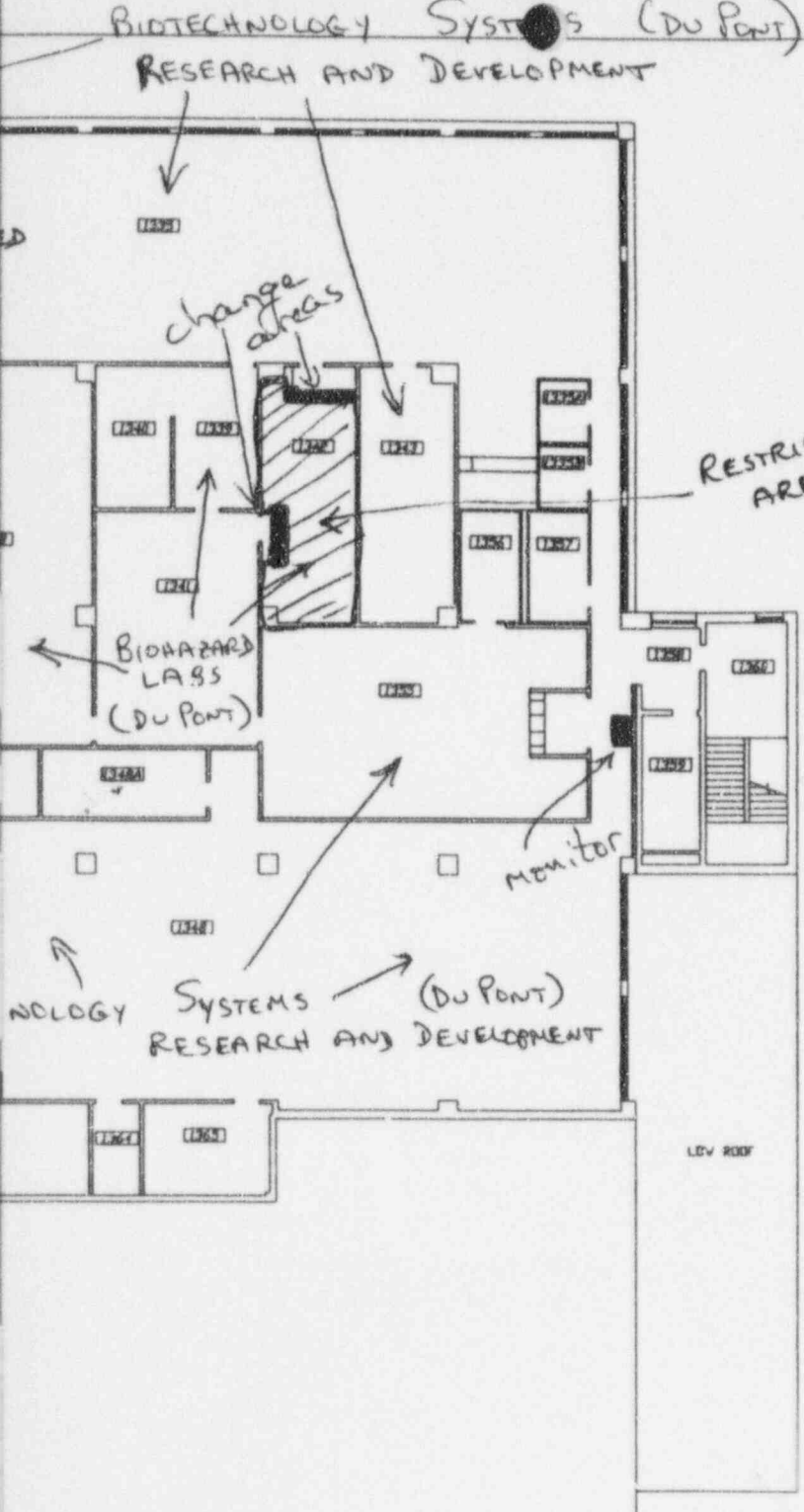


9707070178-17

DUPONT **Medical Products**

BOSTON AREA SITE
BUILDING 500
FLOOR 2


CONTROLLED AREA
CONTROL AREA
OFFICE AREA
LOW ROOF
ROOF
ROOF
Monitor
Monitor
Monitor



9107070128-13

DUPONT **Medical Products**

BOSTON AREA SITE
BUILDING 500
FLOOR 3

123852

Building #600, Customer Service Center

This building is an office area and conference center.

The license verification, customer service and administration for the distribution operations are located in this building.

ITEM 9 BILLERICA FACILITIES

C. Laboratory Descriptions (General)

1. Change areas located at the entrance to each restricted area.

   The locations of the change areas are noted on the enclosed maps for buildings 200, 250, 400 and 500.

   Each change area consists of a bench, platform and shoe rack system which serves as the boundary to the unrestricted area.

   Radioactive contamination monitors are positioned in each change area. The monitors utilize detectors such as gas-flow, geiger-muller, and sodium-iodide, based on the type of radionuclide contamination to be monitored.

   Monitoring systems are also located at the entrance to controlled areas.

2. Fume hoods are located throughout the restricted area laboratories. Work involving potentially volatile radioactive material is conducted in containment systems.

   NOTE: Examples of containment systems are glove boxes, plastic containment boxes with openings for work access, and roto-vap systems.

   a. Air velocity measurements are made at the face of each restricted area or controlled area fume hood on at least a quarterly basis. Air velocity measurements will be made as necessary after an exhaust systems malfunction or major system maintenance that has the potential to result in a change in the exhaust airflow. Fume hoods measuring below the Radiation Protection Officer's specified criteria are posted and continued work in the unit prohibited until necessary repairs are completed.

      NOTE: The RPO's specified criteria will be at 100 lfm, however, different specifications will be established for specially designed ventilation enclosures.

b. In Billerica, restricted area hoods of buildings #200 and #250 exhaust through HEPA filters fitted with prefilters prior to the final stack effluent release.

The building #250 iodination laboratories exhaust through banks of activated charcoal.

c. Fume hood exhaust ducts are equipped with pressure sensitive alarm switches. Exhaust failures results in an alarm activation which alerts laboratory occupants.

3. Containment boxes used in the following areas:

a. Several operations in the restricted areas of buildings #200 and #250.

b. Large scale iodination operations in Billerica.

Containment boxes such as gloves boxes are used when operational studies and historical air sampling data indicates a potential for volatility of specific radionuclides.

4. Several lead "hot cells" are located in the restricted areas of buildings #200 and #250.

These structures are used when manipulation is needed of large quantities of radioactive material where the radiation levels could create a high exposure to the laboratory personnel.

5. On the Billerica Site, storage areas for radioactive materials are in designated areas in buildings #200, #250, #325, #400 and #500.

High levels of radioactive material are stored in shielded enclosures (where appropriate) in restricted areas.

6. Several lead "hot" cells in buildings #250 and #200, used for the handling of large quantities of radioactive material, are fitted with a manipulator arm device as a remote handling tool.

   Remote handling tools such as tongs are used whenever necessary in production or research laboratories where radiation exposure from certain radionuclides can be minimized with distance.

7. Respiratory Protection is not a requirement for any Billerica site operations. A training and fit-test program has been organized for those employees specifically requesting respiratory protection.

8. As established in the Radiation Protection Program for the Billerica site, lab coats as personnel protective equipment are required to be used for operations involving radioactive material. Specifically lab coat use is required in all laboratories within the Restricted Area.

   Certain areas within the Restricted Areas do not require the use of lab coats, such as hallways, elevators, and laboratory worker desks.

   Exceptions to the lab coat policy are reviewed and established as deemed appropriate by the Radioisotope Committee.

ITEM 9 BILLERICA FACILITY

D. Environmental Monitoring

1. Stack Effluent Sampling

Continuous stack effluent sampling for particulate, volatile and gaseous radioactive material is conducted at all stack locations. Samples, consist of particulate filters, TEDA (triethylene di-amine) impregnated carbon cartridges, charcoal paper filters, water and NaOH solution impingers. Real time monitoring systems are operational at Xe-133 and Kr-85 processing stacks utilizing in-situ GM detectors.

2. Emergency Real Time Monitoring System

An independent monitoring system for the detection of air releases of radioactive material from critical stacks. Real time NaI and GM detectors are connected to a central multiple plot chart recorder with visual and audible alarms. Alarms are located in the Safety and Environmental Affairs office; guard shack and outside the building #250 laboratory where the chart recorder is located.

3. Sanitary Sewer Effluent Sampling

Periodic grab samples of liquid effluent discharged to the town sewer are collected from the site holdup discharge tank. Liquid effluent from laboratory areas handling radioactive material is collected in holding tanks. All samples are evaluated for radionuclide content by the Health Physics Office prior to waste water disposal.

4. Environmental Dosimetry

Contribution to environmental radiation from facility operations is monitored at perimeter locations (fence) using LiF thermoluminescence dosimeters (TLD). Dosimeters are collected by the Health Physics Office and processed by an outside vendor.

5. Environmental Air Sampling

Continuous high volume air samplers are operated at locations around the site. Sampling media consists of particulate filters and TEDA impregnated carbon cartridges. Samples are collected at specific intervals and analyzed soon after to allow for the detection of short lived radionuclides.

6. Surface Water Sampling

Grab samples are collected from selected site locations. One liter samples are collected from all locations and an additional three liters from two locations for I-125 analysis.

7. Wind Data Collection

Meteorological wind parameters are continuously recorded. The wind vane-anemometer sensor unit is located atop building #300. Data is collected to calculate dispersion of stack effluents.

ITEM 9 BILLERICA FACILITY

E. Site Security

The security program is under contract with a private company. The Manager of Facilities Support has overall responsibility for the site's Security program reporting to the Site Operations Manager.

The Billerica Site owns approximately 215 acres of land at the Treble Cove Road address of which 30 acres are currently in use.

The boundary of the area in use is indicated on an enclosed map. One six foot chain link fence collectively surrounds all the site buildings.

The main entrance to the site is through a driveway running on either side of a guard house with guard controlled mechanical arm barriers.

Visitors coming on site must sign in at the guard shack where they are issued a visitors badge.

The guard house is manned continuously, 24 hours a day, seven days each week.

After normal working hours, guards patrol the interiors of each building on site approximately every two hours. Additional guards patrol the exterior building and site areas on a continuous basis.

Access to buildings #110, #150, #200, #250, #400, #500 and #600 is through a coded push-button panel (cypher locks) for the locked doors. The codes are changed frequently with new codes communicated to all employees as needed.

Access to the Environmental Engineering Building #325 is by key. The key is controlled by the Supervisor, Environmental Engineering. Only authorized employees of Safety and Environmental Affairs are to be in the building unaccompanied.

There is one gate in the fence that serves as an alternate entrance to the site which is controlled by a security guard who mans a guard house (near Building #110). During normal working hours this gate serves as the primary access for the shipping and receiving docks behind Building #110. The gate is locked closed after normal working hours.

ITEM 11 WASTE MANAGEMENT

Environmental Engineering is part of the Billerica Site Office of Safety and Environmental Affairs and handles the preparations and disposal of radioactive waste.

Waste is handled in accordance with the most recent regulations of USNRC, USDOT and of the Licensed Disposal Sites.

Since almost 90% of the activity for which the Billerica operations are licensed is of short half-life (100 days and less), the bulk of disposal is by decay.

Disposal-by-decay (for radionuclides with half-life of 100 days and less) procedures are outlined below:

A. Solids and Liquids

1. The waste will be separated, in the laboratory, as liquid or solid. The isotope must be noted on the container.

2. Waste is consolidated into steel drums (DOT Spec 17H or 7A) or high density polyethylene drums and stored in the Environmental Engineering Storage Areas.

3. Radioactive waste material held-for-decay is routinely held for a minimum of 10 half-lives.

   Note: Radioiodine waste is held-for-decay a minimum of 7 half-lives.

4. Prior to disposal, material having been held-for-decay, is transported to predetermined low background areas and is monitored for detectable levels of radioactivity. Personnel performing monitoring confirm radiation background levels prior to each survey. Items found, upon monitoring, to be above background levels are returned to storage for decay for an additional period of time.

5. Once it has been determined that radiation levels measured through the sides of the containers are below background levels, material within each container is removed for individual monitoring.

B. Animals

Animal carcasses or other biological materials containing short half-life radionuclides are stored in designated freezers in the animal areas.

The waste is monit[illegible]d, and, when at background, is sent to a commercial incinerator for final disposal.

C. Long Lived Waste (radionuclide with half-lives greater than 100 days)

1. Liquid waste is solidified by absorption in a commercial absorbent.

2. Solid waste is shielded and contained as necessary.

3. Animals are packed as specified by Disposal Site procedures.

The waste prepared as above, is packed into appropriate DOT specification and disposal site approval containers, surveyed and labeled as required and stored until a truckload shipment is to be made to the appropriate disposal site or shipped to Scientific Ecology Group (SEG), Kingston, Tennessee, for supercompaction or incineration.

The packaged waste is tendered to a common carrier and transported to one of the following:

a. Chem Nuclear, Barnwell, South Carolina

b. U. S. Ecology Co., Inc., Beatty, Nevada

c. U. S. Ecology Co., Inc., Richland, Washington

Environmental Engineering will prepare and issue guidelines and protocols as necessary to keep current with changes that may be made in Governmental regulations and requirements of the disposal contractors or disposal sites.

ITEM 10 RADIATION SAFETY PROGRAM

SUBHEADINGS

A. Radiation Safety Program Organization

B. Radioisotope Committee

C. Control of Procurement and Use of Radioactive Material

D. Restricted Areas, Controlled Areas, Unrestricted Areas

E. Radiological Surveillance

F. Instrumentation

G. Personnel Monitoring Devices

H. Air Sampling

I. Bioassay Program

J. Disposal by Sanitary Sewer

K. Records

L. Transportation of Radioactive Material

M. Handbook of Radiation Protection

N. Radiological Emergency Contingency Plan

ITEM 10 RADIATION SAFETY PROGRAM

A. Radiation Safety Program Organization

The Area Supervisor of the Office of Safety and Environmental Affairs serves as the Billerica Site Radiation Protection Officer.

The Radiation Protection Officer is selected by the Site Operations Manager. In conjunction with line management, the Radiation Protection Officer or qualified designee have the authority to cease and desist any operation, which involved hazardous situations or indicates violations of procedures or USNRC rules, regulations or license conditions.

Two functions managed by the Area Supervisor, Safety and Environmental Affairs that relate to licensed operations are:

1. Supervisor, Radiation Protection

    a. Routine surveys
    b. In-plant and stack sampling
    c. Bioassay program
    d. Personnel dosimetry
    e. Recordkeeping
    f. Training
    g. Instrument calibration

2. Supervisor, Environmental Engineering

    a. Collection of radioactive and toxic wastes
    b. Waste consolidation
    c. Packaging waste for shipment
    d. Maintain disposal-by-decay program
    e. Loading common carriers
    f. Recordkeeping
    g. Training
    h. Regulations

The main Billerica Health Physics laboratory is located on the first floor of Building 300.

ORGANIZATION CHART

RADIATION SAFETY

Operations Manager Imaging Agents
|
Manager, Facilities Management and Support
|
Area Supervisor, Safety and Environmental Affairs
(R.P.O.)

Development Health Physicists (2)

Supervisor, Radiation Protection

Health Physicists (2)

Supervisor, Environmental Engineering

Environmental Engineering Specialist

Managers Billerica
|
Section Managers
|
Laboratory and Area Supervisors
|
Individual Employees

B. Radioisotope Committees

A site Radioisotope Committee will administer the Radiation Protection Program. The generic committee structure and minimum qualifications for committee members are listed below. Documentation detailing individual member training and experience are on file with the Radiation Protection Officer.

I. Billerica Radioisotope Committee

MEMBER POSITION

Chairman - R. Shepard

Boston Area R.P.O. - D. Dumas

Operations Representatives:

- Specialty Technologies (Du Pont)
- Cyclotron, Cyclotron Support
- Imaging Agents Production, Sources
- Bionuclides (Du Pont)
- R & D Imaging Agents
- Marketing, Technical Services
- R & D Biotechnology Systems (Du Pont)
- Environmental engineering
- Facilities Engineering
- Distribution and Packaging
- Health Physics (Safety and Environmental Affairs)

The Radioisotope Committee meets at least quarterly. Minutes and agendas are maintained for each committee and are filed with the Supervisor, Radiation Protection. A quorum consists of the Chairman, Radiation Protection Officer or qualified designee and 70% of the membership representing each site operation listed above.

III. Qualifications and Experience

The following describes minimum qualifications and experience for members of the Billerica Radioisotope Committee.

1. Minimum Experience

Chairman and Radiation Protection Officer are required to have at least five years working experience under a Type A License of Broad Scope that includes operational radiation protection. Chairman must be of an Area Supervisor management level or above.

All members are required to have at least three years working experience under an USNRC or Agreement State Licensed operation.

2. Minimum Training

Chairman and Radiation Protection Officer are required to have a B. S. degree with some graduate training, have accomplished the Master's degree level or equivalent level of experience. Incumbents must have received training in the requirements for handling the full range of radionuclides listed in the Du Pont Greater Boston Area USNRC Byproduct Material License.

All members are required to have at least a B. S. degree with training in a manufacturing or research environment involving the uses of radioactive material.

C. Control of Procurement and Use

The procurement of radioactive material listed on the Du Pont Merck Pharmaceutical Company license involves the initial action of the purchasing operation. Prior to the utilization of new types of radionuclides procured for a new procedure, a review of the proposed use is done by the Radiation Protection Officer, or qualified designee, in conjunction with the Radioisotope Committee.

D. Restricted Areas, Controlled Areas, Unrestricted Areas

1. Restricted Areas

a. Established for purposes of contamination control.

b. Allows storage, use and handling of radioactive material.

c. Contains within its boundary any Radiation Areas or High Radiation Areas established as defined in 10CFR20.105.

d. Change areas are set up at specific entry points to these areas.

i. Change into "restricted area" shoes or shoe covers and put on safety glasses prior to entry.

ii. Protective clothing is to be worn in the laboratory areas in the restricted area as specified in the policy set by the Radioisotope Committee.

iii. On exiting, all personnel must remove their "restricted area" shoes or shoe coverings and protective clothing.

iv. All personnel monitor themselves for contamination before leaving the restricted area using the appropriate detectors or other ratemeter systems set up for this purpose.

v. All personnel monitor themselves for contamination immediately upon entry into the unrestricted area using the ratemeter and hand held detector set up for this purpose at each change area.

e. Sink drains in the Restricted Areas drain into holding tanks (except in Buildings #400 and #500). Holding tank waste water is evaluated for radionuclide content prior to disposal to sewer systems.

f. Radiation Safety Training is required of any employees assigned to work in the Restricted Areas.

g. All visitors to the Restricted Areas are accompanied by a responsible employee authorized to enter the Restricted Areas.

2. Controlled Areas

   a. Established for storage, use and handling of radioactive material at 10 times the individual quantity specified for each radionuclide in Title 10 CFR Part 20 Appendix C (unrestricted area contamination limits apply; ref. Radiation Protection Handbook Appendix D).

   b. Ratemeter contamination monitoring stations with appropriate detectors are available to workers in the controlled areas.

3. Shipping and Receiving Dock Areas

   a. Under the control of the responsible dock employee.

4. Unrestricted Areas

   a. All other site areas included.

   b. No radioactive material is stored or handled in this area unless sealed in a strong tight configuration and authorization is received from the Radiation Protection Officer.

   c. Transfer of radioactive material between the specific facility areas and buildings is allowed only if proper packaging and monitoring practices are followed. Procedure is subject to review and approval by the Radioisotope Committee.

E. Radiological Surveillance

The Health Physics Group personnel make routine surveys for contamination and radiation levels in all appropriate site areas in accordance with the guidelines set in USNRC Regulatory Guide 8.21.

Site areas are surveyed for removeable and fixed contamination in accordance with the regulations of 10CFR Part 20 at frequencies established by the Radiation Protection Officer, based on historic surveillance records and operational evaluations.

Limits of contamination are set as action levels in Appendix D of the Site Handbook of Radiation Protection, Required Rules and Procedures.

F. Instrumentation

A. The attached charts include information according to the following categories:

1. Portable Survey Meters

   a. Types
   b. Quantities
   c. Radiation Detected
   d. Sensitivity Range (mR/hr or cpm)
   e. Calibration and Frequency of Calibration

2. Analytical Measuring Systems

   a. Types
   b. Quantity
   c. Radiation Detected
   d. Calibration and Frequency of Calibration

3. Air Monitors Fixed/Portable

   a. Type
   b. Quantity
   c. Sensitivity
   d. Calibration and Frequency of Calibration

4. Any Special Monitoring/Measuring Devices

   a. Whole Body Counters
   b. Thyroid Monitoring System
   c. Hand and Foot Monitors

B. Calibration Techniques

1. Quantitative portable survey meters are calibrated at two points on each scale against a known field of radiation from a source, or quantity of radionuclide traceable to NBS.

2. Qualitative radiological surveillance equipment (e.g. laboratory ratemeter and monitors) are checked for battery operation and response to a check source.

3. Quantitative efficiency and/or energy calibrations for analytical measuring systems are performed as listed on the attached tables.

4. Qualitative efficiency and/or energy checks on analytical measuring systems are performed as listed on the attached tables.

BILLERICA SITE INSTRUMENTATION

	Type of Instrument	Quantity	Radiation Detected	Sensitivity Range	Frequency of Calibration	Type of Use Quantitative vs. Qualitative
1. Portable Survey Meters	Remmeter (LiI probe)	2	0^{n}	0-5 Rem/hr	6 months	Quantitative
	Alpha Probe	1	a	0-500 kcpm	6 months	Quantitative
	Pressurized Ion Chamber	2	g, x	.001-5000 mr/hr	6 months	Quantitative
	Survey Meter (GM)	1	ß, g, x	0-200 mR/hr	6 months	Quantitative
	Contamination Monitor (GM, NaI)	2	ß, g, x	0-500 kcpm	6 months	Quantitative
	Contamination Monitor (GM, NaI)	4	ß, g, x	0-300 kcpm	6 months	Quantitative
	Ionization Chamber Survey Meter	6	ß, g, x	0-50 R/hr	6 months	Quantitative
	Long Pole 20 ft. extendable GM Survey Meter	1	ß, g, x	0-999 R/hr	6 months	Quantitative
2. Analytical Measuring Systems	3" x 3" NaI (Tl) Well Crystal	2	g, x	----	6 months, check 2 times per week	Quantitative nuclide ID sample counting
	Planar Ge	1	g, x	---	6 months, check daily, & 2 times per week	Quantitative nuclide ID sample counting
	REGe	1	g, x			
	Ge(Li)	1	g, x			
	L.S.C.	1	ß	----	6 months, check prior to each run	Quantitative
	Gas Flow Proportional Counter	1	ß, g, x	----	6 months, check prior to use	Quantitative
	Alpha, Beta, Gamma Counter Gas Flow proportional & 2"x2" Na(Tl) Solid	1	a, ß, g, x	---	6 months	Quantitative
	AutoGamma Counter 3"x3.25" NaI(Tl)	1	g, x	---	6 months	Quantitative/ Qualitative

	Type of Instrument	Quantity	Radiation Detected	Sensitivity Range	Frequency of Calibration	Type of Use Quantitative vs. Qualitative
Air Monitors	Real Time Stack Effluent Monitors (GM, NaI)	12	β, g, x	----	6 months monthly maintenance	Quantitative for Noble Gases Qualitative All Others
4. Special Monitoring Devices	2" x 1.5" NaI (T1) Crystal	1	g, x	----	3 months	Quantitative Thyroid Monitoring
	3" x 3" NaI (T1) Crystal	1	g, x	----	3 months	Quantitative Whole Body Counting
	Ratemeter (NaI) Change Areas, Controlled Areas	3	g, x	0-300 kcpm	6 months	Qualitative
	Ratemeter (GM, NaI) Change Areas, Controlled Areas	19	β, g, x	0-300 kcpm	6 months	Qualitative
	Ratemeter (pancake "hand and shoe" GM) Change Areas	8	β, g, x	0-300 kcpm	6 months	Qualitative
	Ratemeter (pancake GM) Change Areas, Controlled Areas	4	β, g, x	0-300 kcpm	6 months	Qualitative

G. Personnel Monitoring Devices

Personnel dosimetry is provided by an outside vendor, TechOps/Landauer, Inc. with headquarters in Glenwood, Illinois.

The Landauer Company provides all of the site dosimetry needs which include:

- Whole body film and TLD badge dosimeters
- Extremity TLD ring dosimeters
- and neutron dosimetry.

Personnel dosimetry badge assignments are based on job assignment and type, and quantity, of radionuclide(s) to be handled.

In general, all personnel entering a Restricted Area are required to wear appropriate personnel monitoring devices.

Visitors or contract workers are issued personnel monitoring devices prior to entry into any Restricted Area.

At a minimum, personnel monitoring devices will be issued by the Radiation Protection Officer, or the RPO's designee, based on the criteria established in 10CFR20.202.

Personnel dosimetry is assigned to select individuals when they first arrive at the Health Physics Office. The Radiation Protection Officer, or qualified designee, makes the decision on the appropriate dosimeter required (frequency of read out, need for extremity or neutron dosimeters).

(Note: The bioassay program is described in Section I.)

H. Air Sampling

1. Air sampling of the atmosphere in laboratories and stacks is conducted by the Health Physics personnel.

   Fixed sampling devices are run continuously to draw the sampled air through a collecting media appropriate to the radionuclide(s) involved. Air flow through these devices is controlled by rotometers.

   Stack sampling is performed through sampling heads installed to ensure isokinetic air monitoring.

   The selection of sampling points in the work areas are based on the radionuclide and the operation to determine the breathing zone radionuclide concentration.

   The air sampling program requirements for sampling type, sample location, frequency of collection and maintenance are established by the Radiation Protection Officer based on historical data and the results of operational evaluations.

2. Investigations are initiated at:

   a. 1.0 times the 168 hour MPC_a from 10CFR20, Appendix B, Table II. Column 1 for the stack sample results.

   b. 0.25 times the 40 hour MPC_a from 10CFR20, Appendix B, Table I, Column 1 for the breathing zone sample results.

3. Real time monitors are installed in certain critical stacks that continuously sample the effluent from laboratory operations by drawing a certain volume of air through appropriate detection chambers based on the radionuclides being stored or handled in the laboratories.

4. The fenced perimeter around the facility is the final point of control for radionuclide effluent released to the air. High volume environmental air samplers continuously monitor the air concentrations at specific perimeter locations.

I. Bioassay Program

The bioassay program is implemented according to the following guidelines:

- USNRC Regulatory Guide 8.9 - Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program.

- USNRC Regulatory Guide 8.20 - Application of Bioassay for I-125 and I-131.

In addition, the bioassay program has incorporated the use of ICRP 30 Methodology to initially evaluate and determine the significance of radionuclide intakes.

1. Urinalysis

   a. Urine samples of about 20cc are submitted by certain laboratory personnel as required by the Radiation Protection Officer.

      The submittal of routine and non-routine urine samples is based on the potential for an intake resulting in excess of a 40 MPC - hr uptake of radionuclide.

      This determination is made by operational studies, historical data and air sampling program data.

      Routine urine samples are initially counted on an automatic gamma counter (or well crystal) and/or a liquid scintillation counter to determine gross radionuclide content.

      Radionuclide identification for routine and non-routine samples is performed using the analytical solid crystal detectors accessed by the Health Physics computer system.

   b. At specified frequencies determined by the Radiation Protection Officer certain laboratory personnel submit 24 hour urine samples to monitor for intakes of low energy beta-emitting radionuclides or other material such as depleted uranium.

      These samples are evaluated by radiochemical analysis either in-house or by an outside commercial laboratory.

2. Thyroid Counting (in-vivo measurement)

Direct in-vivo measurement of the thyroid using a fixed solid crystal detector is the primary means of determining thyroid burden.

The Radiation Protection Officer will establish the criteria and frequency of monitoring based on historical data and operational evaluations in addition to setting investigation action levels.

At a minimum, a formal investigation is initiated when the thyroid burden indicates intake of radioiodine in excess of 40 MPC-hrs in any 7 consecutive days. This represents a thyroid burden after 7 days of 40 nCi I-125 (intake 240 nCi) and 43 nCi I-131 (intake 440 nCi).

3. Whole Body Counting (in-vivo measurement)

A solid crystal detector mounted in a chair configuration is used to measure body burdens of gamma-emitting radionuclides.

The Radiation Protection Officer will establish the frequency of whole body counting and the need for counting due to contamination incidents. This determination is based on the potential for an intake in excess of 40 MPC-hrs.

This determination is made by operational studies, historical data and air sampling program data.

Formal investigations are initiated with documentation of the results whenever a bioassay analysis indicates the potential for a 40 MPC-hr intake of radionuclide.

J. Disposal by Sanitary Sewer

1. Billerica Site holding tank waste water is discharged to the sanitary sewer.

2. A quantitative evaluation of radionuclide content is performed of the waste water discharge to the sanitary sewer.

3. Billerica Site waste water is released into the sanitary sewer in accordance with the requirements of 10CFR20.303.

K. Records

1. Appropriate records as required by the Du Pont Merck Pharmaceutical Company USNRC license conditions are maintained on file at the Billerica site Health Physics Office.

   Other applicable USNRC required records are maintained by the appropriate responsible operations group (e.g. shipping and receiving documents, license verification records or customer sealed source certificates).

L. Transportation of Radioactive Material

1. General

The site has more than one area designated as receiving locations that could receive packages of radioactive material.

The site has a central shipping area from which packages of radioactive material are distributed. The shipping area is from Building #200 and can be from Building #110, #250, and #400.

2. Incoming Packages

In Billerica the primary responsibility for the evaluation of incoming packages containing radioactive material belongs to the site Receiving group in Building #110.

In certain situations, the responsible operational personnel will monitor incoming packages of radioactive material that are to be processed in their operations.

All incoming packages are evaluated in accordance with the requirements of 10CFR20.205.

The Health Physics group audits all documents and reviews procedures.

The Health Physics group also trains the personnel responsible for the incoming package evaluation procedure prior to initial handling and annually, thereafter.

3. Outgoing Packages

All radioactive material will be prepared for shipments and transported in accordance with the applicable federal (USNRC 10CFR, Part 71, USDOT, Title 49), State and local rules and regulations.

Specific operational site personnel are responsible to comply with all regulations as noted above. The Health Physics group audits the shipping operations.

4. Radioactive material transported by sales personnel to customer locations will be done in compliance with all applicable federal NRC and DOT regulations as well as with State and local requirements.

M. Handbook

The entire contents of the Site Handbook of Radiation Protection, Required Rules and Procedures (submitted herewith) shall be considered a part of the Radiation Protection Program.

N. Radiological Emergency Contingency Plans

The Billerica Site Radiological Emergency Contingency Plan is enclosed establishing the radiological emergency response program.

The Radiological Emergency Contingency Plan for the Billerica site was sent out for comment on August 28, 1990 to the following off-site emergency response organizations:

Billerica Fire Department
St. John's Hospital, Lowell, MA
Billerica Police Department

Written confirmation of the receipt of this plan has been received from these organizations. As of the date of this license application no comments to modify the plan have been received from these organizations.

The DuPont Merck Pharmaceutical Company
Radiopharmaceutical Division
331 Treble Cove Road
N. Billerica, MA 01862
(508) 667 9531

May 15, 1991

United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

DU PONT
MERCK

Attn: Elizabeth Ullrich
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards

Reference: - Docket No. 30-32013
- Mail Control No. 113937

Dear Ms Ullrich:

This is written in response to your letter dated May 6, 1991 requesting additional information in order to continue review of our application dated November 14, 1990 for a Byproduct Material License. The information is as follows:

1. The facilities at 331 Treble Cove Rd, N. Billerica, Massachusetts used by E. I. Du Pont Nemours and Company will not continue to be listed as authorized places of use for License No. 20-00320-21. The Du Pont operations at the Billerica site will be leasing the existing space from the Du Pont Merck Pharmaceutical Company. All activities in which licensed material is used by Du Pont employees will be approved by the Du Pont Merck Radioisotope Committee at the Billerica site and performed in accordance with conditions of the license issued to Du Pont Merck. The Du Pont Merck Health Physics operations will continue to administer the Radiation Protection Program for the Du Pont operations still remaining in Billerica.

2. Item 6 of our license application dated November 14, 1990 requests authorization to receive packaging material returned from customers for reuse, recycling, or disposal. We would like to withdraw our request for this authorization; at this time we will not be receiving packaging material from customers.

   Item 6 also requests continued authorization for the return of sealed sources to the Billerica Site for the purpose of refurbishment or disposal. We would like this existing license condition to remain for the Du Pont Merck license. All such return shipments will be handled in compliance with the conditions of the appropriate Du Pont Merck Pharmaceutical Company USNRC Materials License, as well as applicable DOT regulations.

DUPONT

123852

3. This is written to confirm that animal carcasses or other biological materials containing short half-life radionuclides will be held a minimum of ten half-lives, and surveyed to verify that radiation levels do not exceed background levels, prior to disposal.

Please contact me if you need any additional information.

Sincerely,

Dennis Dumas

Dennis O. Dumas
Area Supervisor,
Safety and Environmental Affairs

The Du Pont Merck Pharmaceutical Company
Radiopharmaceutical Division
331 Treble Cove Road
N. Billerica, MA 01862
(508) 667 9531

August 16, 1991

U. S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

DU PONT
MERCK

Attn: Elizabeth Ullrich
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards

Reference: Docket No. 30-32013
Mail Control No. 113937

Dear Ms. Ullrich:

This is written in response to your verbal request for additional information to continue the review of our application for license renewal and amendment.

The license application dated November 14, 1990 requests in the License Application Item 5M authorization to possess any byproduct material with atomic numbers 84-94 in any form and at activity levels of 60 millicuries for each radionuclide. We request that an additional requirement be added to the activity possession limits to read as follows:

> Maximum quantity of activity which will be possessed at any one time: 60 millicuries each radionuclide with atomic numbers 84-94 with a total possession limit of 5 Curies.

The Du Pont operations at the Billerica, Massachusetts facility will no longer be covered under the existing license, number 20-00320-21, but will be authorized by this new license to be issued by your office. Therefore building numbers 500 and 400 housing Du Pont operations at the Billerica site will be authorized under this new license for the Du Pont Merck Pharmaceutical Company.

In order to expedite the issuance of this license please disregard our request for radioiodine waste to be held for decay 7 halflives prior to monitoring for disposal. Instead we request authorization for the standard 10 halflives for the hold-for-decay of the radioiodine waste. Any request for modification in this aspect of our hold-for-decay program will be handled in a future amendment request.

Please contact me if you require any additional information.

Sincerely,

Francis E. Roy Jr.

Francis E. Roy Jr.
Health Physicist

Telephone : (508) 671-8242

The Du Pont Merck Pharmaceutical Company
Radiopharmaceutical Division
331 Treble Cove Road
N. Billerica, MA 01862
(508) 667 9531

Delivered 5/5/93 at 9:07 AM
signed by A Wallace

May 3, 1993

United States Nuclear Regulatory Commission
Attn: Elizabeth Ullrich
Region I
475 Allendale Road
King of Prussia, PA 19406

DU PONT
MERCK

Reference: Materials License #20-28598-01

Dear Ms. Ullrich:

The purpose of this letter is two-fold. First, we request a license amendment to the above-referenced license to increase our possession limit for three radionuclides. Second, we request this license be amended to specifically authorize a means for waste volume reduction.

Possession Limits

Please amend our Materials License to increase the maximum possession limits for Phosphorus-32, Sulfur-35 and Molybdenum-99/Technetium-99m.

We ask that the P-32 possession limit, License Condition #8E, be increased from the current 200 Curies to 400 Curies. This increase is needed to provide for significant increases in the demand for P-32 research products.

In addition, we ask that the S-35 possession limit, License Condition #8F, be increased from the current 800 Curies to 1000 Curies. This is needed to also provide for significant increases in the demand for S-35 research products as well as to provide for a safety margin for the increasing amount of S-35 waste going into storage.

Finally, we ask that the Mo-99/Tc-99m possession limit, License Condition #8J, be increased from the current 8,000 Curies to 10,000 Curies. This is needed to provide for an expected increase in Technetium generator manufacturing.

Radioactive Waste Volume Reduction

As you know, the low level radioactive waste disposal issue in the United States has reached crisis proportions. Our operations have been fortunate, radioactive waste continues to be shipped from our site since we still have access to the Chem-Nuclear waste repository in Barnwell, South Carolina. However, it appears this situation will come to an abrupt halt in the near future. When we do get "closed-out" from the Barnwell repository we need to continue having our volumes of radioactive waste reduced in order to optimize the use of our on-site storage capacity.

May 3, 1993

Elizabeth Ullrich
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Therefore, we request authorization via a license amendment to transfer, and receive back, radioactive waste to the licensed waste processing company Scientific Ecology Group (SEG) in Oak Ridge, Tennessee for the purpose of waste volume reduction (for example, by supercompaction). The processed waste would be shipped back to the Du Pont Merck Billerica site for storage until disposal is again permitted at a licensed repository. .

A check is enclosed in the amount of $250 in payment of the fee for this license amendment request as specified for Fee Category 3A in Title 10 CFR Part 170, §170.31.

Please contact me if you require any additional information.

Sincerely,

Dennis Dumas

Dennis Dumas
Manager, Safety and Environmental Engineering

Telephone: (508) 671-8669

Toll Free: 1-800-362-2668, ext. 8669.

The Du Pont Merck Pharmaceutical Company
Radiopharmaceutical Division
331 Treble Cove Road
N. Billerica, MA 01862
(508) 667 9531

File

November 8, 1993

879 1427 531

United States Nuclear Regulatory Commission
Attn.: Duncan White
Region I
475 Allendale Road
King of Prussia, PA 19406

Delivered on 11/11/93 at 9:24 AM
signed by A. Wallace

DU PONT
MERCK

Reference: Materials License #20-28598-01

Dear Mr. White:

This is written to request a license amendment to the above-referenced Materials License.

We ask that our Broad Scope Material License be amended to allow possession of a small quantity of depleted uranium as source material in the form of shielding to be used in DOT Type A shipping containers. Our process engineers are in the preliminary design stage of a DuPont Merck technetium generator that would incorporate depleted uranium as the primary shielding material. In order for the development work to proceed we need the ability to possess a total quantity of depleted uranium not to exceed 100 pounds.

Once our license is amended the depleted uranium will be shipped to us as radiation shields, about four units, by Nuclear Metals Inc. of West Concord, MA. The final shields will then be evaluated as part of a new technetium generator design.

After the design and development work is complete and the proper regulatory approvals obtained, we will start production of a new technetium generator shielded with depleted uranium. In anticipation of full scale manufacturing, we will submit a separate license application to your office for a new source material license to authorize the possession of a certain number of these depleted uranium shields to be incorporated into the new technetium generator.

Nuclear Metals, Inc. is now in the process of preparing these depleted uranium shields for our development work. Your earliest attention to this request would be greatly appreciated.

I have enclosed a check in the amount of $460.00 in payment of the license amendment application fee for Fee Category 3A of 10 CFR Part 71, §170.31. Please contact me if you require any additional information.

Sincerely,

Francis E Roy Jr.

Francis E. Roy Jr. (Skip)
Development Health Physicist

Telephone: 508-671-8242

Toll Free: 1-800-362-2668, ext. 8242.

The Du Pont Merck Pharmaceutical Company
Radiopharmaceutical Division
331 Treble Cove Road
No. Billerica, MA 01862
(508) 667 9531

359 9281 822

3-November-1994

Delivered 11/4/94 at 8:58 AM
Signed by G. Coorman

U.S. Nuclear Regulatory Commission
Attn: Elizabeth Ullrich
Region I
475 Allendale Road
King of Prussia, PA 19406

DU PONT
MERCK

Reference: Materials License #20-28598-01

Dear Ms. Ullrich:

This is written to request an amendment to the above-referenced license for the following:

1. to remove building 350 from our license;
2. to remove the name of the specific external personnel dosimetry service;
3. to modify the calibration schedule of our whole-body counter;
4. to update our listing of instrumentation as submitted with our license application dated 14-November-1990;
5. to notify you of the closing of building 400.

1. We would like to remove building 350 from our license because the building is being prepared for demolition. The original purpose of this 4600 ft^2 building was as an animal facility for quality control testing of radiopharmaceutical products. The primary radionuclides handled were ^{99m}Tc, ^{201}Tl, and ^{67}Ga for pyrogen testing up until about 1985 and as an animal facility for toxicological studies in the early 1970's. The quantities of radioactive material possessed in the facility at any one time were no more than several hundreds of millicuries per isotope. This building has not been used since 1987 when it became a storage facility for used office and laboratory furniture and equipment. The complete list of nuclides used in this facility are shown below.

Radionuclide	Half-life	Date First Used	Radionuclide	Half-life	Date First Used
$^{99}Mo/^{99m}Tc$	66hr/6hr	4/14/71	^{75}Se	120d	9/21/71
^{113}Sn	115d	4/13/71	^{67}Ga	3.3d	10/19/71
$^{87}Y/^{87}Sr$	3h	4/13/71	^{139}Cs	9.5m	8/27/71
^{133}Xe	5.3d	4/29/71	^{55}Fe	2.7y	12/8/72
^{84}Rb	33d	4/29/71	^{123}I	13h	4/11/73
^{18}F	109m	5/12/71	^{32}P	14d	10/30/73
^{131}I	8d	6/2/71	^{201}Tl	3d	9/3/74
^{125}I	60d	6/11/71	$^{188}W/^{188}Re$	69d	8/8/78
^{51}Cr	28d	6/8/71	^{192}Ir	5d	N/A

We have attached a copy of the close out survey report for you to review (Attachment #1).

2. We have also decided to change our dosimetry service as listed in the application to our license dated 14-November-1990 (page 59) and would like to make the following revision from:

"Personal dosimetry is provided by an outside vendor, TechOps/Landauer, Inc. with headquarters in Glenwood, Illinois.
The Landauer Company..."

to

"Personal dosimetry is provided by an outside vendor with NAVLAP certification.
The dosimetry company..."

3. Recently we have upgraded our whole-body counter from a NaI(Tl) crystal to a HPGe (high purity germanium) crystal which includes improved resolution and MDA (minimal detectable activity) levels. Since we perform daily energy and efficiency checks on the detector, in accordance with license conditions, we feel we can decrease the current energy and efficiency calibration frequency from every three months to every six months. Currently, our calibration frequency for our germanium detectors is six months and includes an energy and an efficiency calibration using a NIST traceable multinuclide solution. We also perform daily energy and efficiency checks on these detectors to ensure performance. We would calibrate the whole-body counter at the same time and in the same way we calibrate our other germanium detectors.

4. We would also like to update the Billerica Site Instrumentation list shown on pages 57 and 58 of the original license application dated 14-November-1994. The revised table is shown as an attachment to this letter.

5. Finally, in accordance with the regulatory requirements of Title 10 CFR Part 30 Section 30.36 (d)(2), we are notifying you that by the end of this year, 1994, we plan to close down building 400, a separate building located at our Billerica Site. As you know the DuPont occupants of this facility have transferred to the DuPont facility in Boston.

DU PONT
MERCK

Decommissioning of building 400 will be completed in conformance with requirements of Title 10 CFR Part 30 Section 30.36 and in particular paragraph §30.36 (g)(1).

I have enclosed a check in the amount of $470.00 in payment of the license amendment fee as specified for Fee Category 3A in the regulations of Title 10 CFR Part 170, §170.31.

Please contact me if you require any additional information.

Sincerely,

Dennis Dumas

Dennis O. Dumas
Radiation Protection Officer
Telephone: 508-671-8669
Toll Free: 1-800-362-2668, ext. 8669

Attachment #1 - The Close-out Survey of Building 350

Reference: Materials License #20-28598-01

This is a request to amaned the above-referenced license to remove the following facility from the license:

Building 350.

Building 350

Facility

This 4600 ft^2 building has not been used since 1987 when it became a storage facility for used office and laboratory furniture and equipment.

Operation

The original purpose of this 4600 ft^2 building was an animal facility for quality control testing of radiopharmaceutical products. The primary radionuclides handled were ^{99m}Tc, ^{201}Tl, and ^{67}Ga for pyrogen testing up until about 1985 and as an animal facility for toxicological studies in the early 1970's. The quantities of radioactive material possessed in the facility at any one time was no more than several hundreds of millicuries. The complete list of nuclides used in this facility are shown below.

Radionuclide	Half-life	Date First Used	Radionuclide	Half-life	Date First Used
$^{99}Mo/^{99m}Tc$	66h/6hr	4/14/71	^{75}Se	120d	9/21/71
^{113}Sn	115d	4/13/71	^{67}Ga	3.3d	10/19/71
^{87m}Sr	3h	4/13/71	^{139}Cs	9.5m	8/27/71
^{133}Xe	5.3d	4/29/71	^{55}Fe	2.7y	12/8/72
^{84}Rb	33d	4/29/71	^{123}I	13h	4/11/73
^{18}F	109m	5/12/71	^{32}P	14d	10/30/73
^{131}I	8d	6/2/71	^{201}Tl	3d	9/3/74
^{125}I	60d	6/11/71	$^{188}W/^{188}Re$	69d	8/8/78
^{51}Cr	28d	6/8/71	^{192}Ir	5d	N/A

Survey Results

The enclosed survey results indicate that there is no removable contamination levels above background in building 350. The radiation surveys did reveal ^{137}Cs fixed contamination in the floor of the building; however, the area where the contamination existed was removed. The radiation survey was conducted after all materials, equipment, and furniture were removed from the building.

A calibrated survey meter, Ludlum Model 3, Serial # 43589, calibrated 8/22/94, with an end-window Geiger-Müller detector and a Sodium Iodide detector, was used to monitor all areas of the facility of residual radioactive material. A calibrated floor monitor, Ludlum Model 12, Serial # 87865, calibrated 7/19/94, was used to monitor the floors of the building for fixed contamination. Each square foot of the quality control testing areas was checked. A general survey was also conducted using the same instruments, of the office areas. No levels of removable radioactive material above background were detected. In one of the quality control testing areas, three spots of nonremovable contamination were found. After removing the floor where the contamintion existed, no levels of radioactive material above background were detected.

The wipes for removable contamination were taken at 1374 locations within the building; including the ceilings. The wipes were 4.25 cm Whatman filter paper discs, wiped dry on the surface of the documented locations. The wipes were counted on a Canberra Alpha-Beta-Gamma Counter, Model 2404F (2"x2" NaI Detector, Serial #GO-036, Gas Flow Proportional Counter, Serial # 590754), and approximately 15% of the wipes, at random, were counted on a Packard Liquid Scintillation Counter, for gross beta contamination. The results are attached to the maps.

Fixed Contamination Survey Results

On the following maps, arrowed lines are used to designate that the entire area was monitored. There are two numbers listed in various spots. The top number refers to the count rate measured using the NaI probe, and the bottom number refers to the count rate measured using the end-window Geiger-Müller detector. In the case of the floor surveys, the measurements taken with the gas flow proportional counter floor monitor are listed as a third set of numbers below the NaI and GM results.

Removable Contamination Survey Results

On the following maps, a grid is shown as reference to the areas where the wipe tests were performed. The first map has a legend which indexes the nomenclature used to identify the wipes.

Attachment #2 - Instrument Calibration Schedule

BILLERICA SITE INSTRUMENTATION

	Type of Instrumentation	Quantity	Radiation Detected	Sensitivity Range	Frequency of Calibration	Type of Use Quantitative vs. Qualitative
1. Portable Survey Meters	Remmeter (LiF probe)	2	n	0-5 rem/hr	6 months	Quantitative
	Alpha Probe	1	α	0-500 kcpm	6 months	Quantitative
	Pressurized Ion Chamber	3	γ,x	0.001-5000 mR/hr	6 months	Quantitative
	Survey Meter (GM)	1	γ,x	0-2 R/hr	6 months	Quantitative
	Survey Meter (GM)	3	γ,x	0-200 mR/hr	6 months	Quantitative
	Contamination Monitor (GM, NaI)	2	β,γ,x	0-500 kcpm	6 months	Quantitative
	Contamination Monitor (GM, NaI)	4	β,γ,x	0-300 kcpm	6 months	Quantitative
	Ionization Chamber Survey Meter	6	β,γ,x	0-50 R/hr	6 months	Quantitative
	Micro-rem Survey Meter (Ion chamber)	1	β,γ,x	0-5 R/hr	6 months	Quantitative
	Micro-rem Survey Meter (tissue equivalent gas)	1	β,γ,x	0-5 R/hr	6 months	Quantitative
	Long Pole 20 ft. extendible GM Survey Meter	2	β,γ,x	0-999 R/hr	6 months	Quantitative
2. Analytical Measuring Systems	3"x3" NaI(Tl) Well Crystal	2	γ,x	N/A	6 months, daily checks	Quantitative nuclide ID sample counting

	Type of Instrumentation	Quantity	Radiation Detected	Sensitivity Range	Frequency of Calibration	Type of Use Quantitative vs. Qualitative
	Planar Ge REGe HPGe	1 1 1	γ,x γ,x γ,x	N/A	6 months, daily checks	Quantitative nuclide ID sample counting
	L.S.C.	1	β	N/A	6 months, checks done prior to each use	Quantitative
	Gas Flow Proportional Counter	2	α,β,γ,x	N/A	6 months, check done prior to use	Quantitative
	α,β,γ Counter Gas Flow Proportional Counter & 2"x2" NaI(Tl) Crystal	1	α,β,γ,x	N/A	6 months	Quantitative
	AutoGamma Counter 3"x3¼" NaI(Tl) Crystal	1	γ,x	N/A	6 months	Quantitative Qualitative
3. Air Monitors	Real Time Stack Effluent Monitors (GM, NaI)	6	β,γ,x	N/A	6 months, monthly maintenance	Quantitative for Noble Gases, Qualitative All Others
4. Special Monitoring Devices	2"x1½" NaI(Tl) Crystal	1	γ,x	N/A	3 months	Quantitative Thyroid Monitoring
	3"x3" HPGe Crystal	1	γ,x	N/A	6 months	Quantitative Whole Body Counting
	Ratemeter (NaI) Change Areas, Controlled Areas	3	γ,x	0-300 kcpm	6 months	Qualitative

	Type of Instrumentation	Quantity	Radiation Detected	Sensitivity Range	Frequency of Calibration	Type of Use Quantitative vs. Qualitative
	Ratemeter (GM, NaI) Change Areas, Controlled Areas	22	β,γ,x	0-300 kcpm	6 months	Qualitative
	Ratemeter (pancake "hand and shoe" GM, NaI) Change Areas	7	β,γ,x	0-300 kcpm	6 months	Qualitative
	Ratemeter (pancake "hand and shoe" GM) Change Areas	4	β,γ,x	0-300 kcpm	6 months	Qualitative
	Ratemeter (pancake GM, NaI) Change Areas, Controlled Areas	5	β,γ,x	0-300 kcpm	6 months	Qualitative

The Du Pont Merck Pharmaceutical Company
Radiopharmaceutical Division
331 Treble Cove Road
No. Billerica, MA 01862
(508) 667 9531

File

January 9, 1995

359 9294 657

U.S. Nuclear Regulatory Commission
ATTN.: Elizabeth Ullrich
Region I
475 Allendale Road
King of Prussia, PA 19406

DU PONT
MERCK

Reference: Materials License #20-28598-01

Dear Ms. Ullrich:

This is written to request an amendment to the above-referenced license.

In anticipation of a large scale business venture involving the manufacture of Sm-153 in a medical therapeutic product for bone palliation, we are asking for an increase in the possession limit for this radionuclide on our broad scope license. We request a possession limit be authorized on this license as follows:

Byproduct material	Chemical and/or physical form	Maximum amount to be possessed at any one time
Samarium-153	Any	2,000 Curies

The use of this material will be as part of the manufacturing, and the subsequent packaging and distribution, of Sm-153 as a radiopharmaceutical to specific licensees operating under the jurisdiction of the U.S. Nuclear Regulatory Commission or of an Agreement State.

Once procured from a commercial reactor facility, the Sm-153 as a raw material will be received at the Billerica site and will be processed in the restricted area laboratories of building #250. The Sm-153 radiopharmaceutical will then be dispensed and packaged in building #200. Certain laboratory facilities in these two buildings are now in process of renovation/retrofitting to accommodate this new product. All Sm-153 operations will be conducted in compliance with the conditions of our licensed radiation protection program as well as with newly developed operating procedures.

A check in the amount of $470 is enclosed in payment of the license amendment fee specified for Fee Category 3A in Title 10 CFR Part 170, §170.31. Please contact me if you require any additional information.

Sincerely,

Francis C Roy Jr.

Francis E. Roy Jr.
Development Health Physicist

Radiopharmaceutical Division
331 Treble Cove Road
No. Billerica, MA 01862
(508) 667 9531

783 0269 264

December 5, 1995

DU PONT
MERCK

U.S. Nuclear Regulatory Commission
ATTN.: Elizabeth Ullrich
Region I
475 Allendale Road
King of Prussia, PA 19406

Reference: Materials License #20-28598-01

Dear Ms. Ullrich:

This is written to request an amendment to the above-referenced license.

We request authorization to change the Chairman of our Radioisotope Committee from Ray Shepard to Glenn Gerecke. Mr. Gerecke is the Associate Director of our radiopharmaceutical manufacturing operations. He has been responsible for various operations in the production area since 1981. A summary of his Radioisotope Committee membership qualifications is attached for your review. With his years of direct experience in a critical part of our site operations coupled with his senior management responsibilities Mr. Gerecke is eminently qualified to replace Mr. Shepard as the Chairman of the Billerica site's Radioisotope Committee.

A check in the amount of $530 is enclosed in payment of the license amendment fee specified for Fee Category 3A in Title 10 CFR Part 170, §170.31. Please contact me if you require any additional information.

Sincerely,

Dennis Dumas
Associate Director
Safety and Environmental Engineering

Radioisotope Committee Membership Qualifications

Name: GLENN A. GERECKE Title: AREA SUPERVISOR, MFG Date: 4-29-92

1. Training

Subject	Where Trained	Dates	Formal Training	On Job Training
a. Principles and practices of radiation Protection	DMPC	8-87	✓	
b. Radioactivity measurements monitoring, and instruments	DMPC	89		✓
c. Mathematics and calculations relative to radioactivity	DMPC	89		✓
d. Biological effects of radiation	DMPC	8-87	✓	

2. Experience *

	Isotope	Maximium Amount Handled	Location	Dates	Type of use
DIRECT EXPERIENCE	^{99}Mo	6000 Ci/WEEK	DMPC	89-90	GENERATOR PRODUCTION
	^{133}Xe	600 Ci/WEEK	DMPC	89-90	XENON VIAL PRODUCTION

* OTHER EXPERIENCE INCLUDES CYCLOTRON VOLUNTEER WORK & INDIRECT EXPERIENCE IN SUPERVISION OF CYCLOTRON CHEMISTRY & TL/GA RADIOGRAPHY OPERATIONS

The Du Pont Merck Pharmaceutical Company
Radiopharmaceutical Division
331 Treble Cove Road
No. Billerica, MA 01862
(508) 667-7601

783 0292 014

Delivered 4/1/96
10:31 AM
signed B Conday

March 29, 1996

U.S. Nuclear Regulatory Commission
ATTN.: Elizabeth Ullrich
Region I
475 Allendale Road
King of Prussia, PA 19406

DU PONT
MERCK

Reference: Materials License #20-28598-01

Dear Ms. Ullrich:

This is written to request a license amendment authorizing a modification in the method we currently use to determine Transport Index and surface radiation measurements for the outbound, newly manufactured DuPont Merck Technelite® Tc-99m generators.

As you know, during the routine inspection of our operations last year representatives of Region I were shown the construction, now completed, for an upgraded radiopharmaceutical manufacturing facility. This new facility, located adjacent to our existing manufacturing operation, houses state-of-the-art pharmaceutical manufacturing systems. This upgrade will allow us to further reduce occupational radiation exposures to members of the manufacturing team as regulated under our NRC materials license as well as continuing to ensure our full compliance with the FDA's current good manufacturing practices (cGMP) requirements. From a business standpoint this new manufacturing operation will produce the same high quality technetium generators as previously approved by your office but at a much more efficient rate of production.

It was determined early in the upgrade planning that this more efficient rate of production would result in a greater throughput of manufactured units per each run. A limiting factor to the rate of production for this new facility was found to be the individual monitoring of each of the outgoing generators. The existing integrating count, Transport Index radiation monitoring system will not allow the new operation to reach an optimum rate of production. A management decision was made to petition the U.S. D.O.T., and subsequently the U.S. N.R.C. through a licensing action, to authorize the use of a statistical approach to the determination of surface and transport index radiation measurements rather than utilize actual physical measurements for each manufactured unit.

We received a letter from the U.S.D.O.T. in response to our petition in December of 1994 (see attached copy) specifying that within certain constraints a rigorous statistical approach may be used in lieu of physical measurements for determining the radiation level at the surface or at one meter from the package. Through 1995 a team of experts representing the Radiation Protection Office, Engineering, Manufacturing, Packaging/Distribution, and Statistical Methods (R&D) developed the procedural criteria and implemented the monitoring study that resulted in a statistical model that can now be used to accurately determine the surface and 1 meter radiation levels expected from each unit to be manufactured in the new facility. A summary of this endeavor is attached for your review including the charts that show how the statistical model can be used to assign radiation levels to each unit manufactured.

DU PONT
MERCK

March 29, 1996

U.S. Nuclear Regulatory Commission
ATTN.: Elizabeth Ullrich
Region I
475 Allendale Road
King of Prussia, PA 19406

Reference: Materials License #20-28598-01

This statistical model will be part of an active quality assurance program that will continue to ensure accurate determinations of radiation levels on the Technetium generators. On a periodic basis, we are planning monthly, a representative sample of generators from the manufacturing run will be physically monitored for surface radiation levels and transport index. This data will be compared to the predictions of the statistical model and confirmation will be determined of the continued validity of the model. Any discrepancies outside the acceptance criteria specified in the attached report will result in the implementation of a confirmation study and possible modification of the model as soon as possible but not later than the next manufacturing run. In addition, a confirmation of the statistical model will also be triggered with any modifications of the product and packaging that has potential impact on the radiation levels from each unit as specified by the communication from the U.S.D.O.T. dated December 5, 1994.

We believe that this new manufacturing facility with the upgraded Technetium generator manufacturing processes and the statistical approach to the determination of radiation levels for these units will ensure the continued high quality of the product both in terms of regulatory compliance and customer utilization. In addition, these modifications will help our business to optimize the level of production in order to meet our customers needs for Technelite. Thus, we have a critical business need to get these modifications implemented as soon as possible prior to May 1, 1996 and request your office's earliest attention to this license amendment request.

I have enclosed a check in the amount of $530 in payment of the license amendment fee pursuant to Title 10 CFR Part 170 §170.31 for Fee Category 3A. Please contact me or Dennis Dumas at 508-671-8669 if you require any additional information.

Sincerely,

Francis E. Roy, Jr.
Senior Health Physicist

Telephone: 508-671-8242

U.S. Department
of Transportation

**Research and
Special Programs
Administration**

400 Seventh Street, S.W.
Washington, D.C. 20590

DEC 5 1994

Mr. Ermes DeMaria
The Du Pont Merck
Pharmaceutical Company
331 Treble Cove Road
North Billerica, MA 01862

Dear Mr. DeMaria:

This is in response to your letter dated August 15, 1994, regarding the determination of the transport index (TI) for a radioactive material package. Specifically, you ask if the use of a rigorous statistical approach, in place of physical measurements, may be used to determine the TI for a particular package.

In your letter you stated that the following procedures would be implemented in order to determine the TI for a packages by use of statistical methods in lieu of direct measurements:

1. Before shipment of a specific package design for radioactive material sufficient radiation measurements have been made to determine the radiation level (RL) and transport index. The RL and TI for categorization are within the acceptable range of an appropriate survey meter calibrated and operated by a trained individual.

2. The design, construction, contents, and quantity of each subsequent shipment of the package is identical to the design, construction, contents, and quantity of the initial tested package.

3. Written quality control procedures are in place to ensure that the packaging components are within manufacture's specification, the assembly of the components are in accordance to the specific packaging design, the contents of the package is within the quantity and radioisotopic purity of the initial radiation measurements.

The Hazardous Materials Regulations (49 CFR Parts 171-180) do not specify a method for determining the radiation level at the surface or at one meter from the package. The HMR specify limits, and it is the responsibility of the person offering the packages for transport to assure that the radiation levels and transport index are correct.

It is the opinion of this office that by following the above procedures, statistical methods, rather than direct measurements, may be used to determine the TI of a radioactive material package.

I hope this satisfies your inquiry.

Sincerely,

Thomas G. Allan

Thomas G. Allan
Deputy Director, Office of
Hazardous Materials Standards

Memorandum
Confidential

To: F. Roy
From: M. N. Bresnick MNB
Date: 29 March 1996

RPD/MNB/96/05

Subject: Technelite® Transport Index and Surface Field Measurement Studies

Introduction

A study of 29 generators employing four technicians was conducted to enable development of statistical models of the relationship between the transport index (TI) and surface field measurements, and the generator size and the packaging configuration. A total of 99 measurements were used to develop the models. Expected mean values of TI and surface field can be calculated using the models, given the load (mCi Mo-99) and the packaging (shield type). A model confirmation study of 12 generators was conducted to confirm the accuracy of the models.

Experimental

Four technicians performed multiple surveys of 29 generators. All measurements were made with a Ludlum Model 3 survey meter equipped with an energy compensated G-M detector Model 44-38. A total of 99 measurements were used to develop mathematical models for the transport index (maximum field at 1 meter) and surface field (maximum at package surface) values. Separate equations were derived for the two shield types, B and C, using linear regression techniques. The models are based on the mCi Mo-99 present at the time of the measurement. The Mo-99 values of the test generators were obtained from the Mo-99 loading by adjusting for the decay from the calibration point (noon on day of calibration) to the day and time of reading.

Model accuracy was confirmed through a 12 generator confirmation study, employing three operators. Each operator performed single determinations of the TI value and surface field for the 12 generators (4 generators each). These determinations were compared with the predicted values as calculated for the mCi load decayed to the time of determination. Acceptance criteria established prior to the study were (1) not more than two measurements outside of the 95% prediction interval and (2) no measurements outside of the 99.9% prediction interval.

Results: Transport Index (TI)

The TI models are shown below. The regression details for each are provided in Table 1. X-Y plots of the data are provided in Figures 1 and 2.

Shield Type: B

$$TI = 0.122 + 0.00114 * \text{mCi Mo-99} \qquad \text{(Eq. 1)}$$

Shield Type: C

$$TI = -0.138 + 0.00054 * \text{mCi Mo-99} \qquad \text{(Eq. 2)}$$

Predicted mean TI values were calculated for all currently planned generator sizes. Table 2 presents these calculated mean TI values. Also shown in Table 2 are the 95% confidence interval for the predicted mean and the 95% prediction interval for future generators.

The results of the confirmation study, shown in Table 3, met the acceptance criteria. All measurements were within their respective prediction intervals. In addition, the overall mean deviation from predicted value was -0.042 (standard deviation = 0.138) which is not significantly different from zero at a 95% confidence level (p = 0.32). The six B shield measurements had a mean deviation from predicted of -0.12 (standard deviation = 0.098). This result is marginally significantly different from zero at the 95% confidence level (p=0.03). The six C shield measurements had a mean deviation from predicted of 0.033 (standard deviation = 0.137). This result is not significantly different from zero at the 95% confidence level (p=0.58).

The B shield result suggests that the model may be slightly overestimating the maximum field at 1 meter. The magnitude of the possible bias, 0.1 units, is on order of the inherent measurement random variability (root mean square = 0.14) and much smaller (1/5) than the expected variability due to all sources, as represented by the prediction interval for future individual generators. The possible bias should have no impact on the use of the models.

Results: Surface

The surface models are shown below. The regression details for each are provided in Table 4. X-Y plots of the data are provided in Figures 3 and 4.

Shield Type: B

$$\text{Surface} = 5.31 + 0.0283 * \text{mCi Mo-99} \qquad \text{(Eq. 3)}$$

Shield Type: C

$$\text{Surface} = 3.80 + 0.01285 * \text{mCi Mo-99} \qquad \text{(Eq. 4)}$$

Predicted mean surface values were calculated for all currently planned generator sizes. Table 5 presents these calculated mean surface values. Also shown in Table 5 are the 95% confidence interval for the predicted mean and the 95% prediction interval for future generators. All predicted values are <200 mR/hr.

The results of the confirmation study, shown in Table 6, met the acceptance criteria. All measurements were within their respective prediction intervals. In addition, the mean deviation from predicted value was -0.42 (standard deviation = 4.1) which is not significantly different from zero at a 95% confidence level (p = 0.73). The six B shield measurements had a mean deviation from predicted of -3.0 (standard deviation = 3.5). This result is not significantly different from zero at the 95% confidence level (p=0.09). The six C shield measurements had a mean deviation from predicted of 1.8 (standard deviation = 3.5). This result is not significantly different from zero at the 95% confidence level (p=0.26).

Conclusions

Models for prediction of the TI value and surface field based on mCi Mo-99 and shield type have been developed and satisfactory accuracy demonstrated. They are suitable for use in the determination of package labeling values. Prediction intervals for individual generators can be calculated permitting on-going performance check of the models and providing a statistical estimation of the inherent variability in measurement and manufacturing. The models support labeling at mean predicted TI values and provide a statistical basis for evaluation of observed deviations from labeled values.

Figure 1

TI Measurement vs mCi at time of Read

Shield Type: B

$$TI = 0.122 + 0.00114 * mCi$$

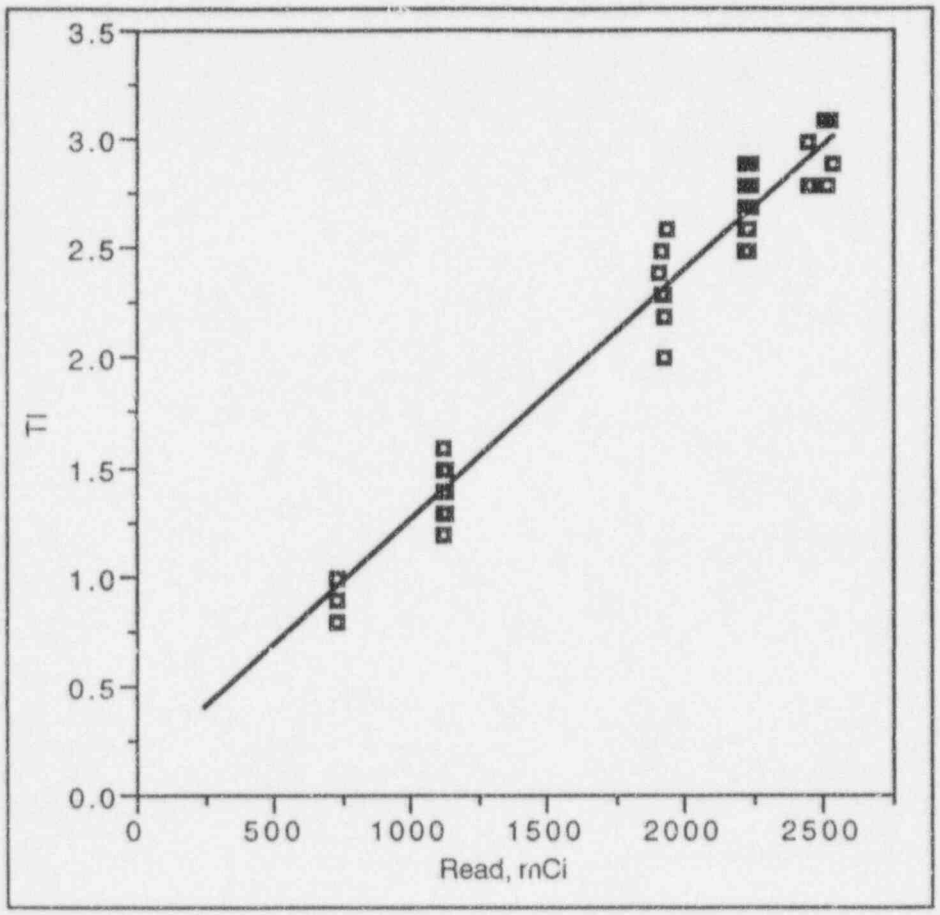


Figure 2

TI Measurement vs mCi at time of Read

Shield Type: C

TI = -0.138 + 0.00054 * mCi

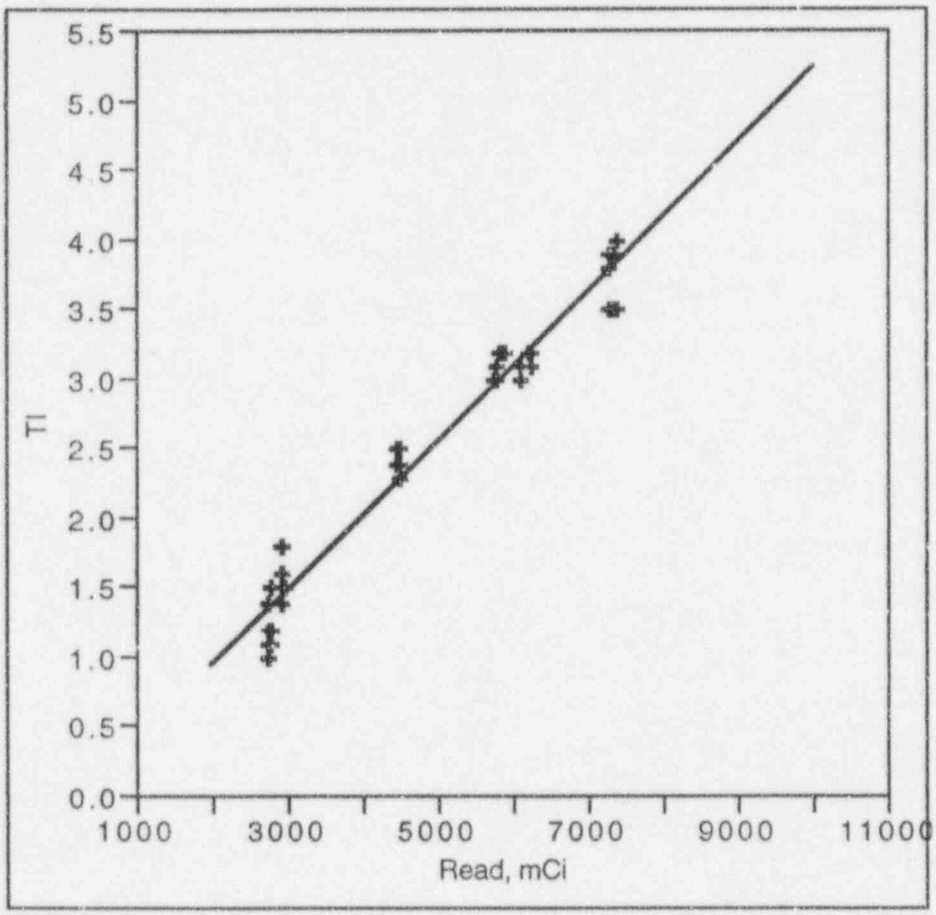


Figure 3

Surface Measurement vs mCi at time of Read

Shield Type: B

Surface = 5.306 + 0.0283 * mCi

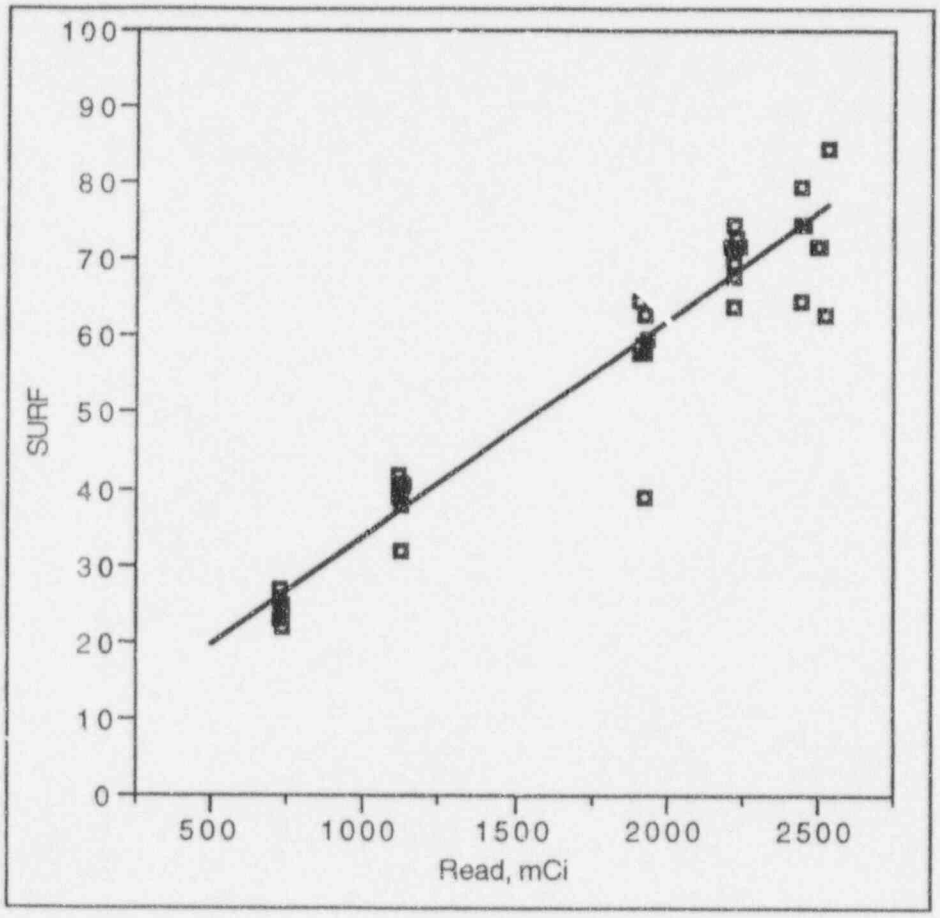
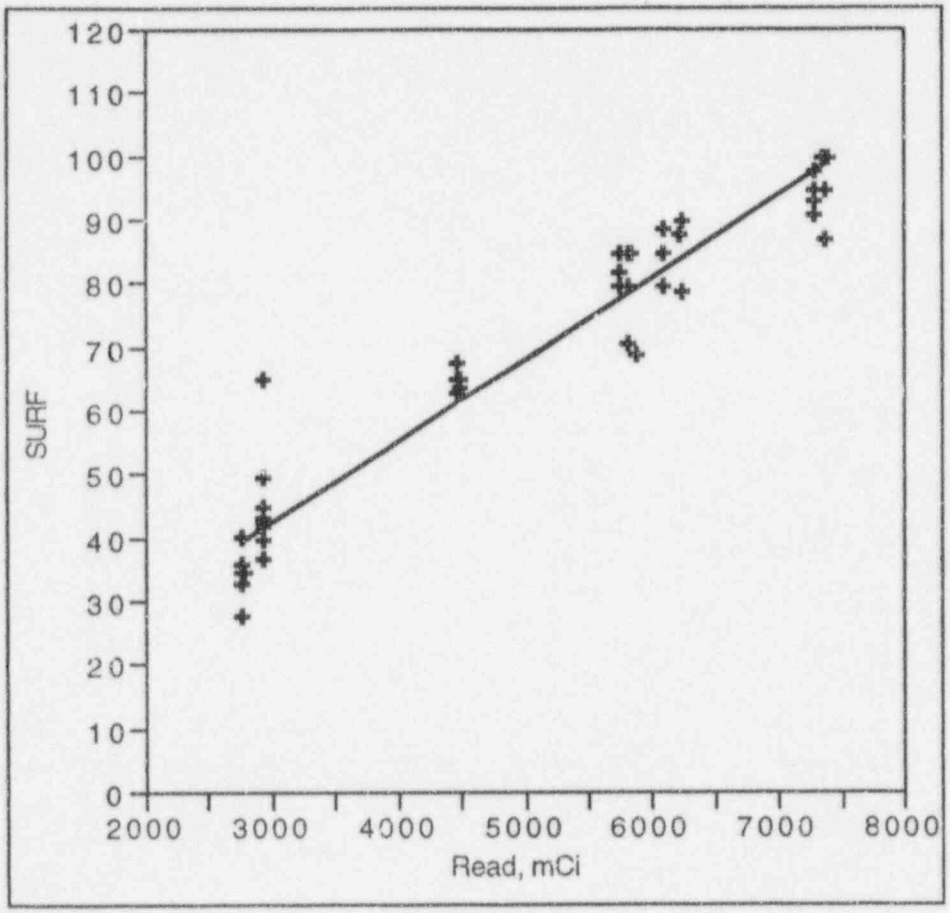


Figure 4

Surface Measurement vs mCi at time of Read

Shield Type: C

Surface = 3.803 + 0.0128 * mCi



The Du Pont Merck Pharmaceutical Company
Radiopharmaceutical Division
331 Treble Cove Road
No. Billerica, MA 01862
(508) 667 9531

783 0294 927

April 19, 1996

Delivered by F.D/Ex
on 4/22/96 at 9:30AM
signed by G. Cowan.

U.S. Nuclear Regulatory Commission
ATTN.: Penny A. Lanzisera
Region I
475 Allendale Road
King of Prussia, PA 19406

DU PONT
MERCK

Reference: Materials License #20-28598-01

Dear Ms. Lanzisera:

This is written in response to your April 18 verbal request for additional information concerning our license amendment request dated March 29, 1996, to modify the existing methods used to monitor the outgoing, newly manufactured technetium generators for Transport Index and surface radiation levels.

1. The report submitted with our application titled, "Technelite® Transport Index and Surface Field Measurement Studies" does not have to be classified/processed as confidential business information. This report was marked confidential as part of a standard procedure within our research and development organization. The methods and data presented in this report are not considered confidential and can be included as part of our license amendment request in your files and the public document room.

2. This is written confirmation that while, by definition, the values of Transport Index shown in the report have no units, all the values for the surface measurements shown are in units of millirem per hour.

3. The details of our program to assure the continued validation of this statistical approach to the determination of surface radiation levels and transport index for the technetium generators is as follows:

   a. The final packaging group of the Customer Service/Distribution organization will be responsible for the physical measurements to be taken to verify the continuing effectiveness of the statistical model.

      Initially, once a week, a trained final packaging person will randomly select several technetium generator units from the production line (i.e. at least 4 units of each shield size, B and C) and determine by physical measurement the surface radiation level and the transport index for each package selected. After 13 weeks of data is collected the values will be forwarded to the site's statistician for analysis against the predictions expected from the statistical model. If the values seem to deviate from the model additional confirmation studies will be implemented and the model modified as needed. If the model continues to be valid, then a determination will be made on the frequency of this sample monitoring performed by the packaging group, but it will be at least quarterly.

   b. This statistical method of determining surface radiation levels and Transport Index for technetium generators will be described in a written procedure to be included in the quality assurance document control system for the manufacturing operations, as well as included in the site radiological procedures document control system. This will ensure that this statistical model is

DU PONT
MERCK

considered by the cGMP Change Control Board when there are any proposed changes in the technetium generator design, manufacturing or packaging that could have impact on the package surface radiation levels or Transport Index.

c. On an ongoing basis and initially monthly the site Radiation Protection Office (RPO) will conduct audits of this program to ensure the continued effectiveness of this statistical method approach. Once a month an RPO representative will select several final packaged technetium generator units (i.e. at least 10 units) from the manufacturing run and physically measure the surface radiation level and the transport index for each unit. In addition, the RPO auditor will determine the status of any changes made in the design, manufacturing or packaging of the unit and, where applicable, if these changes have been dealt with in the model.

   After 3 monthly audits the RPO will reassess the need to continue the monthly frequency or the appropriateness of changing the audit frequency to quarterly. Future audits will at least be performed quarterly.

4. This is written confirmation that the Radiopharmaceutical Division of DuPont Merck will implement the following procedures just as we committed to for the U.S.D.O.T.:

   a. Before shipment of a specific package design for radioactive material sufficient radiation measurements have been made to determine the radiation level (RL) and Transport Index. The RL and TI for categorization are within the acceptable range of an appropriate survey meter calibrated and operated by a trained individual.

   b. The design, construction, contents, and quantity of each subsequent shipment of the package is identical to the design, construction, contents, and quantity of the initial tested package.

   c. Written quality control procedures are in place to ensure that the packaging components are within manufacture's specification, the assembly of the components are in accordance to the specific packaging design, the contents of the package is within the quantity and radioisotopic purity of the initial radiation measurements.

This statistical approach to the determination of surface radiation levels and Transport Index for technetium generators has been reviewed and approved by the site Radioisotope Committee as well as the Radiopharmaceutical Division senior management. U.S. Nuclear Regulatory Commission authorization for this new method will assist our efforts at improving the efficiency of our manufacturing operations, while further limiting the radiation exposure to our workers and optimizing our ability to meet the customers' needs for Technelite®.

Please contact us if you require any additional information.

Sincerely,

Raymond Shepard

Raymond Shepard
Director, Billerica Site

Billerica Site

Handbook

of

Radiation Protection

Required

Rules and

Procedures

DuPont Merck Pharmaceutical Company

&

DuPont Medical Products

331 Treble Cove Road

North Billerica, Massachusetts 01862

Revised April 20, 1994

ALARA Commitment

To All Employees:

The Billerica site is a major manufacturer of radiopharmaceuticals and radioactive research products, and is licensed by the U.S. Nuclear Regulatory Commission to manufacture and distribute these products. To qualify for this license, we must employ appropriately engineered safety controls, trained personnel, protective devices, procedures and rules, and safety audits to ensure the protection of our employees, our customers, and the general public.

This Handbook is an integral part of our NRC license, and the basic rules and responsibilities contained within must be understood and complied with. In addition, we must all adhere to area-specific procedures and apply basic radiation safety measures at all times. Our failure to do so could result in unnecessary dose to employees or to members of the public, radiological incidents, and violation of regulatory safety requirements.

Management is committed, legally and morally, to ensuring that radioactive materials are handled in accordance with the conditions of our license and all applicable regulatory requirements. We must commit ourselves not only to safe operations, but also to a continuous effort to improve safety and reduce both employee doses and environmental impact to levels that are As Low As Reasonably Achievable (ALARA). Fulfilling this commitment to ALARA requires the effort and attention of Management, Radioisotope Committee members, Radiation Protection Office staff, Supervisors, and each individual employee.

I encourage all of you to look for and make suggestions regarding opportunities for improvements in the radiation safety of your operations, and remind you that unsafe conditions must be reported immediately to your supervisor. Together we can maintain a safe and productive workplace, and I know I can count on each of you for your continuing effort and support.

Roger Heiser
Senior Vice President
Radiopharmaceuticals

TABLE OF CONTENTS

SECTION I: RADIATION PROTECTION RESPONSIBILITIES

A. BILLERICA SITE MANAGEMENT

Billerica Site Management shall:

1. Have the ultimate responsibility for the radiation protection program.
2. Approve radiation protection policy, based on Radioisotope Committee recommendations.
3. Provide adequate facilities for safe handling, storage, distribution and disposal of radioactive materials.
4. Ensure the safety of operations.
5. Supervise major emergency responses.
6. Ensure the implementation of appropriate corrective and preventive actions, based on the recommendations of the Radioisotope Committee.

Billerica Site Management ALARA responsibilities:

1. Approve new ALARA goals and action levels.
2. Support ALARA efforts.

B. SITE RADIOISOTOPE COMMITTEE

The Radioisotope Committee shall:

1. Establish radiation protection policies that will provide adequate radiation protection and compliance with pertinent regulations.
2. Evaluate proposed uses of radioactive materials submitted by authorized supervisors and approve those meeting radiation protection, ALARA, and safety requirements. Evaluation should include considerations of the adequacy of appropriate supplemental rules, facilities and equipment, operating, handling and emergency procedures, and the experience and training of the proposed users.
3. Advise supervisors on additional radiation protection requirements for the areas they are responsible for.
4. Review reports of events that exceed radiological action levels and infractions of any rules or regulations. Recommend appropriate and timely corrective and preventive actions.

Radioisotope Committee ALARA responsibilities:

1. Establish radiation protection policies that ensure occupational doses and doses to members of the general public are maintained as low as reasonably achievable (ALARA).

2. Implement new ALARA goals and action levels.

3. Audit progress towards ALARA goals.

4. Review and approve new radiation safety policies and standard operating procedures.

C. RADIATION PROTECTION OFFICER

The Radiation Protection Officer shall:

1. Advise management on developments of the radiation protection program based on established policies and changes in current technology, regulations and public perception.

2. Provide for comprehensive audits of the radiation protection program.

3. Advise management on the continuing status of the radiation protection program.

4. Participate in and approve on any changes in this handbook or license.

5. Authorize required reports to the U.S. Nuclear Regulatory Commission, equivalent state agencies, and employees.

6. Be a permanent member of the Radioisotope Committee attending the committee meetings as required by license condition.

7. In conjunction with management, the Radiation Protection Officer, or qualified designee, may cease and desist any operation which involves hazardous situations or indicates violations of procedures or U.S. Nuclear Regulatory Commission (USNRC) rules, regulations or license conditions.

Radiation Protection Officer ALARA responsibilities:

1. Approve new ALARA goals and action levels.

2. Support ALARA efforts.

D. RADIATION PROTECTION SUPERVISOR

The Radiation Protection Supervisor shall:

1. Supervise the Radiation Protection Office to implement and maintain radiation protection services.
2. Provide training and information to personnel relative to radiation risks and protection.
3. Supervise special decontamination procedures.
4. Be represented on the Radioisotope Committee.
5. Maintain all records required by the radiation protection program.

Radiation Protection Supervisor ALARA responsibilities:

1. Provide ALARA program training, data and feedback.
2. Support ALARA efforts in operations groups.
3. Lead and audit site's ALARA efforts.

E. OPERATIONS SUPERVISORS

The Operations Supervisors shall:

1. Be responsible for the safe conduct of operations performed within the work area.
2. Provide training and information to employees and visitors in the work area relative to radiation protection considerations specific to that area.
3. Post supplementary rules that are pertinent to the operations in the work area.
4. Be responsible for ensuring that the work area is properly secured at the end of each work period.
5. Be responsible for ensuring provision of adequate radiation detection instrumentation for their operations.
6. Make a safety analysis of each proposed new operation or procedure. This safety analysis shall be submitted to the Radioisotope Committee for approval.
7. Investigate and report on all incidents in the area.

Operations Supervisors ALARA responsibilities:

1. Review new action levels, policies and procedures with workers.
2. Lead ALARA efforts in your area.
3. Audit own areas, request support from the Radiation Protection Office.
4. At the end of each work period ensure that radiological surveillance of work areas are conducted by employees to confirm contamination and radiation levels are maintained ALARA.

F. INDIVIDUAL EMPLOYEES

Individual employees shall:

1. Conduct all operations in a safe manner.
2. Learn and comply with supplementary rules specific to any work area the employee may be in.
3. Perform their work in a manner that will minimize their exposure, exposure to other employees and to the general public.
4. Report to their immediate supervisor and to the Radiation Protection Office any condition that may have caused or threatens to cause any exposure to radiation or release of radioactive materials in excess of any limits set forth in this Handbook.

Individual Employees ALARA responsibilities:

1. Ask questions about program, request training, learn about ALARA.
2. Make ALARA suggestions.
3. Conduct radiological surveillance of work areas to ensure radiation and contamination levels are maintained ALARA.

SECTION II: AUTHORIZATION TO HANDLE RADIOACTIVE MATERIAL

A. The supervisor of each operation involving radioactive materials will be authorized by the Radioisotope Committee to use and to supervise the use of radioactive material provided that:

1. The individual has the appropriate training and experience as deemed necessary by the Radioisotope Committee.

2. The individual is registered with the Radiation Protection Office.

3. The individual has signified in writing that he/she has read this Handbook and agrees to comply with its provisions.

B. An employee shall not handle radioactive materials without continuous supervision unless the following requirements are satisfied:

1. The individual has registered with the Radiation Protection Office.

2. The individual has signified in writing that he/she has read this Handbook and agrees to comply with its provisions.

3. The individual has satisfactorily completed Radiation Protection training.

4. The individual has been authorized to handle radioactive material by their supervisor.

C. Contractors, off-site employees, and other unauthorized site employees, shall not work in restricted areas unless:

1. The person has registered with the Radiation Protection Office.

2. The person has been supplied with appropriate radiation exposure monitoring devices.

3. The person has received training commensurate with potential radiological health protection problems in the restricted area they will enter.

4. The person is escorted by the operations supervisor or qualified designee.

5. The person agrees to comply with all radiological requirements including the returning of radiation protection equipment and completion of radiological records.

D. Visitors entering, but not working in restricted areas must be:

1. Registered on visitor entry form by an authorized site escort and provided information on potential hazards of the restricted area.

2. Provided appropriate radiation exposure monitoring devices.

3. Escorted at all times while in the restricted area.

4. Monitored for contamination, by the escort, upon exiting the restricted area.

SECTION III: REQUIRED PROCEDURES

A. COMPLIANCE WITH REGULATIONS

1. Each employee shall comply with the rules and procedures specified in this Handbook.

2. The Handbook has been submitted to the U. S. Nuclear Regulatory Commission as a part of the site's application for a USNRC Byproduct Material License. The Radiation Safety Officer reserves the right to make changes, consistent with good radiological safety practices, in the contents of the Handbook in any section except Sections I, II, III, and Appendices A, C, and E.

3. A substantive change in Sections I, II, III, or Appendices A, C, and E, shall not be made without prior approval of the USNRC.

4. It is management's responsibility to achieve compliance with the rules and procedures of this Handbook. Failure of management to initiate corrective action for deficiencies or for non-compliance is cause for a USNRC Notice of Violation.

B. CONTROL OF RADIATION EXPOSURE AND CONTAMINATION BY EMPLOYEES

1. Each person handling radioactive material shall be responsible for conducting their work in a manner that will:

   a. Keep radiation exposure to themselves and other employees as low as reasonably achievable.

   b. Minimize the spread of radioactive contamination from work surfaces or enclosures designated for handling radioactive materials.

   c. Maintain radioactive contamination levels as low as reasonably achievable, below those specified in Appendix E of this Handbook.

2. The Radiation Protection Officer, or designee, shall be notified immediately by the operations supervisor or designee when any of the following circumstances arise:

   a. Known or suspected over-exposure to external or internal radiation.

   b. Known or suspected spread of contamination on surfaces caused by spilled, transferred or released radioactive material.

   c. The release of significant quantities of radioactive material into a ventilated enclosure.

3. In the event of an incident involving radioactive materials and/or radiation, assigned employees are required to assist operations management, the Radiation Protection Officer, the Chairman of the Radioisotope Committee, or qualified designees, in the prompt initiation of appropriate action in one or more of the following ways:

   a. Investigate and document the degree and cause of contamination and/or exposure.

   b. Post and isolate the radiation and/or contamination area and contaminated equipment.

   c. Evaluate the degree of personal contamination and internal and external exposure.

   d. When indicated, suspend operations and/or suspend work of an individual.

   e. Schedule and supervise appropriate decontamination and other recovery procedures.

C. RECEIPT OF RADIOACTIVE MATERIAL SHIPMENTS

All incoming radioactive shipments shall be inspected according to the regulatory requirements established by the USNRC. Records of the inspection of all incoming radioactive material shipments shall be maintained by the receiving group.

D. DISPOSAL OF RADIOACTIVE WASTE

1. Radioactive waste shall be disposed of in accordance with the specifications of Appendix C of this Handbook.

2. Any disposal procedure not covered by Appendix C shall not be performed unless approved by the Radioisotope Committee.

E. EMERGENCY PROCEDURE

1. Dial the site emergency number.

   Billerica ext. 5580

2. See Appendix F.

SECTION IV: LABORATORY RULES

1. Laboratory coats or other designated protective clothing shall be worn when in a restricted area as specified by posted area rules. Protective clothing shall be appropriately buttoned or fastened and the sleeves worn extended to cover the arms and wrists. Protective clothing shall be monitored daily for contamination. Protective clothing shall not be worn if it is contaminated in excess of the applicable limits of Appendix E.

2. Approved, distinctively marked work shoes shall be worn at all times inside a contamination control restricted area, by all personnel who routinely work in the area. Open footwear such as sandals are not permitted. Persons not permanently assigned to a restricted area may wear shoe covers or rubbers. Steel-toe shoes are to be worn in areas where there is a potential of foot injury.

3. Whole body dosimetry shall be worn by personnel at all times on-site, as assigned by the Radiation Protection Officer, or qualified designee. Extremity dosimetry, as assigned by the Radiation Protection Officer, or qualified designee, shall be worn when handling or working with radioactive materials.

4. Personnel shall submit bioassay samples and report for other internal dosimetry assessments (for example, thyroid measurements) as assigned or requested by the Radiation Protection Officer, or qualified designee.

5. There shall be no eating, drinking, application of cosmetics, or smoking in restricted areas. Food, including candy, gum and beverages shall not be brought into a restricted area.

6. Mouth pipetting is prohibited.

7. Persons not permanently assigned to a particular area shall not perform any work in that area without reading the specific rules and receiving prior permission from the authorized supervisor.

8. Work in a restricted area during periods other than the normal work hours must have prior and specific approval of the authorized supervisor.

9. Before the end of each work day, employees shall inspect, survey and clean work areas wherever radioactive materials have been handled. When it is necessary to postpone clean-up at the end of the work day, an appropriate sign shall be posted. Decontamination must be completed prior to starting a new operation.

10. Appropriate protective gloves shall be worn whenever operations are performed that may produce hand contamination. Gloves must be changed or monitored when the hands are removed from the immediate local area of radioactivity, such as a fume hood, glove box and/or radionuclide handling cell.

11. Eye protection must be worn as specified by posted area rules.

12. All work involving radioactive material shall be conducted in such a manner that any spills are contained and contamination is controlled.

13. As a general rule, as much radioactive work as possible should be performed in an appropriate vented enclosure. Operations which may give rise to airborne contamination shall be performed in an appropriate vented enclosure. Any operation that may cause a particulate or volatile discharge in excess of allowable limits into the air exhaust system must be absorbed or trapped in an appropriate medium to prevent discharge into the environment.

14. Each exhaust fan, servicing a restricted area, shall be operated to provide specified protection whenever radioactive material is being handled in the area. Any change in this procedure must have prior approval of the Radiation Protection Office.

15. Fume-hood faces must be down at all times, except for maintenance and transfer of equipment. Proper air flow must be verified prior to starting any operation in a fume hood.

16. All AC-operated radioactivity ratemeters must be left on 24 hours a day.

17. All chromatograms must be dried in a vented enclosure.

18. Restricted area and change area doors shall be closed at all times except for entering and exiting, unless otherwise authorized by the Radiation Protection Office.

19. All radioactive materials and operations must be properly labeled (see Title 10 CFR Part 20).

20. Used protective clothing, shoe covers and work shoes shall not be worn or carried out of a restricted area, except for disposal as packaged waste material, in case of emergency evacuation, or unless otherwise authorized by the Radiation Protection Office.

21. Except for emergency evacuation, on leaving a contamination control restricted area each employee shall:

    a. Monitor hands and shoes for gross contamination prior to leaving the restricted area.

    b. Observe the radioactive contamination limits set in Appendix E of this handbook.

    c. Store or dispose of protective clothing and shoes at the assigned location.

    d. Wash and monitor their hands.

    e. Upon entry to the unrestricted area, monitor themselves and personal clothing worn in the restricted area.

22. Unless specifically authorized by the Radioisotope Committee, radioactive material in amounts greater than the values listed in Title 10 CFR Part 30, Section 30.71, Schedule B, shall not be used, handled, or stored outside of a restricted area or stored outside of a designated receiving area.

23. Close-down procedures:

    a. Each person is responsible for closing down their operation.

    b. Any apparatus that is required to be operated overnight must be conspicuously marked.

    c. The supervisor or designee is responsible for checking their entire area, turning off the lights and closing all doors.

24. Any radiation instrumentation found to be out of calibration, defective, or suspected to be malfunctioning, shall be immediately labeled as out of service, physically removed from service, and promptly reported to the supervisor.

25. Equipment, objects or packages shall not be carried out of a restricted area until the surface has been measured for radioactive contamination and verified to be below the limits of Appendix E.

APPENDIX A: LIMITS FOR OCCUPATIONAL DOSE

The values listed below are specified in the U.S. Nuclear Regulatory Commission's Regulations Title 10 CFR Part 20, "Standards for Protection Against Radiation". The values are also consistent with those specified in the "Rules and Regulations to Control Radiation Hazards" of the Massachusetts Department of Labor and Industries and the Massachusetts Department of Public Health.

I. OCCUPATIONAL DOSE LIMITS FROM EXTERNAL RADIATION

Radiation doses shall not exceed the following annual limits:

1. Whole body: head, trunk, gonads, arms above elbow and legs above knee.	5 rem
2. Lens of eye	15 rem
3. Skin of whole body	50 rem
4. Extremity: hand, elbow, arms below elbow, foot, knee, and legs below knee	50 rem

II. OCCUPATIONAL DOSE LIMITS FROM INTERNAL AND EXTERNAL RADIATION

1. The total effective dose equivalent from both internal and external radiation must not exceed 5 rem in a year, or 50 rem in a year to any individual organ or tissue.

2. The total dose from both internal and external radiation to an embryo/fetus of an occupationally exposed declared pregnant woman must not exceed 0.5 rem during the entire pregnancy.

III. OCCUPATIONAL DOSE GUIDELINES

The Radioisotope Committee shall establish and periodically review occupational dose guidelines. Individuals may not exceed these dose guidelines without prior review by the Radiation Protection Officer and prior authorization by the Operations Manager.

Operations managers establish, and the Radioisotope Committee reviews and approves, annual occupational dose reduction goals.

APPENDIX B: MEASUREMENT AND CONTROL OF EXTERNAL EXPOSURE

External exposure is the irradiation of live tissue from sources outside the body. Most occupational exposure on the Billerica site is due to external exposure. The basic strategies for limiting external exposure are to minimize the TIME spent in the radiation field, to maximize the DISTANCE between you and the radiation source, and to use SHIELDING to reduce the radiation levels reaching the work area. Another basic approach to minimizing external exposure is to limit the amount of activity being handled at any one time to the lowest possible level.

In addition to the above steps, measurements of radiation levels in the work area should be performed regularly so that time, distance and shielding measures can be applied in the most effective combination possible. In fact, the awareness gained from performing radiation surveys is critical to being able to keep doses as low as reasonably achievable (ALARA). Radiation surveys are conducted using an exposure rate meter with readout in mR/hour or R/hour. Always use a calibrated meter and verify proper function of the meter prior to starting the survey. Open the beta window of the detector if appropriate for the radionuclides handled. Take measurements throughout the work area in order to identify all the radiation sources. Do not ignore "background" radiation levels of 2 or 3 mR/hr since they can add up to a significant amount of dose over the course of a year, depending on how much time is spent in the work area.

One important way of communicating external radiation levels is to post an appropriate sign. Accessible radiation levels greater than 5 mR/hr require a "Caution, Radiation Area" sign. Accessible radiation levels in excess of 100 mR/hr require both a "Caution, High Radiation Area" sign, and strict access control. Proper posting of these signs is required by NRC regulations.

To accurately measure occupational dose, proper use and care of dosimetry is essential. Assigned body badges shall be worn at all times while on site. If extremity badges are assigned, they shall be worn while handling radioactive materials. Badges must be positioned where they will measure the highest overall dose, and should be oriented toward the source of the radiation. Lost, contaminated or damaged dosimeters must be reported to the Radiation Protection Office immediately for replacement. Results of badge readouts are provided regularly to supervisors for review with employees, and serve to document dose and confirm the adequacy of dose control measures. Dose reports must NOT be used as a dose control measure since they are always after-the-fact indicators.

APPENDIX C: DISPOSAL OF RADIOACTIVE WASTE

To assure the safe transfer, packaging, and transport of low-level radioactive waste the Billerica site has instituted a waste guidelines policy. These guidelines shall be used by employees for the initial phase of waste packaging. Waste properly packaged following these guidelines, enables Environmental Engineering personnel to prepare radioactive waste shipments that will meet the regulations and requirements of the appropriate federal and state regulatory agencies, storage and disposal facilities.

The Billerica site must comply with many regulations and requirements including the following:

- Regulations of the United States Nuclear Regulatory Commission, Title 10 CFR Parts 19, 20, 21, 61 and 71.
- Official Information Notices from the U.S. Nuclear Regulatory Commission.
- Regulations of the United States Department of Transportation, applicable parts of Title 49 CFR Parts 171 through 173.
- Regulations of the United States Environmental Protection Agency, applicable parts of Title 40 CFR Parts 261 through 263, 268 and 302.
- State and local regulations applicable to radioactive waste storage and disposal.

Copies of the relevant regulations and permits are maintained on record by Environmental Engineering, Building 150.

Due to the continuous updating and promulgating of federal and state regulations regarding low-level radioactive waste, Environmental Engineering is always up-dating the guidelines and procedures for packaging and transport of low-level radioactive waste. Through periodic training meetings and by specific request, Environmental Engineering will provide detailed instructions and operating procedures incorporating the most current regulations and requirements on handling any waste generated in each work area.

It is the responsibility of every individual who supervises, generates, or handles waste to know, understand, and follow the latest guidelines, instructions and operating procedures. If you have any questions, contact Environmental Engineering.

APPENDIX D: CONTAMINATION CONTROLS

Radioactive contamination may be defined as radioactive material in any place where it is not desired. The presence of radioactive contamination may result in unnecessary exposure to radiation. Every effort shall be made to prevent and minimize radioactive contamination.

Removable contamination is contamination that may be wiped or smeared from a surface. Our standard procedure to assess the quantity of removable contamination on a surface is to wipe, with medium pressure, a disc of dry paper over an area of 100 square centimeters.

The disc is then measured with an appropriate radiation detection instrument. Fixed contamination is measured directly with an appropriate instrument. For both fixed and removable contamination the count rate measurements in counts per minute (cpm) are converted to the level of radioactivity in disintegrations per minute (dpm) using the efficiency (counts per decay of a radionuclidic standard) of that instrument for the radionuclide involved.

$$\text{DISINTEGRATIONS PER MINUTE} = \frac{\text{COUNTS PER MINUTE}}{\text{EFFICIENCY}}$$

The preferred regulatory unit for levels of contamination is the microcurie. The level of radioactivity in units of disintegrations per minute is converted to units of microcuries as follows:

$$\text{ACTIVITY IN MICROCURIES} = \frac{\text{DISINTEGRATIONS PER MINUTE}}{\text{2.22E6 DPM PER MICROCURIE}}$$

Fixed contamination can also be measured as the dose rate at one centimeter from the surface provided that the instrument is calibrated for this application.

The levels of contamination listed in Appendix E are not intended to be allowable levels. If, as a result of a contamination survey, contamination at or above these levels is found, immediate clean-up shall be initiated.

Skin contamination should always be kept ALARA (as low as reasonably achievable). Skin contamination shall be prevented by using tools to handle potentially contaminated items, decontaminating items to be handled and monitoring them prior to handling, as appropriate. Exposed areas of the body of persons working with radioactive materials should be monitored frequently and should be washed immediately when any contamination is detected. It is important, however, that decontamination efforts be controlled to ensure that the skin is not damaged. Harsh methods of decontamination that may cause an intake of radioactivity must be avoided. Significant and persistent skin contamination must be promptly reported to the supervisor and the Radiation Protection Office.

APPENDIX E: CONTAMINATION LEVELS REQUIRING IMMEDIATE CORRECTIVE ACTION

REMOVABLE CONTAMINATION
(In disintegrations per minute/100 cm2 of wiped surface.)

Type of Surfaces	Type of Radioactive Material* Alpha Emitters	Beta or X-Ray Emitters
1. Unrestricted areas	22	1,000
2. Restricted areas:		
a. floors	4,000	10,000
b. other surfaces	10,000	25,000
3. Personal clothing worn outside of restricted areas	22	220
4. Protective clothing worn only in restricted areas	2,000	5,000

* Precise definition of Type of Radioactive Material is given in U.S.N.R.C. Regulatory Guide 8.21, which is available at the Radiation Protection Office.

FIXED CONTAMINATION**

Type of Surfaces	Alpha Emitters	Beta or X-Ray Emitters
1. Unrestricted areas	100 dpm/100 cm2	0.2 mrem/hr
2. Restricted areas:		
a. floors	20,000 dpm/100 cm2	2.0 mrem/hr
b. other surfaces	50,000 dpm/100 cm2	5.0 mrem/hr
3. Personal clothing worn outside of restricted areas	100 dpm/100 cm2	0.2 mrem/hr
4. Protective clothing worn only in restricted areas	10,000 dpm/100 cm2	1.0 mrem/hr

** The mrem/hr values above are measured by an end window GM detector at 1 cm through no more than 7 mg/cm2 of total absorber.

APPENDIX F: EMERGENCY RESPONSE

Emergency procedures for situations that involve radiation or radioactive contamination.

In the event of an emergency, ALWAYS CALL FOR HELP.

Situations which involve high radiation exposure potential require instructions from the Radiation Protection Office. If the situation involves a life-saving operation, structure the assistance so that emergency personnel do not receive an exposure greater than 25 rem/person (reference NCRP Report No. 39, Pages 100 to 101).

I. In the event of an injury, the primary consideration is to assist the injured person. Low-level radiation exposure and spread of contamination should be confined but not allowed to be an obstruction to supplying emergency aid.

   A. Call for help from:

      1. Other workers in the area.

      2. Your supervisor.

      3. Dial Extension 5580.

   B. Contact your First Aider.

   C. Know the locations and proper use of equipment such as eye wash stations, safety showers and fire extinguishers in your area, as well as any antidotes or specific first aid procedure for emergencies such as chemical inhalation or electric shock.

II. Minimize exposure and prevent spread of contamination.

   A. Evacuate the immediate contaminated area to a specific safe location.

   B. Remove grossly contaminated clothing.

   C. Wash, with flushing action, contaminated skin and eyes.

   D. Secure the contaminated area.

   E. Keep all persons involved in one area to minimize spread of contamination.

   F. When you use the emergency phone number, extension 5580, to obtain help:

      1. TELL THIS IS AN EMERGENCY CALL.
      2. TELL WHO YOU ARE.
      3. TELL WHERE YOU ARE.
      4. TELL HOW YOU CAN BE CONTACTED.
      5. TELL WHAT THE PROBLEM IS.
      6. WAIT FOR INSTRUCTIONS.

NOTE: The site radiological emergency program is described in detail in the Radiological Emergency Contingency Plan which is part of our U.S.N.R.C. byproduct material license, and is maintained by the Radiation Protection Office.

APPENDIX G: REFERENCES

The following references are maintained in the Radiation Protection Office and are available for review. They include regulations, license conditions and regulatory guidelines. Regulatory limits and action levels expressed in this handbook may be changed to correspond with any amendments to the regulations. The Radiation Protection Office may be consulted for the most recent applicable regulation.

1. USNRC Byproduct Materials License No. 20-28598-01; including the license application, the Handbook of Radiation Protection Required Rules and Procedures, the site Radiological Emergency Contingency Plan, and the site Radiological Decommissioning Funding Plan.

2. USNRC Title 10 CFR Part 19, "Notices, Instructions, and Reports to Workers: Inspections and Investigations".

3. USNRC Title 10 CFR Part 20, "Standards for Protection Against Radiation".

4. USNRC Title 10 CFR Part 21, "Reporting of Defects and Noncompliance".

5. USNRC Title 10 CFR Part 30 "Rules of General Applicability to Domestic Licensing of Byproduct Material". These regulations, in Section 30.71, Schedule B, list allowable quantities of radioactive material outside of a restricted area .

6. USNRC Title 10 CFR Part 61 "Licensing Requirements for Land Disposal of Radioactive Waste".

7. USNRC Regulatory Guide #8.21 "Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants".

RADIOLOGICAL EMERGENCY CONTINGENCY PLAN

for the

DUPONT MERCK PHARMACEUTICAL COMPANY

331 Treble Cove Road
North Billerica, Massachusetts
01862

Contact: Dennis O. Dumas,
Associate Director Safety and Environmental Engineering
(508) 671-8669

Revised August 1996.

TABLE OF CONTENTS

TABLE OF CONTENTS

RADIOLOGICAL EMERGENCY CONTINGENCY PLAN FOR THE DUPONT MERCK PHARMACEUTICAL COMPANY

1. FACILITY DESCRIPTION

1.1 Description of Licensed Activity

The DuPont Merck Pharmaceutical Company (DMPC) is located at 331 Treble Cove Road, in North Billerica Massachusetts. Activities involving radioactive material include the manufacture, research, development, packaging, and transportation of radioactive pharmaceutical products used in nuclear medicine for diagnostic imaging. Additional DMPC operations involve the manufacture and distribution of medical and industrial, sealed radioactivity sources. DMPC operations are conducted under U.S. Nuclear Regulatory Commission (NRC) License 20-28598-01. Additional NRC licenses for DMPC operations are:

20-00320-16MD	-	Distribution of Technetium Generators
20-00320-17MA	-	Distribution of Reagent Kits
20-00320-18MD	-	Distribution of Medical Sources
20-28598-02E	-	Distribution of Exempt Quantities

DMPC operations involving naturally occurring and accelerator produced radioactive materials (NARM) are licensed by the Massachusetts Department of Public Health, Radiation Control Program (license number: 60-0088). These operations include the manufacture and distribution of sealed radioactivity sources containing accelerator produced radioactive material, cyclotron operations, and cyclotron produced radioactive materials.

NEN Life Science Products (NEN) radioactive labeled chemical operations are conducted on the Billerica site under a separate NRC license. Radiological surveillance and emergency response is performed by the DMPC Radiation Protection Office (RPO).

Operations involving radioactive material conducted at the Billerica site do not approach the level of potential hazard to the surrounding community posed by a nuclear power reactor. Nor are criticality accidents involving the fission of certain radioactive materials possible, since fissile materials are not possessed on the Billerica site. It is very improbable that accidents involving radioactive material on the Billerica site would result in significant hazard to the surrounding community.

A large number of hazardous chemicals are used on site (typically in small quantities), and are stored locally in small vented cabinets or storage areas. A computerized inventory of all hazardous chemicals ordered for the site is maintained and contains the quantity, location, group, and order date. A printed inventory is included with the Radiological Emergency Contingency Plan (RECP) records. Material Safety Data Sheets (MSDS) for all hazardous chemicals used on site are maintained by the NEN Safety Health and Environmental Affairs (SHEA) (industrial safety) group, on the second floor of Building 300.

Additional site activities conducted in support of the operations described above include: receiving, purchasing, accounting, waste handling and disposal, customer service, distribution, quality control, custodial, security, radiation protection, human resources, industrial safety, engineering, facilities maintenance, medical services, marketing, information resources, etc.

1.2 Description of Facility and Site.

1.2.1 Communication and Assessment Centers

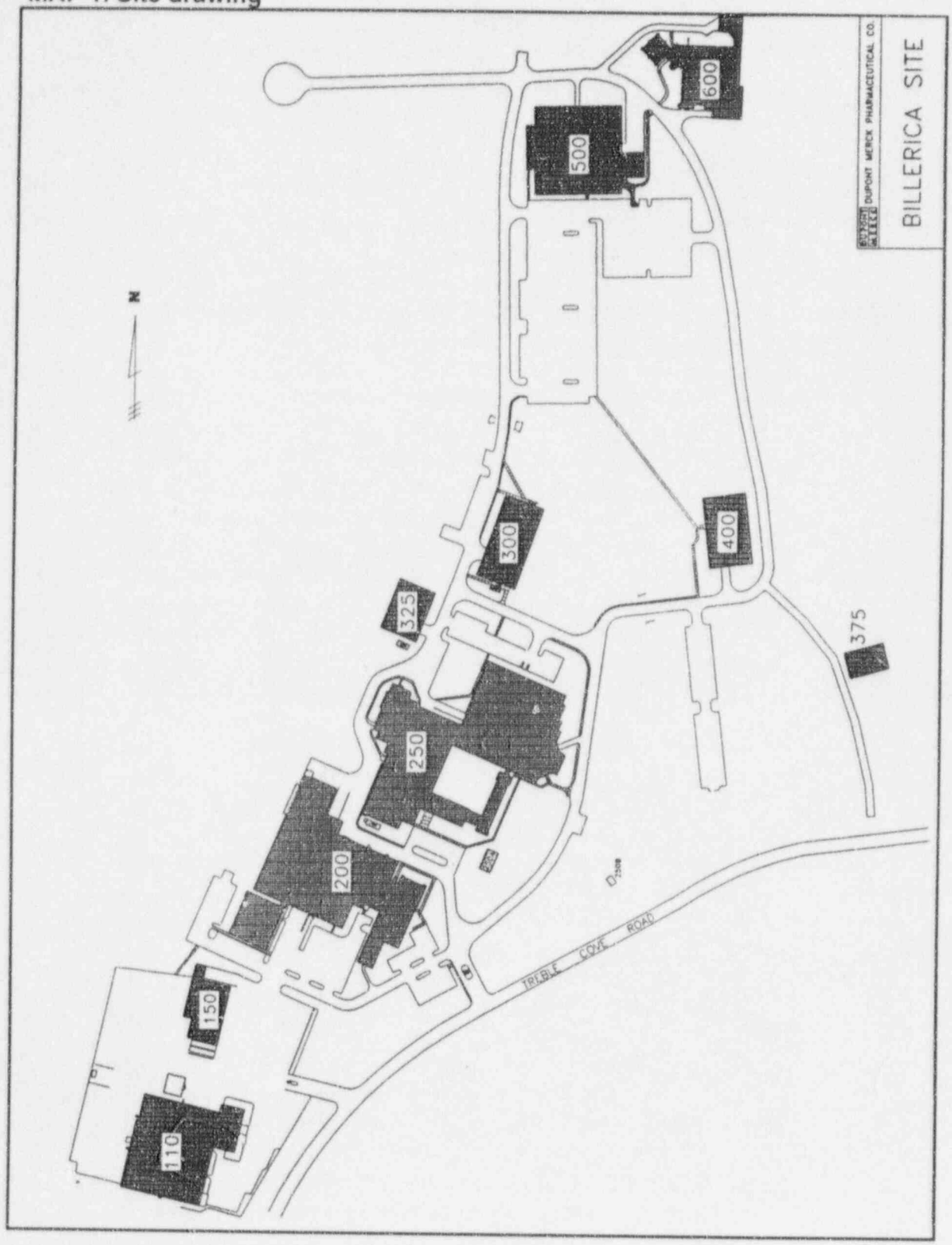
The main communication and assessment centers are located in Building 300. The RPO laboratory, offices, and conference room that serves as the Control (or Command) Center during site emergencies, are located on the first floor. The RPO laboratory contains analytical instrumentation used for bioassay, air, liquid, etc., sample analysis. Portable radiation detection and measurement instruments are stored in the RPO laboratory.

The Employee Occupational Health Services office and examination rooms are located on the second floor of Building 300. SHEA offices are also located on the second floor of Building 300.

1.2.2 Assembly and Relocation Areas

Designated evacuation and assembly areas are established for each building on site. Personnel evacuated from buildings can be relocated to other areas that include the Building 250 cafeteria, Building 300 second floor Learning Center, and Building 500, second floor conference room. There are no established off-site relocation areas.

MAP 1. Site drawing



1.2.3 Process and Storage Areas

Radioactive material and hazardous chemicals are processed and stored throughout the facility. The bulk of the radioactive material though, is handled in Buildings: 150, 200, 250, and 325 (storage only).

1.2.3.1 Building 110 - Receiving, Warehouse, Accounting, Purchasing.

Description: 1 story building containing office areas, quality control laboratories, receiving dock, and warehouse.

Process areas: None involving radioactive materials. Quality control operations involve some hazardous chemicals.

Storage areas: Radioactive material and hazardous chemical packages for the site are delivered to the receiving dock. The receiving dock has a fenced area for short term storage of radioactive material packages, and cabinets for temporary storage of hazardous chemicals.

The warehouse contains a small, bulk chemical storage area where caustic, flammable, etc., chemicals are stored in chemical cabinets in their original shipping containers. Only complete containers are delivered to site operations, containers are not broken down for partial delivery or dispensed into smaller quantities.

The warehouse also contains storage areas for EPS foam, corrugated cardboard, plastic bottles, lead, etc. Quality Control maintains a portion of the warehouse for inspection of incoming materials.

Other operations: Accounting and Purchasing office areas.

1.2.3.2 Building 150 - Environmental Engineering.

Description: 2 Story building with office mezzanine. Approximately 11,000 ft^2.

Process areas: Radioactive material operations conducted by Environmental Engineering include processing "hold-for-decay" radioactive waste and returned radiopharmaceuticals and sealed sources, receipt of radioactive waste (^{3}H, ^{14}C) from NEN Boston site operations, and preparation of radioactive waste for shipment to disposal sites. Hazardous chemical waste from the site is accumulated, processed, and prepared for shipment in a separate section of the building.

Storage areas: Limited to short term handling of sealed radioactive material containers. Hazardous chemical waste is handled in a segregated portion of the building and includes a maximum of 900 - 1000 gallons of flammable waste, and much lower amounts of corrosive, toxic, reactive etc., waste. Frequent pick up of hazardous chemical waste maintains low levels within the building.

Other operations: Offices. Storage of bulk spill response absorbents and neutralizers.

1.2.3.3 Building 200 - Radiopharmaceuticals

Description: Single story of 69,330 ft^2, with second and third floor heating, ventilation, and air conditioning (HVAC) mechanical mezzanines over the "New" manufacturing facility. Attached 2 story office area of 18,861 ft^2.

Process areas: The "New" Radiopharmaceutical Manufacturing Facility includes $^{99}Mo/^{99m}Tc$ generator manufacturing (primary), and ^{153}Sm, ^{201}Tl, ^{67}Ga, vial operations. Total area: 12,000 ft^2.

Radiopharmaceutical Manufacturing restricted area: $^{99}Mo/^{99m}Tc$ generator manufacturing (backup), ^{133}Xe gas dispensing, ^{201}Tl and ^{67}Ga (cyclotron produced) vial operations. Also contains Radiometric (quality control) operations. Total area is approximately 12,000 ft^2.

Radiopharmaceutical Support restricted area totals 5,596 ft^2. Processes involve operations conducted in support of the radiopharmaceutical manufacturing operations.

Radiopharmaceutical packaging and shipping operations are conducted in restricted areas adjacent to the two manufacturing restricted areas.

Storage areas: Liquid effluent holding tanks, consisting of two, 200 gallons tanks, are located in three areas in both radiopharmaceutical manufacturing areas. The holding tanks receive liquid effluent from the radiopharmaceutical sterilyzers. Two designated radioactive waste storage rooms are located in the old radiopharmaceutical manufacturing restricted area.

Other operations: Customer service, license verification, quality, distribution, component preparation, microbiology, and cold chemistry.

1.2.3.4 Building 250 - Cyclotron, Sources, NEN Bionuclides.

Description: Single story building with second floor mezzanine office area and four separate, second floor mezzanine air handling and HVAC mechanical rooms. Total area approximately 94,855 ft^2.

Process areas: "Old Wing" restricted area contains the six cyclotrons, cyclotron support and chemistry operations, and NEN Bionuclides (^{35}S, ^{32}P, ^{33}P, ^{51}Cr, ^{90}Sr, ^{90}Y, ^{131}I, ^{125}I, etc.) processing and dispensing operations.

"New Wing" restricted area includes source manufacturing and quality control operations, and NEN iodination (^{125}I) and sterile radionuclide (^{153}Sm) production operations.

Storage areas: Six holding tanks receive liquid effluent from restricted area laboratory and change area sink drains. DMPC and NEN packaging and inventory storage areas are located in areas adjacent to the restricted areas. Radioactive waste collection and compacting rooms are located in each restricted area.

Other operations: Offices, Sources Sales and Marketing, Area Engineering, Electronic services, cafeteria.

1.2.3.5 Building 300 - Services

Description: 2 Story building of 38,495 ft^2.

Process areas: None. Low radioactivity, sealed sources are used in the RPO laboratory for instrument calibration and quality assurance. Low radioactivity sealed sources are occasionally engraved in the machine shop.

Storage areas: Paint, paint thinner etc., stored in paint shop.

Other operations: Human Resources, Employee Occupational Health Services, SHEA, Facilities Engineering, Services (custodial, word processing), Process Engineering, Facilities Maintenance (machine, paint, and carpentry shops), mail room.

1.2.3.6 Building 325 - Radioactive Waste Storage

Description: Single story building of 11,132 ft^2 with 16 foot ceiling.

Process areas: None.

Storage areas: Hold-for-decay storage of ^{35}S, ^{32}P, ^{131}I, ^{125}I, etc., waste. No storage of hazardous chemicals, but long term storage of mixed (flammable, radioactive) waste. Interim storage of ^{3}H, ^{14}C, etc., waste from Boston NEN operations awaiting shipment to disposal site. Holding tank effluent held in 280 gallon storage tanks for decay. Storage of ^{241}Am waste.

Other operations: None

1.2.3.7 Building 375 - Storage

Description: Large garage. 5,000 ft^2.

Process areas: None

Storage areas: None.

Other operations: Storage of excess office furniture and laboratory equipment.

1.2.3.8 Building 400

Description: 2 Story building, 32,665 ft^2.

Process areas: None

Storage areas: None

Other operations: None. Building is currently unoccupied.

1.2.3.9 Building 500 - Research and Development

Description: 3 Story building, 137,000 ft^2.

Process areas: Radiopharmaceuticals research and development, biodistribution, and animal care operations use low quantities of radioactive material (^{99m}Tc, ^{99}Tc, ^{125}I, ^{111}In).

Storage areas: Radioactive waste storage room on first floor.

Other operations: Offices, Pilot Plant, library.

1.2.3.10 Building 600

Description: 2 Story building of 35,602 ft^2.

Process areas: None.

Storage areas: None.

Other operations: Executive offices, Sales and Marketing, Finance, Information Resources, Clinical Research and Development, Regulatory Affairs.

1.2.4 Additional Site Features.

The site consists of approximately 209 acres of woodland and wooded swamp, about a a third of which is currently developed. The site lies at an elevation of 180 feet above sea level and is surrounded by four small hills (270 - 355 feet). Several small brooks traverse the site indicative of the shallow water table. Dolly Brook flows through the site and under Treble Cove Road into Winning Pond. Outflow from Winning Pond flows into the Concord River. Treble Brook is an ephemeral brook that also flows into the Concord River.

Access to the site is through the two entrances on Treble Cove Road maintained by contracted security service personnel. The main site entrance is continuously open, the receiving entrance near Building 110, is only open during normal work hours.

Winds are typically from the northwest (cool, dry air) or the southwest (warm, moist air).

Approximately 600 workers are employed at the site, most work normal work hours (first shift) between 7:30 AM and 4:00 PM. Second, third, and weekend shift work is limited to cyclotron operations in Building 250, and pharmaceutical manufacturing in Building 200.

1.3 Description of Area Near the Site.

1.3.1 Principle Characteristics of the Area Near the Site.

The area surrounding the site is primarily woodland with single family housing developments. The Middlesex County House of Correction is on adjoining land east of the site. An industrial-office park is located further east along Treble Cove Road. The site is located near several heavily traveled highways The area surrounding the site is not used extensively for agricultural purposes.

1.3.2 Population Centers

1.3.2.1 South - Southeast

The nearest dwelling is immediately adjacent to the developed portion of the site on Treble Cove Road, approximately 520 ft south of Building 250 stack effluent release points. Rio Vista is a thickly settled development of approximately 250 single family homes across Treble Cove Road to the south-southeast of the site. Rio Vista extends for approximately 1 mile (1.6 km). The Rio Vista housing development is located on the side of a low hill that rises to approximately 260 ft, 0.8 miles from the site.

1.3.2.2 Southwest

A smaller residential housing development of about 64 single family homes occurs to the southwest of the site across (state) Route 4, starting at a distance of 0.3 miles (from the major stack release points) and extending to 0.6 miles. The development lies at an elevation of 170 ft to 220 ft.

1.3.2.3 Northwest

A small housing development of 11 units is constructed northwest of the site on adjoining land. The nearest of these houses lie approximately 0.4 miles from the major stack release points at an elevation of 240 feet.

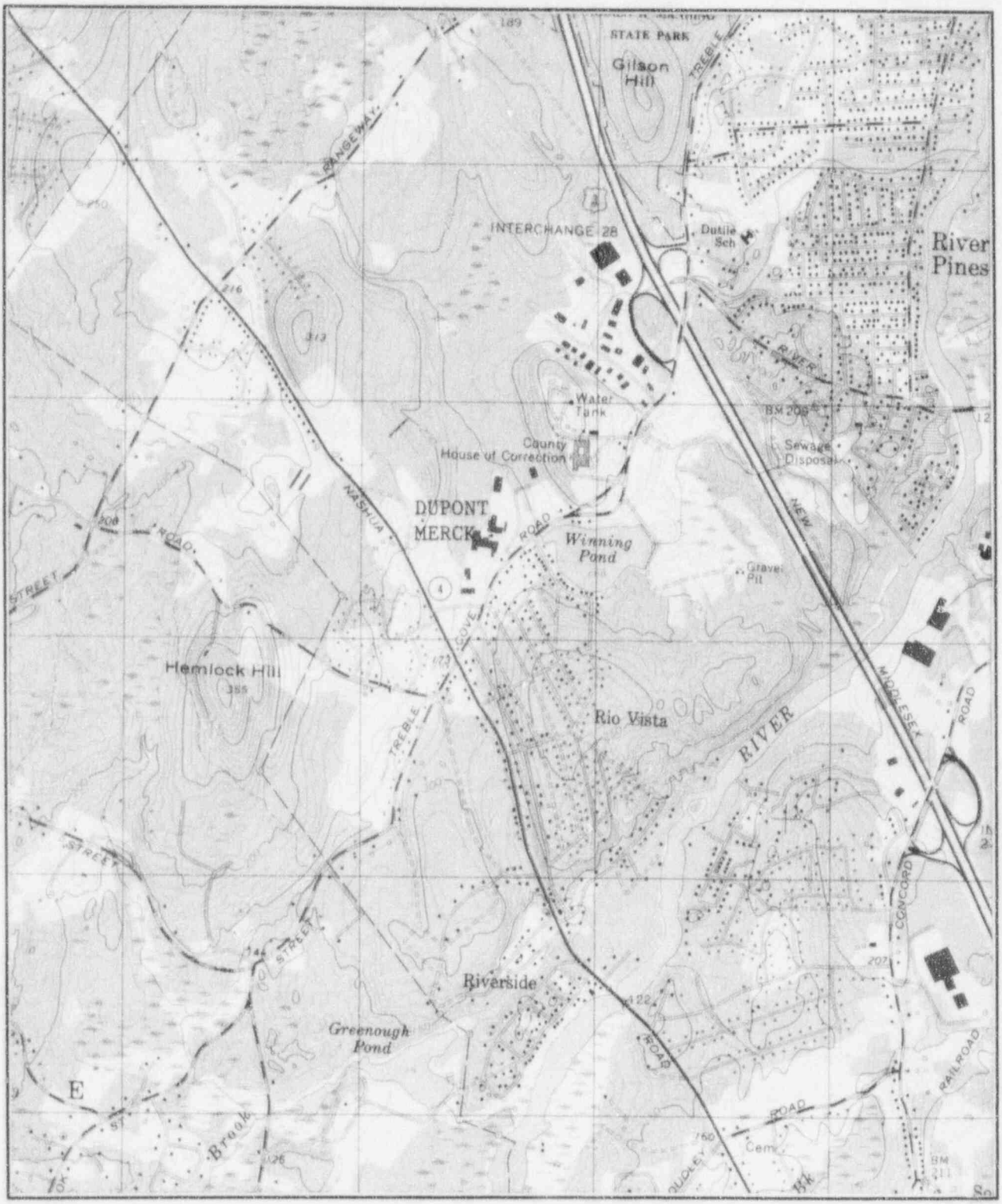
1.3.2.4 Northeast

On adjoining land to the northeast is the Middlesex County House of Correction. The main buildings are approximately 0.3 miles from the major stack release points, at an elevation of 240 - 280 feet. Starting 0.5 miles to the northeast and extending for over 1 mile, lies a light industrial and office park. Heavily traveled U.S. Route 3 lies 0.7 miles past the office park, east and northeast of the site. An extensive, thickly settled section of Billerica called the River Pines lies further to the northeast starting at 0.9 miles and extending over 2 miles from the site. The nearest school, the Dutile School, is 1 miles from the site.

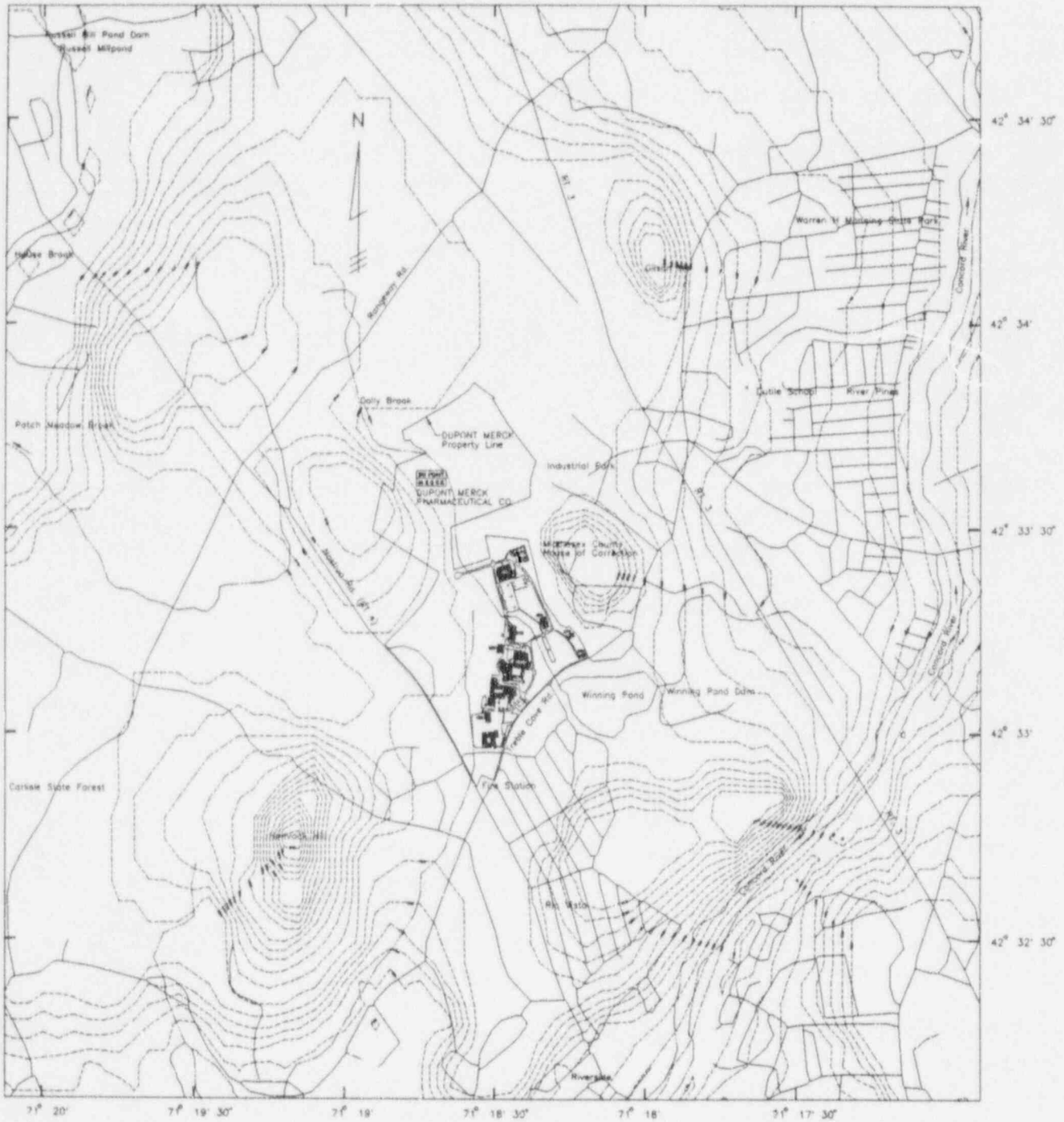
Map 2: Eastern Massachusetts.

123852

Map #3: U.S. Geological Survey Map (7.5" series) Topographic map (1 mile radius)



Map 4: Billerica Site and Surrounding Area.



1.3.2.5 East

A large recreational area lies directly east of the site, extending for 0.6 miles, consisting of Winning Pond and open public land with soccer fields. Undeveloped woodland extends to the Concord River and Rte 3 a distance of about 1 mile.

1.3.3 Facilities with Potential Protective Action Problems

Given worst case scenarios involving radioactive material or hazardous chemicals, the only areas that could require emergency evacuation are single family homes and roadways immediately adjacent to the site along Treble Cove Road.

1.3.4 Access Routes

U.S. Route 3 is 0.8 miles northeast on Treble Cove Road. Interstate Route 495 is 4 miles north on Route 3 and (state) Route 128 (Interstate 95) is approximately 7 miles south on Route 3. Interstate Route 93 is approximately 12 miles from the intersections of Rte 3 and Rte 495, and 6 miles from the intersection of Rte 3 and Rte 128. Route 4 is 0.3 miles on Treble Cove Road from the site. The site is approximately 10 miles from Hanscom Field Air Force Base in Bedford Massachusetts. Boston's Logan Airport is approximately 30 miles from the site. Traffic is characteristically very heavy during rush hours (south in the morning and north in the evening) on all major highways.

1.3.5 Location of Offsite Emergency Support.

The Billerica Fire Department maintains a station located a short distance from the site at the intersection of Treble Cove Road and Route 4. The main Billerica Fire and Police stations are located approximately 5 miles from the site on Boston Road (state Rte. 3A).

Saints Memorial Medical Center (SMMC), a Federal Emergency Management Agency hospital, is located in Lowell Massachusetts, approximately 10 miles from the site. SMMC is equipped and trained to handle injured workers with radioactive contamination.

The Massachusetts, Region 1 HAZMAT Team is based in Lowell. The HAZMAT team is trained primarily for response to hazardous chemical accidents.

1.3.6 Sites of Potential Emergency Significance

Site electrical power passes through a sub-station on the site. Buildings 200, 250, and 500 have emergency electrical generators.

2.0 TYPES OF ACCIDENTS

2.1 Description of Postulated Accidents

2.1.1 Airborne Release.

Airborne releases of radioactive material could result from the release of radioactive material in stack exhaust effluent, or smoke from building or area fires. Areas where radionuclides are handled in quantities exceeding Title 10 Code of Federal Regulations, Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material", 30.72 Schedule C, require consideration of an emergency plan for responding to airborne releases and the need for emergency release monitors. Radionuclides are handled in the following areas in quantities exceeding 10 CFR 30.72 Schedule C.

Bld	Stack	Laboratory	Process	Radio-nuclide	Maximum (Ci)	10 CFR 30.72 Sch. C (Ci)
250	H17	H17	Bionuclides	P-32	100	100
250	H27-33	H29	Bionuclides	I-125	13	10
		H33	Bionuclides	I-131	15	10
325	325		Waste Storage	Am-241	84	2

2.1.1.1 Bld 250 - H17 Stack.

Process: Approximately 100 Ci of ^{32}P (with 30 Ci of ^{35}S contaminant) are processed in the lead walled processing cells in H17 every week. During the (^{32}P) capsule opening, and dissolution, volatile radioactive material is trapped using an in-cell containment system.

Accident Cause: Failure of capsule opening filtration system or spill of radioactive material onto hot plate. Failure of back-up stack filtration systems consisting of HEPA and charcoal filters. Operator error.

Complicating factors: Exhaust air handling system failure. Failure of real time monitoring system or operator to alert the RPO. Power failure, or air sampling system pump failure.

Stack height: approximately 7.3 meters. Stack flow: 3E7 mls/min.

2.1.1.2 Bld 250 - H27-33 Stack.

Process: Approximately 13 Ci of ^{125}I (every two weeks) and 15 Ci (weekly) of ^{131}I are received from an outside vendor and placed into ventilated glove boxes in separate laboratories serviced by the H27-33 stack. uCi to mCi quantities are dispensed into shielded containers for shipment to customers.

Accident Cause: Spill of volatile radioactive material inside ventilated enclosure not immediately recovered and contained. Equipment or containment system malfunction resulting in loss of containment inside or outside of ventilated system of volatile material. Material received with high pH or other "out of specification" property. Operator error.

Complicating factors: Exhaust air handling system failure. Failure of real time monitoring system or operator to immediately notify the RPO. Power failure, or air sampling pump failure.

Stack height: approximately 8.2 meters. Stack flow: 2E8 mls/min.

2.1.1.3 Bld 325 - Waste Storage.

Description: 84 Ci of ^{241}Am waste (mostly in the form of sealed sources) is held for long term storage (pending opening of a disposal facility) in Bld 325. ^{241}Am waste is stored in 55 gallon steel drums and other strong, tight, containers. Typically less than 10 Ci of ^{125}I hold-for-decay waste is stored for greater than 10 half-lives in many, 55 gallon barrels.

Accident Cause: The only event that could involve the entire volume of radioactive waste would be a major accident involving an explosion and fire. Malfunctions, such as a natural gas leak from the building heating system, or leak from a fork truck propane gas tank, could create an explosive mixture and ignite.

Complicating factors: Explosion and fire could involve other radioactive waste stored in the building that includes mixed waste containing flammable chemicals, ^{3}H (up to 12,000 Ci) and ^{14}C (650 Ci), hold-for-decay radioactive waste containing ^{32}P (up to 10 Ci), ^{35}S (up to 130 Ci), ^{131}I (up to 5 mCi), and holding tank effluent containing ^{99}Mo (up to 1 Ci). Building or facility power or building fire alarms or sprinkler system failure.

Stack height: approximately 5.3 meters. Stack flow: 2E7 mls/min.

2.1.1.4 On site consequences: Potential for personnel intake and contamination from airborne radioactivity in laboratories, roof tops, and building wakes. Potential for high radiation due to loss of containment. Contamination of vehicles and areas outside of buildings.

2.1.1.5 Off site consequences: Airborne radioactivity at site boundary.

2.1.2 Sewer Effluent Release.

Restricted area laboratory sink drains typically discharge into holding tanks that are routinely pumped into temporary storage tanks by Environmental Engineering. A sample of the tank effluent is taken and analyzed by the RPO. Based on the radionuclide concentration and total activity, the RPO determines whether the tank may be discharged to the site sanitary sewer, or held for additional radioactive decay. Sewer effluent monitoring is also performed at the discharge point from the site. Release of significant radioactive material into the site sanitary sewer system could result from an accidental release of a storage tank, release from a restricted area sink not connected to a holding tank, release from the holding tank that operates in an overflow mode, or release from the manually discharged tank.

Bld & Location	Process	Operation Mode	Radionuclides
200, H245A	Radiopharm	Over flow	^{99}Mo, ^{99m}Tc, ^{201}Tl, ^{67}Ga
200, C508	Radiopharm	Manual Discharge	$^{99}Mo/^{99m}Tc$, ^{153}Sm, ^{152}Eu, ^{154}Eu, ^{201}Tl, ^{67}Ga
200, H101-111	Radiopharm.	Direct discharge	^{99}Mo, ^{99m}Tc
325	Storage tank	Manual discharge	^{99}Mo, ^{99m}Tc, ^{103}Ru, ^{106}Ru,
500	Research	Direct discharge	^{99}Mo, ^{99m}Tc, ^{99}Tc

2.1.2.1 Bld 200, H254A.

Description: Holding tank receives water from autoclaves used to sterilize radiopharmaceutical products including $^{99}Mo/^{99m}Tc$ Technelite® generator core units and ^{201}Tl and ^{67}Ga vials. Tank is operated in "overflow" capacity mode whereby the volume of effluent received is equal to the volume of effluent discharged.

Accident Cause: Large number of generator core units or vials break during autoclaving due to equipment malfunction or material defect.

Complicating factors: Operations personnel fail to monitor the holding tank after processing and do not report problem immediately to the RPO. Area and personal contamination resulting from post autoclave product packaging activities.

2.1.2.2 Bld 200, C508.

Description: Effluent from the "New" pharmaceutical facility is discharged to one of two, 200 gallon holding tanks. Effluent is manually transferred from one tank to the other when the first tank is full, providing additional radioactive decay. Prior to discharging the decayed tank, a sample is collected, analyzed and authorized by the RPO for release to the sewer.

Accident Cause: Operator error by releasing tank effluent to the sanitary sewer system before authorization, or operator inadvertently opens wrong valve while attempting to transfer effluent from tank 1 to tank 2. Equipment malfunction.

Complicating factors: Failure of operations personnel to immediately identify or report to the RPO the inadvertent release of effluent. Power failure or malfunction of sewer effluent sampler results in release not being detected.

2.1.2.3 Bld 200, H101-111.

Description: Sink drains are not connected to a holding tank.

Accident Cause: Operator error in releasing radioactive material to a sink drain in violation of site policy.

Complicating factors: Power failure or malfunction of sewer effluent sampler results in release not being detected.

2.1.2.4 Bld 325.

Description: Storage tanks containing holding tank effluent are held by Environmental Engineering for radioactive decay or while awaiting RPO analysis and authorization for discharge to the sanitary sewer.

Accident Cause: Operator error results in the discharge of storage tank effluent with high radioactivity. Storage tank failure.

Complicating factors: Operator does not immediately recognize or report that the wrong storage tank was discharged. Power failure or malfunction of sewer effluent sampler results in release not being detected.

2.1.2.5 Bld 500 Research Laboratories.

Description: Restricted area laboratory sink drains are not connected to holding tanks.

Accident Cause: Operator error in releasing radioactive material to a sink drain in violation of site policy.

Complicating factors: Operator does not immediately recognize or reports that radioactive material was released to the sink. Power failure or malfunction of sewer effluent sampler results in release not being detected.

2.1.2.6 On site consequences: Potential for personal and area contamination resulting from post autoclave product handling. Contamination of site sewer lines. Discharge exceeding NRC monthly concentration or annual activity limit.

2.1.2.7 Off site consequences: Discharge results in contamination of sewer lines. Bolus of radioactive material received and treated by Billerica sewer treatment facility.

2.1.3 Injured and Contaminated Worker.

Description: Injured worker with intake of radioactive material, personal contamination (skin or clothing) or acute external exposure.

Accident Cause: Operator error, equipment malfunction, accident resulting in injury.

Complicating factors: Injury occurs during off-hours, or severe weather resulting in delayed response to the emergency.

2.1.3.1 On-site consequences: Contamination of First Aiders and onsite medical responders, and their equipment. Spread of contamination to unrestricted areas.

2.1.3.2 Off-site consequences: Contamination of emergency medical and hospital personnel, equipment, vehicles, and facilities.

2.1.4 Environmental Spill.

Location	Process	Radionuclides
Site roadways	Transfer of holding tank effluent to Bld 325	^{99}Mo, ^{99m}Tc,
Roadway 200 - 250	Transfer of radiopharmaceuticals from Bld 250 to 200.	^{99}Mo, ^{99m}Tc, ^{153}Sm, ^{201}Tl, ^{67}Ga
Site roadways	Accident involving vehicle transferring Type A or B radioactive material container.	$^{99}Mo/^{99m}Tc$, ^{125}I, ^{131}I, ^{32}P, ^{35}S

2.1.4.1 Transfer of holding tank effluent.

Description: Loss of containment of holding tank effluent during pumping or transfer to Bld 325 for storage.

Accident Cause: Vehicle accident or storage tank failure. Malfunction of effluent transfer hoses, valves or connectors. Operator error.

Complicating factors: Severe weather. Pedestrian and vehicle traffic spread contamination.

2.1.4.2 Transfers of Radiopharmaceuticals from Bld 250 to Bld 200.

Description: ^{67}Ga, ^{201}Tl, and ^{153}Sm (10's to several 100 Ci) are transferred in shielded containers from Bld 250 restricted areas to Bld 200 pharmaceutical manufacturing restricted areas.

Accident Cause: Collision with vehicle. Operator error.

Complicating factors: Severe weather or accident occurring off-hours or weekends would slow response. Injured worker. Fire.

2.1.4.3 Transfer of Type A or B Radioactive Material Container.

Description: Accident involving vehicle carrying a Type A or B radioactive material container.

Accident Cause: Operator error, vehicle collision with another vehicle, fork truck or with stationary object resulting in fire.

Complicating factors: Personnel injured. Fire.

2.1.4.4 **On-site consequences.** Contamination of site roadway, personnel and vehicles. High external radiation levels resulting from loss of shielding.

2.1.4.5 **Off-site consequences:** Potential for contamination to be spread to wetlands and brooks, and off-site by personnel and vehicles.

2.1.5 Receipt of Leaking Radioactive Material Package or Waste.

Bld & Location	Process	Radionuclide
Site roadways, Blds 150 and 325	Receipt of radioactive waste shipment from Boston NEN	^{3}H, ^{14}C
Site roadways, Bld 110 Receiving	Receipt of Type A or B radioactive material container by Receiving group	^{99}Mo, ^{32}P, ^{35}S, ^{131}I, ^{125}I, etc.

2.1.5.1 Boston Radioactive Waste Shipment.

Description: Shipments of ^{3}H and ^{14}C waste from Boston NEN operations are received in Bld 150 and stored in Bld 325.

Accident Cause: Leaking waste container. Operator error.

Complicating factors: Contaminated vehicle, personnel, on and off site roadways.

2.1.5.2 Leaking Type A or B Radioactive Material Container.

Description: Leaking radioactive material package delivered to Bld 110 Receiving dock.

Accident Cause: Containment failure, package damaged during transit.

Complicating factors: Delivery at times other than normal working hours could potentially result in delay of package monitoring and discovery until the next working day. Internal and external exposure to receiving and delivery personnel. Potential airborne radioactivity.

2.1.5.3 **On-site consequences:** Personal contamination, intake, and external exposure. Contamination of receiving dock, radioactive material package storage area, delivery vehicle and roadways.

2.1.5.4 **Off-site consequences:** External exposure, intake and contamination of delivery personnel. Contamination spread to vehicle, other facilities, and roadways.

2.1.6 Severe Natural Phenomenon

Description: Rare, severe natural phenomenon.

Accident Cause: Hurricane, tornado, earthquake, wild fire.

Complicating factors: Occurrence during off-hours, holidays or weekends. Roads and highways damaged or obstructed, resulting in delayed arrival of emergency personnel.

2.1.6.1 **On-site consequences:** Damaged buildings, structures, fire, loss of containment of radioactive material.

2.1.6.2 **Off-site consequences:** Spread of radioactive material to site surface waters, airborne radioactivity resulting from fire.

2.1.7 Sabotage.

Description: Sabotage by disgruntled worker, or terrorist. Acts include bombing, and bomb threats, security incursions, damage to containment structures. Also includes stolen radioactive material.

Accident Cause: Radioactive material released from containment, fire.

Complicating factors: Personnel injured and contaminated.

2.1.7.1 **On-site consequences:** Spread of contamination to unrestricted areas, high external exposure rates associated with unshielded radioactive material, area or building fires, etc.

2.1.7.2 **Off-site consequences:** Airborne radioactivity, contamination spread by personnel and vehicles, injured contaminated workers brought to off site medical facilities.

2.2 Accident Detection and Alerting of Personnel.

2.2.1 Airborne Release.

2.2.1.1 Emergency Stack Monitoring Systems.

Emergency stack monitors are maintained by the RPO in areas where total radionuclide activities exceed quantities specified in 10 CFR 30.72 Schedule C. An alarm and chart recorder in the RPO office would immediately alert RPO staff to the stack effluent release. Additional alarms are located in Building 250 and in the guard shack at the main site entrance. During off-hours security personnel would use call lists to alert RPO personnel of alarm. Some operations maintain their own, separate stack effluent monitoring systems.

All restricted area stacks are sampled for radioactive material emissions using a combination of particulate, charcoal filter or canister, water or NaOH impingers and real time monitors, appropriate for the radionuclides and chemical forms handled in the area. In the event of a release, stack air sampling filters would be collected, analyzed, and concentration and activity released calculated.

Wind direction and speed is continuously recorded from sensors atop the Bld 300 roof, using a wind meteorological software program run on a personal computer located in the RPO office area.

2.2.1.2 Site Emergency Telephone Number.

Operations personnel aware that a stack release has occurred from direct observation of stack monitoring system, or that an accident has occurred with the potential for a significant stack release, would immediately call the site emergency telephone number: 5580. Five designated telephones located in the RPO, Safety Health and Environmental Affairs (industrial safety), Employee Occupational Health Services, Security, and Facilities Maintenance offices ring simultaneously.

2.2.1.3 Building Fire Alarms.

All buildings on site are serviced by fire and smoke alarms and overhead sprinkler systems. An enunciator panel is located in the main guard shack. Security would alert the RPO of a building fire alarm using the site emergency number. Operators would immediately evacuate the building and go to designated assembly areas when fire alarms sound.

Emergency responders are dispatched to assembly areas to gather information, and to provide personnel that had evacuated from restricted areas, a ratemeter, so they can monitor themselves for contamination. A responder is also dispatched to meet the Billerica Fire Department at building entrances.

2.2.1.4 Hood Exhaust Alarms.

All vented enclosure (fume hood, glove boxes, processing cells) ducts are equipted with alarms that sound when air flow is interrupted. Operators would immediately evacuate laboratories and the restricted area when the alarm sounds and use the site emergency telephone number to notify site emergency response groups.

2.2.2 Sewer Effluent Release.

2.2.2.1 Operator Observation.

Monitoring of holding tanks by operations personnel would detect high levels of radioactive material. Direct observation of broken vials, columns, or gross contamination detected during post autoclave operations, would also alert operations personnel of potential for release to holding tanks.

2.2.2.2 Sewer Effluent Sampling.

Sewer effluent is continuously sampled as it is discharged from the site at the sewer injection station. Samples are routinely collected and analyzed several times a week. A release that was not detected or reported by operations personnel would be detected by analysis of the collected sample.

2.2.3 Injured Worker Brought to Off-Site Medical Facility.

During normal working hours an injured or ill worker with acute external, or internal exposure or contamination, requiring off site medical attention, would be reported through the site emergency telephone to site medical personnel and the RPO. Off hour occurrences would be reported by security to medical and emergency responders using the off-hour emergency call list.

2.2.4 Environmental Spill.

Spills would be reported using the site emergency telephone system by the involved workers.

2.2.5 Receipt of Leaking Radioactive Material Package or Waste.

Receipt of radioactive material packages with elevated radiation levels or removable contamination would be reported by Receiving personnel using the site emergency telephone system.

2.2.6 Severe Natural Phenomenon

Potential for a severe hurricane striking the area would be forecasted several days before the actual event. Suitable precautionary steps would be taken to ensure the safety of essential site personnel remaining on site, and the containment of radioactive and other hazardous materials. Precautions would be taken during a severe drought to minimize the risk of fire. Tornadoes and earth quakes typically provide no advanced warning.

2.2.7 Sabotage

Incidents would be reported to Security using the site emergency telephone system. Security would immediately alert the Billerica Police Department.

3.0 CLASSIFICATION AND NOTIFICATION OF ACCIDENTS

3.1 Classification System

Radiological incident classifications are specified in USNRC Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities".

3.1.1 ALERT

An Alert is defined as "**an incident that has led or could lead to a release to the environment of radioactive or other hazardous material, but the release is not expected to require a response by an off site response organization to protect persons off site**". An Alert declaration indicates mobilization of emergency response in either a standby or response mode. Although offsite impact is not expected, offsite agencies may still be required to respond to onsite conditions such as a fire. Emergency Action Levels are listed below.

Accident	ALERT - Emergency Action Levels
Airborne release	• Incident may result in an airborne release of radioactive material exceeding the product of the release fraction, and radionuclide quantity listed in 10 CFR 30, 30.72 Schedule C.
Sewer release	• Release to sewer that may exceed 5 Ci (5 times the annual release limit).
Injured, Contaminated Worker	• Injured or ill worker with personal contamination (clothing or skin) or acute exposure removed to offsite medical facility, with potential for member of the public to exceed the annual exposure limit.
Environmental Spill	• Loss of containment of radioactive material that may result in the potential for exposure to workers, or members of the public to exceed 5 times an annual exposure limits.
Receipt of Leaking Radioactive Material Package or Radioactive Waste Shipment	• Radioactive material package exceeding 200 mrem/hr on contact or with removable contamination > 22 dpm/cm^2. • Receipt of leaking radioactive waste shipment that may result in potential exposure to workers or member of the public to exceed 5 times any annual limit.
Severe Natural Phenomenon	• Hurricane may strike with sufficient force to damage facility and potentially affect the control of radioactive material. • Tornado, earth quake, wild fire may have caused damage to facility affecting the control of radioactive material.
Sabotage	• Bomb threat received, bomb found in immediate area of radioactive material exceeding 10 CFR 30, 30.72 Schedule C quantities. • Ongoing security compromise exceeding 15 minutes. • Lost, stolen, missing, radioactive material >100X 10 CFR 20 App. C quantities.

3.1.2 SITE AREA EMERGENCY

A Site Area Emergency is defined as "**an incident that has led to or could lead to a significant release to the environment of radioactive or other hazardous material and that could require a response by an off site organization to protect persons off site**". Declaration of a Site Area Emergency indicates full mobilization of emergency response. Emergency Action Levels are listed below.

Accident	SITE AREA EMERGENCY Emergency Action Levels
Airborne release	• Incident has resulted in an airborne release of radioactive material exceeding the product of the release fraction, and radionuclide quantity listed in 10 CFR 30, 30.72 Schedule C.
Sewer release	• Release to sewer exceeding 5 Ci (5 times the annual release limit).
Environmental release	• Loss of containment of radioactive material has resulted in potential for exposure to workers, or members of the public to exceed 5 times an annual exposure limit.
Receipt of Leaking Radioactive Material Package or Radioactive Waste Shipment	• Receipt of leaking radioactive material package or waste shipment has resulted in potential exposure to workers or member of the public to exceed 5 times any annual exposure limits.
Severe Natural Phenomenon	• Hurricane, tornado, earth quake, or wild fire has caused damage to the facility affecting the control of radioactive material.
Sabotage	• Bomb explosion involves radioactive material greater than 10 CFR 30, 30.72, Schedule C quantities. • Terrorist act has resulted in immanent or actual loss of control of site operations and radioactive material.

3.2 Notification and Coordination

3.2.1 Alert

The following table defines notification and coordination actions and decisions that are the responsibility of the DMPC Radiation Safety Officer (RSO) who is the Associate Director, Safety and Environmental Engineering.

Action	Means
Decision to declare an Alert	Based on incident exceeding an Alert Emergency Action Level.
Activation of on site emergency response team	Emergency telephone, direct notification, personal beepers, off-hour call lists.
Notification of offsite response authorities.	Telephone,
Notification of the NRC Operations Center	Telephone (301-951-0550).
Decision to initiate onsite protective actions	Communication with Coordinator in the Command Center.
Decision to escalate to a Site Area Emergency	Site Area Emergency Action Level exceeded.
Decision to request support from offsite organizations	Discussion with emergency response team and site management..
Decision to terminate the emergency or enter recovery mode	Evaluation of data and information based on final assessment operations.

3.2.2 Site Area Emergency

The following table defines notification and coordination actions and decisions that are the responsibility of the DMPC RSO.

Action	Means
Decision to declare a Site Area Emergency	Information indicates that incident exceeds a Site Area Emergency, Emergency Action Level.
Activation of onsite emergency response team	Emergency telephone, on-hour personal beepers, off-hour call lists, direct communication,
Notification of offsite response authorities:	Telephone.
Notification of the NRC Operations Center	Telephone (301-951-0550).
Decision on appropriate onsite protective actions	Communications with Coordinator in the Command Center, and Team Leader at accident scene. Discussion with site management.
Decision on appropriate offsite protective actions	Discussion with site management and off site response authorities..
Decision to request support from offsite organizations	Discussion with emergency response team and site management..
Decision to terminate the emergency or enter recovery mode	Evaluation of data and information based on final assessment operations.

3.3 Information to be Communicated

The following Information would be communicated to offsite response authorities during a declared Alert, or Site Area Emergency.

Provide:	Name	
	Title	
	Company name	DuPont Merck Pharmaceutical Company
	Location	331 Trebie Cove, Billerica Massachusetts.
	Telephone number:	(508)-671-8673
State:	Emergency Classification	
	Emergency Action Level exceeded	
	Nature of the accident	
	Accident location	
Provide:	Radionuclide	
	Quantity	
	Relative hazard	
	Other hazardous materials involved.	
	Potential on site consequences	
	Potential offsite consequences	
	Offsite area potentially impacted	
	Other response authorities contacted	
Instruct:	Specific offsite emergency response actions to be taken	
	Specific area actions are to be taken	

4.0 RESPONSIBILITIES

4.1 Normal Facility Organization

The general facility organization for manufacturing, quality, research, services, and all other operations, during normal site operation is indicated below.

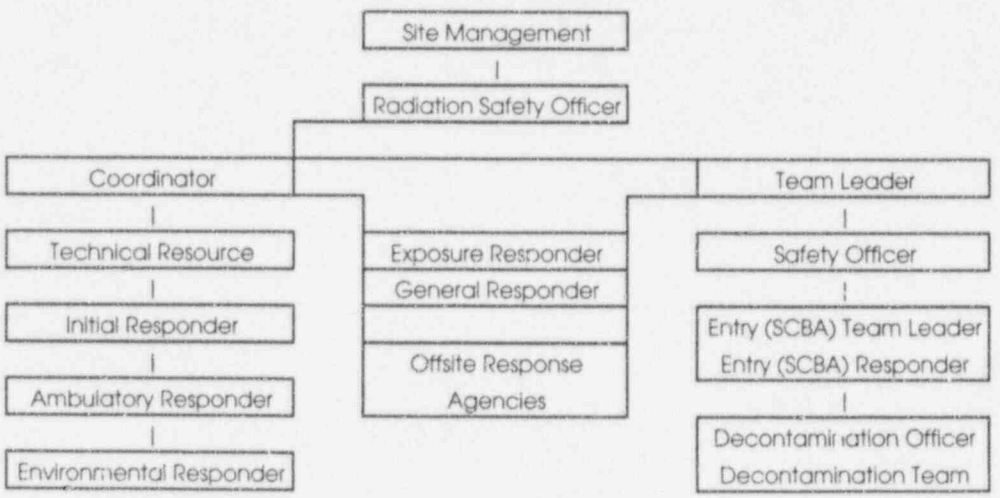
Table 4.1

- President
  - Vice President
    - Director
      - Associate Director
        - Manager
          - Supervisor
            - Individual Worker

4.2 Onsite Emergency Response Organization

The Billerica site Emergency Response Team is organized into specific responder roles with clearly defined responsibilities and communication pathways indicated in the diagram below. Responders are authorized to perform specific roles based on their knowledge, training, and experience. The Team Leader has responsibility for emergency response actions near the scene of the accident, while maintaining communication with the Coordinator in the Command Center. The Coordinator is responsible for organizing the response and providing data to the RSO and management. Offsite emergency response organizations responding to the site would coordinate their actions with the Team Leader.

Billerica Site Emergency Response Organization



The Emergency Response Team is comprised of individuals from the RPO, Safety and Environmental Engineering, and NEN SHEA groups. NEN personnel report to the DMPC Associate Director, Safety & Environmental Engineering. The organizational chart is presented below. All emergency response personnel work normal work hours but are available through call lists, or a beeper and cellular telephone. Other groups that coordinate their activities with the Emergency Response Team include Security, Custodial Services, Facilities Maintenance, and Employee Occupational Health Services.

Table 4.3

- President
  - Vice President Radiopharmaceuticals
  - Director Radiopharmaceutical Quality
  - Director Billerica Site
    - Associate Director Safety/Environmental Engineering
      - Senior Health Physicist
      - Senior Health Physicist
      - Staff Industrial Hygienist
      - Supervisor Radiation Protection & Environmental Engineering
        - Health Physicist
        - Health Physicist
        - Senior Technologist
        - Senior Technologist
        - Technologist
        - Technologist
        - Lead Technologist (EE)
        - Technologist (EE)
        - Technologist (EE)
        - Technologist (EE)
        - Technologist (EE)
    - Environmental Specialist (SHEA)
    - Industrial Engineer (SHEA)
    - Industrial Safety Specialist (SHEA)
    - Database Administrator (SHEA)

Individuals with the authority to declare an Alert or Site Area Emergency include the Associate Director of Safety and Environmental Engineering, up through the President.

4.2.1 Direction and Coordination

Senior site management have ultimate authority and responsibility in the event of an emergency. These individuals will review incident facts and data, and make all final decisions. They are also responsible for issuing official statements relative to the emergency to the media.

The RSO has overall responsibility for implementing and directing emergency response actions. The RSO is responsible for ensuring that Command Center resources are in place, and that information from the emergency response Coordinator in the Command Center, is communicated to senior management. The RSO will assist site management in assessing radiological significance and prioritizing response actions.

In the event that the RSO is not available, management would consult with Senior Health Physicists, the Radiation Protection Office supervisor, and Health Physicists.

4.2.2 Onsite Staff Emergency Assignments

Emergency Activity	Organization Responsible	Duties, authority, interface
Facility system operations	Facilities Maintenance	Responsible for restoring facility services with permission from the RPO, after assessments and recovery actions are performed.
Fire control	Billerica Fire Department	Enter restricted areas with escort and assistance from site emergency responders who maintain communication with the Team Leader.
Personnel evacuation and accountability	Senior Fire Marshals (or alternate) Zone Checkers (or alternates)	Senior Fire Marshals report to assembly areas, ensure all areas are evacuated and all personnel are accounted for. Communicates information to arriving fire personnel, and site emergency responders. Zone checkers are assigned area to inspect prior to evacuation and report to the Senior Fire Marshall results of area inspection.
Search and rescue operations	Billerica Fire Department	Enter radiological restricted areas. RPO and Medical Responder provide escort and assistance.
First Aid	Area First Aiders, Employee Occupational Health Services nurses and physician.	Trained First Aiders are responsible for providing First Aid to injured personnel prior to arrival of Employee Occupational Health Services nurse or physician.
Communications	RPO	Maintain communication systems, backup systems, and call lists to ensure information flow between all emergency response organizations.
Radiological survey and assessment	RPO Environmental Engineering	Assessments and monitoring are performed to determine conditions. Team Leader near the incident scene reports to the Coordinator in the Command Center.
Personnel decontamination	RPO Employee Occupational Health Services	Assist in monitoring, decontamination and record keeping. Exposure Responders reports to Team Leader or Coordinator. Ambulatory responder accompanies injured contaminated workers to offsite medical facilities to provide Health Physics services.
Facility decontamination	RPO, Environmental Engineering, Operations, Custodial Services	Gross decontamination and waste disposal, Report to Team Leader.
Facility security and access control	Security	Restrict access to areas, buildings, or site. Receive direction from Coordinator or Team Leader.
Facility repair and damage control	Facilities Maintenance	Responsible for restoring facility services with permission from the Team Leader after assessment and recovery.
Post-event assessment	RPO	Final assessments, and evaluations are made to determine return to normal operating conditions.
Record keeping	RPO	Maintain log of emergency response actions and measurements to assist in incident investigation.
Media contact	Human Resources, Communications Coordinator, or site management	Responsible for contact with media by telephone or direct contact.

4.3 Local Offsite Assistance to Facility

4.3.1 Medical Treatment Facilities.

Saints Memorial Medical Center (formerly St. Johns and St. Joseph's Hospitals) in Lowell, Massachusetts is a Federal Emergency Management Agency (FEMA) medical facility. A formal agreement has been established with the facility for the treatment of injured personnel with radioactive material contamination. SMMC would be notified using the telephone.

4.3.2 First Aid Personnel and Ambulance Services.

The Town of Billerica operates an ambulance service. The ambulance is operated by certified Emergency Medical Technicians and is contacted through the Billerica Police Department. The ambulance service is contacted by calling the Police Department emergency number 911.

4.3.3 Fire Fighters

Workers are permitted to use portable extinguishers to put out small, isolated fires. The Billerica Fire department is notified automatically when manual pull stations or smoke or heat detectors (located throughout site buildings) are activated. In the main guard shack a fire panel indicates the building the fire alarm has been activated. Security calls the Billerica Fire department to confirm that the alarm has been received and that the fire department is responding to the site. Security then notifies site emergency response groups using the site emergency telephone system. A fire alarm box is located in the traffic island on the front (side) of Building 250. The Billerica fire department consists of approximately 60 full time fire fighters. The nearest station is located a very short distance away at the intersection of Treble Cove Road and Rte 4.

4.3.4 Law Enforcement Assistance

The town of Billerica Police Department consists of over 50 full time personnel. The Billerica Police are part of the North Eastern Middlesex Law Enforcement council (Tactical Police Force) that consists of approximately 100 officers from over 20 cities and towns.

4.4 Coordination with Participating Government Agencies

4.4.1 State

The Massachusetts Department of Public Health, Radiation Control Department operates a Nuclear Incident Advisory Team (NIAT). The team is composed of members, advisors, and consultants. The team on call at all times and provides trained radiation specialists along with necessary instrumentation.

4.4.2 United States Nuclear Regulatory Commission.

Notification is made by telephone to the USNRC Operations Center at (301)951-0550. NRC Region I offices are in King of Prussia, Pennsylvania.

The Massachusetts Department of Public Health, Radiation Control Program is notified by telephone at 617-727-6214.

5.0 EMERGENCY RESPONSE MEASURES

5.1 Activation of Emergency Response Organization

A single system is used to activate the emergency response organization for Alerts and Site Area Emergencies during normal, off-hours, weekends and holidays. Notification of incidents by workers to emergency response personnel is accomplished through the site emergency telephone system. When workers dial "5580", five dedicated telephones ring. The five emergency telephones are located in the Radiation Protection, Safety Health and Environmental Affairs, Employee Occupational Health Services, and Facilities Maintenance office areas and with Security at the main site entrance guard shack.

During normal work hours emergency responders are notified of an emergency directly, or by using their personal pagers when they are not in the office areas. Security maintains a call list for normal work hours containing the telephone extensions and personal pager numbers of selected emergency response personnel.

Off-hour notification of emergencies is accomplished using the site emergency telephone system. After receiving notification from operations personnel of an emergency, security notifies emergency response team members using the "off-hours" call list. The emergency response person contacted by Security contacts operations personnel to gather additional information and provide instructions on initial emergency response actions. The emergency response person then coordinates the response by contacting other responders using another call list that contains the home telephone numbers of all the emergency response personnel.

Operation of building fire alarm pull stations is another means by which to notify and summon site emergency responders and the Billerica Fire Department.

A typical response after receipt of the initial notification of an emergency, would involve the Coordinator dispatching the Initial responder to the scene with a portable radio, the Initial Responder backpack, and appropriate instrumentation. The Coordinator then selects the Team Leader and Safety Officer. The Team Leader assembles the emergency response team and necessary equipment and goes to the incident scene.

5.2 Assessment Actions

The following assessment actions may be taken to evaluate the extent and severity of a radiological incident. No attempt is made here to relate the individual actions with the incident classifications but rather to list the capabilities of the Billerica site. Many of these actions are performed routinely during surveillance of normal operations.

5.2.1 Information Gathering.

5.2.1.1 Workers and supervisor are questioned to determine the nature of the emergency, including the release location, radionuclide involved, quantity, form, etc.

5.2.1.2 Workers are questioned to determine actions and occupancy times in affected areas and requested to provide written documentation of their actions.

5.2.1.3 Workers are questioned to determine the status of operations and the presence of other potential hazards in the affected area.

5.2.2 Determination of Airborne Radioactivity Concentrations.

5.2.2.1 Stack, emergency release monitor, room, and environmental air sampling filters, cartridges, and liquid impinger samples are collected and analyzed.

5.2.2.2 Radionuclide air concentration in stack, room air, site boundary, and breathing zones are calculated.

5.2.2.3 Wind direction and speed data is collected using the site wind monitoring system to determine which area offsite is potentially affected, and to calculate radionuclide concentration at site boundary.

5.2.2.4 Wearing SCBA and appropriate protective clothing, Entry (SCBA) Responders enter the affected area to install air samplers to determine airborne radioactivity concentrations.

5.2.3 Determination of area exposure rates.

5.2.3.1 Direct area monitoring using portable exposure rate survey monitors are used to measure x, gamma, beta, and neutron radiation fields.

5.2.4 Determination of area and personal contamination levels and extent.

5.2.4.1 Surfaces are directly monitored using portable contamination survey monitors used to detect low level radioactive contamination.

5.2.4.2 Surfaces are wiped using paper filter circles to determine levels of removable contamination.

5.2.5 Determination of Personal Dose.

5.2.5.1 Personal dosimeters are sent to offsite dosimetry vendor for emergency processing.

5.2.5.2 Electronic dosimeters (if worn) are read out.

5.2.5.3 Dose is estimated by direct measurement of area exposure rates and estimated worker's exposure time.

5.2.5.4 Contaminated personnel undergo decontamination. Skin dose is then calculated.

5.2.5.5 Bioassays (e.g. thyroid and whole body counts, urine analysis) are collected or performed, and evaluated.

5.2.6 Determination of Radionuclide Concentrations in Liquid Effluents.

5.2.6.1 Sewer, storage, or holding tank effluent samples are collected and analyzed.

5.2.6.2 Surface water samples are collected and analyzed.

5.3 Mitigating Actions

5.3.1 Airborne Release.

Exhaust air systems in areas handling radioactive materials are equipped with HEPA (high efficiency particulate air) filters. Laboratories with volatile radioactivity also have charcoal filtration systems. Certain operations that have the potential to release significant volatile radioactivity have additional containment and filtration systems. ^{133}Xe and ^{85}Kr gas processing hoods have liquid nitrogen cooled charcoal traps to contain releases.

Leaking radioactive material containers may be overpacked with an absorbent such as activated charcoal, sealed and placed into a ventilated enclosure to minimize radionuclide releases.

Smoke resulting from fires in a processing cell, fume hood, or other ventilated enclosure, may clog pre and HEPA filters, resulting in reduced air flow, and limiting the release to the environment.

All buildings are equipped with fire alarms, smoke detectors, and sprinkler systems.

Restricted area walls are typically 1 foot thick concrete.

5.3.2 Sewer Release.

To minimize the release from the holding tank that operates in an over flow mode, tank effluent can be pumped to a temporary storage tank and held for decay.

5.3.3 Injured Contaminated Worker.

Monitoring, decontamination, waste containment and disposal activities would be performed on ambulance, emergency medical, and offsite medical facility personnel, vehicles, equipment and facilities, to control the spread of contamination and minimize personal exposures to radiation and radioactive material.

5.3.4 Environmental Release

Diking and application of absorbent materials would be performed to contain environmental spills. Environmental Engineering personnel have ready access to absorbent booms, etc., while pumping holding tank effluent into storage tanks.

Monitoring and decontamination of personnel and vehicles leaving the site would be performed to limit the spread of contamination offsite.

5.3.5 Receipt of Leaking Radioactive Material Package or Waste.

Monitoring and decontamination actions would be performed on vehicles, personnel, and areas. Leaking radioactive material packages would be contained in sealed containers with absorbent material and placed into ventilated enclosures.

5.3.6 Severe Natural Phenomenon

A severe hurricane warning would permit the site to shutdown and evacuation, except for essential personnel. Radioactive material operations would be secured to minimize the potential for loss of control. Tornadoes and earth quakes typically do not provide sufficiant advance warning to enable mitigating actions to take place.

5.3.7 Sabotage

The site maintains control of site access at the two site access Security guard shacks. Most buildings entrances are equipped with cipher locks or electronic card key access controls.

5.4 Protective Actions

5.4.1 Onsite Protective Actions

5.4.1.1 Personnel Evacuations and Accountability

An individual laboratory would be evacuated in the event of, for example:

a. A spill outside of a hood or ventilated enclosure, or a volatile or radioactive compound.

b. A strong chemical or natural gas odor.

c. The sounding of an audible alarm indicating exhaust ventilation system failure.

d. The sounding of an audible alarm by a real time stack exhaust air monitor, indicating that a significant airborne release of radioactive material has occurred.

e. The sounding of a fire alarm.

An evacuation would be initiated by the laboratory supervisor or on a person's own initiative if involved in the emergency situation. The RPO would be immediately notified via the site emergency phone number.

Onsite assembly or relocation areas are established for each building. Zone Checkers are assigned to search their assigned areas prior to evacuation, and report their findings to the Senior Fire Marshall at the assembly area. Head counts are performed at the assembly area and results reported to the Senior Fire Marshall.

An enunciator panel is located in the main site entrance guard shack that indicates which building has alarmed. Security guards are instructed to call the Billerica Fire Department to confirm that the automatic alarm has tripped and that fire department personnel and engines are responding to the site. Security then reports the fire alarm using the emergency telephone number. Emergency responders are dispatched to each assembly area with a portable radio and contamination monitor. A separate responder with a portable radio and an exposure monitor is sent to meet Billerica Fire Department personnel at the building entrance.

5.4.1.2 Use of Protective Equipment and Supplies

The site does not maintain designated equipment and supplies for emergency purposes. Supplies of protective clothing used during routine site operations are available throughout the site and include shoe covers, lab coats, coveralls, gauntlets, and protective gloves. Contamination and exposure monitoring instruments are widely available in all site restricted areas.

During normal operations, the site has no occupied airborne radioactivity areas., hence respiratory protective equipment is not widely distributed amongst workers. In the event of an accident, personnel would evacuate locations of potential airborne radioactivity.

Designated emergency equipment, supplies, and respiratory protective equipment, including eight Survivair self contained breathing apparatus (SCBA) and four spare 60 minute air cylinders, are maintained for emergency response use in the Radiation Protection laboratory, emergency response trailer (located in front of Building 300), and Bld 150. These supplies are inspected monthly using detailed inspection forms. Twelve full face, air purifying respirators are distributed to individual emergency response team members.

Potassium iodide is maintained by Employee Occupational Health Services to block uptakes of radioactive iodine and minimize thyroid dose. Use criteria, supervision, and administration of potassium iodide is addressed by a site policy.

5.4.1.3 Contamination Control Measures

The principle methods of contamination control are isolation, monitoring, decontamination, containment, and disposal.

During the initial phase of an emergency response, areas would simply be evacuated and isolated by securing and preventing access. Securing access to a laboratory, area, building, or the entire site would be accomplished by posting and securing (locking, installing barriers, or assigning security guards).

Monitoring and decontamination of floors and other surfaces, equipment, and personnel would be accomplished by various methods that clean or abrade contaminated surfaces.

Contaminated materials used during decontamination, grossly contaminated items, or items with non-removable contamination, would be contained by sealing in plastic bags. These items could be disposed of as radioactive waste or held for decay. If radiation levels permit, contaminated floors and other surfaces (after repeated cleaning) could be covered with heavy vinyl or plastic sheeting to control contamination.

Contamination and radiation limits for personnel and items in unrestricted areas are specified in the site Handbook of Radiation Protection, Required Rules and Procedures, and RPO procedure guides.

5.4.2 Offsite Protective Actions

In the event of a severe accident with potential offsite impact, offsite authorities would be provided with specific information as to the scope of the accident, the area potentially affected, and the following actions to initiate, to protect individuals offsite.

5.4.2.1 Traffic Control.

In the event of an accident, traffic could be blocked and diverted around the site on Treble Cove Road or Route 4.

5.4.2.2 Evacuation.

In the event of an accident, individuals from near-by houses, could be evacuated from specific locations.

5.4.2.3 Prevention of Unauthorized Access to the Site

Billerica Police department could assist in maintaining site access security in the event of severe natural phenomenon that has seriously effected the integrity of the site boundary fence, or during periods of potential incursion.

5.5 Exposure Control in Radiological Emergencies

5.5.1 Emergency Radiation Exposure Control Program

5.5.1.1 Radiation Protection Program

The Director of the Billerica Site has the authority to approve workers to receive emergency dose.

The basic methods of controlling personnel external exposure to radiation, in accordance with Title 10 Code of Federal Regulations Part 20, ALARA (As Low As is Reasonably Achievable) regulation and annual dose limits are: time, distance, and shielding. After assessing exposure levels and establishing a limit on personnel dose, the exposure time an individual would be allowed to perform recovery actions would be calculated. Remote handling tools would be used to minimize exposure by increasing the distance from the individual to the source of the radiation. Shielding could be put in place to reduce exposure levels, or quick decontamination actions such as remotely transferring gross radioactivity into shielded containers would be used to reduce external exposure levels.

To limit internal exposures, respiratory protective equipment including SCBA and air purifying respirators would be used. Protective clothing is used to minimize skin contamination and skin absorption. Administration of potassium iodide could be authorized to limit uptake of radioactive iodine and thyroid dose.

5.5.1.2 Exposure Guidelines.

Site emergency exposure guidelines for life saving actions are based on the EPA's "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents" (EPA 520/1-75-001-A, January 1990).

EPA Guidelines	Total Effective Dose Equivalent Limit
Lifesaving activities and protection of large populations	25 rem
Protection of Valuable Property	10 rem
Dose to workers and emergency responders performing assessment and recovery actions	5 rem

5.5.1.3 Monitoring

All site workers that enter restricted areas are assigned personal dosimeters for recording their exposure to radiation. A considerable number of workers that do not enter restricted areas during their normal work activities are also assigned dosimeters.

Billerica Fire Department personnel pick up dosimeters at the guard shack when they enter the site. Other offsite emergency responders would also be provided dosimeters when they arrive at the site guard shack. Personal data consistent with information requested on from site worker on RPO registration forms, would be gathered for all offsite responders in order to establish a permanent record of their doses.

Direct reading electrostatic dosimeters are worn routinely by some groups on site in addition to their dosimeter badges. Direct reading electrostatic dosimeters are available through the RPO. Dose data from direct reading dosimeters is used for reference only, it is not entered into permanent dose records.

Internal exposures resulting from inhalation, ingestion, or skin absorption of radioactive material for site workers and offsite emergency responders would be determined by urine, thyroid and whole body bioassay, and possibly by air sampling. Internal dose to individuals would be assigned to permanent records the same as the external doses.

5.5.2 Decontamination of Personnel

Any member of the site emergency response team or offsite personnel who would have, or may have been contaminated with radioactive materials during an incident would be monitored for contamination. Equipment, vehicles, etc., would also be monitored and decontaminated.

RPO efforts to decontaminate skin would be limited to methods using ordinary soap and water. Any decontamination using chemicals or by flushing eyes, ears, nose, wounds, etc., would be done under the direct supervision of medical personnel. Soap and water are available at all restricted area change areas. Decontamination supplies are maintained in the RPO laboratory and trailer.

Contaminated clothing above site limits would be disposed of as radioactive waste, or held for decay. Tyvek coveralls, and several sets of sweat shirts and pants are available to replace personal clothing.

5.6 Medical Transportation

The town of Billerica operates an ambulance service. The ambulance may be contacted by dialing 911. In the event that an injured person who is contaminated, requires transportation by ambulance, the following would be considered:

5.6.1 The severity of the person's injuries.

5.6.2 The radionuclide and quantity involved.

5.6.1.1 Potential skin dose to the injured worker.

5.6.1.2 Potential intake and internal exposure from skin absorption.

5.6.1.3 Potential for contamination spread and external dose, intake, or skin contamination of emergency medical responders and equipment.

An Ambulatory Responder would be dispatched to the hospital with appropriate instrumentation to assist medical personnel in decontamination, contamination control, and to provide guidance on exposure potential.

5.7 Medical Treatment

DMPC has a formal agreement with Saints Memorial Medical Center (SMMC) in Lowell, Massachusetts. SMMC will accept injured personnel from the Billerica site, who may be contaminated with radioactive material.

The Nuclear Incident Advisory Team (NIAT) has agreements with other hospitals that will handle injures complicated by exposure to radiation.

Any emergency response action by DMPC that involves the services of NIAT will utilize, as appropriate, the emergency medical service organizations that are in formal agreement with the State of Massachusetts or the Federal Emergency Management Agency.

6.0 EMERGENCY RESPONSE EQUIPMENT AND FACILITIES

6.1 Command Center

The Command Center is located on the first floor of Building 300, in the RPO conference room.

6.2 Communications Equipment

6.2.1 Onsite Communications

The site emergency telephone "5580" system is the primary means for site personnel to notify emergency responders of a radiological emergency.

The primary means of communication between the Command Center and accident scene during radiological emergencies is by short wave radio, both base stations and portable units. Short wave radio base stations are also located in the Facilities Maintenance office in Building 300 and in the Environmental Engineering office area in Building 150. The Control Center contains direct off site telephones. A FAX machine is located in the office adjacent to the Control Center.

Secondary means of communication during radiological emergencies include the use of the site telephone system and a cellular telephone.

6.2.2 Offsite Communications

The primary method of notifying and summoning offsite emergency response agencies is by telephone. Cellular telephones could be used as a backup means of providing offsite communications. As mentioned earlier, all buildings fire alarms automatically alarm at the main Billerica Fire station.

The Radiation Protection Office supervisor carries a personal beeper and cellular telephone during off hours.

6.3 Onsite Medical Facilities

First Aiders who have passed the American Red Cross Standard First Aid, and Adult CPR training courses are distributed throughout the site. Locked first aid boxes are also distributed around the site. Keys are provided to the First Aiders.

The Employee Occupational Health Services office is located on the second floor of Building 300. Medical staff include a physician and a nurse. Employee Occupational Health Services is primarily set up for acute care and to perform physical examinations, medical surveillance, laboratory care, and follow-up on patients who have returned from offsite hospitalization or injury recovery.

6.4 Emergency Monitoring Equipment

Portable exposure rate meters are distributed throughout site restricted areas. Contamination meters are found at all restricted area change areas.

6.4.1 Radiation Detection Instrumentation.

A significant quantity of radiation detection and measuring instruments and equipment, including portable survey instruments, change area instruments, air monitors, and laboratory analytical instruments are available to the RPO and operations personnel on site. Most of this instrumentation and equipment is used during normal operations and routine site surveillance. A representative list of the variety of radiation detection and measuring instruments on site is show in the tables on pages 6 -3, and 6 - 4.

Type of Instrument	Description	Type	Radiation Detected	Operational Range	Calibration Frequency
Portable Exposure Ratemeters	Model 3 Ratemeter 44-58 Probe Ludlum Measurements Inc.	Energy compensated, shielded GM detector	β, γ, χ	0.2 - 2.0 R/hr	6 months
	Model 3 Ratemeter 44-38 Probe Ludlum Measurements Inc.	shielded GM detector	β, γ, χ	0 -0.2 R/hr	6 months
	Cutie Pie Model CP44A Technical Associates	Ionization Chamber	β, γ, χ	0 - 0.5 R/hr	6 months
	20 ft extendible Digital Exposure Ratemeter Model 302B Xetex Inc.	GM	γ, χ	0.1 - 999 R/hr	6 months
	Micro Rem Model 450P Victoreen	Pressurized Ionization Chamber	γ, χ	1E-5 - 0.2 R/hr	6 months
	Micro rem Bicron	Ionization Chamber	γ, χ	1E-5 - 0.2 R/hr	6 months
	Model 12-4 Neutron Monitor Ludlum Measurements Inc.	BF_3 detector	η	0 - 10 rem/hr	6 months
Portable Contamination Ratemeters	Model 3 Probes: 44-3, 44-1, 44-21, 44-7, 43-2, 43-5 Ludlum Measurements Inc.	Various scintillation and GM detectors	α, β, γ, χ	0 - 500K cpm	6 months
	Floor Monitor Model 239-1F Model 12 Ratemeter Ludlum Measurements Inc.	18"X6" Thin Window Gas Flow	α, β, γ, χ	0.1 - 500k cpm	As needed
Change Area Contamination Ratemeters	NICO Ratemeter Model MD3 Probes: 44-3, 44-1, 44-21, 44-7	Scintillation and GM detectors	β, γ, χ	0 - 300k cpm	6 months
Data Logger	Model 2350, 2350-1, Computerized data recording and multiple detector capabilities Ludlum Measurements Inc.	Maximum of 16 exposure and contamination probes.	α, β, γ, χ, η	Various	6 months
Air Monitor	Johnson Tritium Monitor	Ion chamber	β	0 -	As Needed

Type of Instrument	Description	Type	Radiation Detected	Operational Range	Calibration Frequency
Analytical Laboratory	Alpha, Beta Gamma Counter, Model 2404F Canberra Industries	Gas flow proportional counter and 2"X2" NaI	α, β, γ, χ	0 - 1E9 cpm	6 months
	Liquid Scintillation Analyzer Model 2200CA Packard Instrument	Scintillation	β	0 - 1M cpm	6 months
	System 100 PC based Multichannel Analyzer, Canberra Industries.	Auto Gamma Counter Packard Minaxi 3.25"X3" NaI	γ, χ	0 - 2000 KeV	6 months
		3"X3" NaI(Tl)	γ, χ	0 - 2000 KeV	6 months
		Thyroid Counter 2"X2" NaI(Tl)	γ, χ	0 - 500 KeV	6 months
	GENIE System, Digital Equipment Corporation Alpha Computer based Multichannel Analyzer Canberra Industries.	Whole Body Counter HPGe (90% relative efficiency)	γ, χ	0 - 2000 KeV	6 months
		HPGe (85% relative efficiency)	γ, χ	0 - 2000 KeV	6 months
		REGe (reverse electrode germanium)	γ, χ	0 - 2000 KeV	6 months
		LEGe (low energy germanium)	γ, χ	0 - 200 KeV	6 months
	Inspector - Portable Laptop PC based Multichannel Analyzer Canberra Industries.	Portable HPGe (17% relative efficiency)	γ, χ	0 - 2000 KeV	As needed
		Portable HPGe (15% relative efficiency)	γ, χ	0 - 2000 KeV	As needed
	Series 20 Portable Multichannel Analyzer Canberra Industries	3.25"X3" NaI	γ, χ	0 - 2000 KeV	As needed

Abbreviations:

GM	Geiger Mueller	HPGe	High purity germanium
α	Alpha radiation	γ	Gamma Radiation
β	Beta radiation	η	neutron radiation
χ	X-ray radiation		

7.0 MAINTAINING EMERGENCY PREPAREDNESS CAPABILITY

7.1 Written Emergency Plan Procedures

Written emergency response procedures are maintained under the site Radiological Safety Documentation Control program. Emergency response procedures are reviewed every 2 years. Copies of radiological emergency response procedures are kept in the Command Center.

7.2 Training

Site emergency response team members receive an initial 24 hour training provided under OSHA 1910.120. Emergency response personnel then receive at least 8 hours of annual training. Training topics include: emergency responder roles and responsibilities, communication, SCBA and respirator use, personal protective equipment, response to biohazardous, flammable, or radioactive material spills, handling injured, contaminated personnel, response to building fire alarms, etc. Training sessions may be presented as classroom sessions, exercises, drills, discussions, etc.

Site workers receive training on initial emergency response actions during introductory radiation and industrial safety training. Annual radiation safety training is provided to all workers issued radiation dosimeters.

Periodic site tours or training sessions have been presented to the Billerica Fire and Police Department personnel, the Regional HAZMAT Team, State Police, ground and air carriers, government agencies, hospitals, universities and professional societies, etc.

7.3 Drills and Exercises

In addition to training, periodic exercises, drills, and tests are conducted to maintain emergency response capabilities.

7.3.1 Quarterly Communications Checks, Equipment Testing, and Exercises.

Quarterly communication checks and exercises may include the following:

7.3.1.1 Review, revision and distribution all emergency responder and security call lists.

7.3.1.2 Testing communication equipment such as the emergency telephone system, portable radios and base stations, cellular telephone, and personal beepers.

7.3.1.3 Testing initial response and communication to building fire alarms.

7.3.2 Health Physics and Hazardous Chemical Drills.

Are conducted twice a year, and may be announced, or unannounced. Drills typically focus on a particular aspect of emergency response such as initial emergency response actions, decontamination, first aid and medical treatment, use of personal protective equipment and SCBA, etc. Drills typically do not involve offsite emergency response organizations.

7.3.3 Biennial Test.

Every two years a major test of the Radiological Emergency Contingency Plan is conducted to evaluate the plan and to test response capabilities. The Biennial Test consists of an unannounced exercise involving radioactive material. Extreme care is used to maintain the exercise scenario, date and time confidential. State and local agencies and response organizations may be invited to observe or participate in the Biennial Test. Previous Tests have involved the receipt of a leaking radioactive material package, the receipt of a leaking waste shipment, a laboratory fire and injured person. The Biennial Test has typically been conducted by the site Emergency Preparedness Committee.

7.4 Critiques

After every exercise or test an in depth evaluation of the response to the emergency is performed. This critique involves participants and observers, and covers all aspects of the response in order to identify areas for improvement and additional training. Critique findings are reported to the Associate Director of Safety and Environmental Engineering.

7.5 Independent Audit

Corporate safety audits are conducted by senior safety managers from various DMPC sites, and include review of contingency plans, radiation and industrial safety programs, and emergency preparedness.

7.6 Maintenance and Inventory of Emergency Equipment, Instrumentation and Supplies.

An annual inspection schedule is generated listing personnel responsible for performing the monthly emergency response equipment, instrumentation, and supplies inspections. Inspection forms are distributed two weeks prior to the last full week of the month. Completed inspection forms are returned and maintained in a record book. Monthly inspections are organized into four parts.

7.6.1 SCBA Inspections.

Eight Survivair self contained breathing apparatus (SCBA) and four 60 minute spare tanks are maintained for emergency response. The SCBAs are kept in the RPO laboratory, or trailer. SCBA are kept in their carrying case and secured with a security seal. SCBA testing, cleaning, and overhaul is performed as specified by the manufacturer.

7.6.2 Radiation Protection laboratory.

Supplies maintained for emergency response purposes in the RPO laboratory include the Initial Responder backpack, portable radios, flashlights, protective clothing (gloves, shoe covers, coveralls), respirator cartridges, radiation and chemical monitoring instruments, etc.

7.6.3 Trailer

The emergency response trailer contains a First Aid kit, spill response supplies including absorbents and neutralizers, Level B, C and D protective clothing packets (containing gloves, shoe covers, boots, coveralls or encapsulating suits), face shields, safety glasses, posting and barricade materials, signs, traffic cones, decontamination supplies (decontamination pools, brushes, spray canisters), a drum patch kit, etc. The trailer is 12 ft long, and 7.5 feet wide, with an interior height of 6.5 feet.

7.6.4 Environmental Engineering

Bulk quantities of spill absorbents and neutralizers are maintained in Building 150.

7.7 Letters of Agreement

Changes or revision of the Radiological Emergency Contingency Plan are communicated to appropriate offsite response organizations. Letters of agreement are maintained with contingency plan records.

8.0 RECORDS AND REPORTS

8.1 Records of Incidents

Action level notification forms are generated by the RPO for radiological incidents that exceed established site action levels for: personal contamination and exposure, area contamination and exposure rates, intakes of radionuclides, radionuclide concentration in stack or sewer effluent, and radioactive material spills. Incident investigation reports are reviewed by the site Radioisotope Committee. Reports include a description of the accident, pertinent facts, underlying causes and corrective actions. Incident investigations are typically conducted by the area supervisor, with the involved workers and RPO representatives.

A separate investigation may be performed by the emergency response team to discuss and review emergency response actions.

8.2 Records of Preparedness Assurance

The following records are maintained by the RPO as documentation of compliance with the site Radiological Emergency Contingency Plan.

8.2.1 Training.

Records of all training sessions conducted for emergency response team members, site workers, and offsite response organizations are maintained and include information on the date, time and duration of training, the individuals trained, the individual providing the training, and the training topic.

8.2.2 Drills, exercises, tests.

Records of all radiological, chemical, or biological hazardous material emergency drills, quarterly communications checks, tests and exercises, and Biennial Tests, are maintained including preparation plans, critique discussion, memos and reports.

8.2.3 Monthly Inspections and Inventories.

8.2.4 Agreements with offsite organizations.

8.2.5 Reviews and updates of the Radiological Emergency Contingency Plan

8.2.6 Notification of all personnel and offsite agencies affected, by an update of the plan or its implementing procedures.

9.0 RECOVERY AND PLANT RESTORATION

9.1 Reentry

Since operations are conducted in individual laboratories and the activities (radiological and physical) are relatively small, it is highly improbable that reentry, except in the case of possible structural damage by a major fire, would present any high dose or imminent danger problems.

The only reentry during the initial emergency phase would be for lifesaving. If the rescue worker were wearing SCBA, their exposure to airborne radioactivity should be minimal.

However, after the initial emergency phase, reentry would be well planned. Among the factors to be considered would be the following:

9.1.1 Airborne concentrations

9.1.2 Dose rates

9.1.3 Contamination levels

9.1.4 Structural damage

9.1.5 Chemical or physical hazards

9.1.6 Waste removal and handling.

Reentry would be in well planned stages with appropriate monitoring being done. If monitoring results indicated abnormal conditions, reentry would stop until the cause of the abnormality was identified and corrected. For example an unshielded source could be covered with temporary shielding using remote manipulators. Reentry would be under the direction of the area supervisor, RPO, and industrial safety groups.

9.2 Plant Restoration

Restoration of an area to safe conditions could involve one or two steps, or hundreds of steps depending on the incident.

We will assume that a laboratory had been involved in a major fire. The emergency phase ended with the Fire Chief declaring the fire out. The reentry phase determined that no major hazard existed or was ongoing in the area.

The recovery phase could include some of the following steps. It is to be understood that this list is not all-inclusive or that all steps would be required for all emergencies.

9.2.1 Replace sprinkler heads

9.2.2 Refill and test sprinkler system

9.2.3 Replace all used fire extinguishers

9.2.4 Have used extinguishers refilled.

9.2.5 With main power off, unplug all electrical equipment involved in the fire.

9.2.6 Plant electrician to inspect for water or fire damage to electrical system.

9.2.7 Inspect all "plug in" apparatus for water damage or burned insulation.

9.2.8 Inspect exhaust system for damage.

9.2.9 Replace clogged pre and HEPA filters.

9.2.10 Restore fixed air sampling systems.

9.2.11 Secure portable air samplers and recharge battery packs.

9.2.12 Check all drawers, cabinets, and storage locations looking for residual water or broken containers.

9.2.13 When the air exhaust system is operable, check hood face velocity with velometer, perform contamination checks, and reset all duct alarms.

9.2.14 Check with reference sources any radiation instruments involved in accident.

9.2.15 Replace or reorder all equipment and supplies used during the emergency response.

9.2.16 Collect and process all dosimeters, perform appropriate bioassay counts.

The persons involved in the above operations would include appropriate tradesmen and laboratory personnel. All operations would be conducted under the direction of the RPO.

Each inspection item cited above would involve appropriate monitoring. For example, if residual water were found, an aliquot would be collected and analyzed.

If the results of monitoring at any step showed unusual radiation or contamination levels, the operations would cease until the conditions were rendered ALARA.

All of the data collected would be documented on appropriate survey forms. These results would be reviewed by the area supervisor, management, and RPO, and a joint decision would be made as to whether or not the area has been safely restored.

Any waste generated as a result of the incident would be collected and handled by the Environmental Engineering department.

9.3 Resumption of Operations.

Continuing the scenario postulated above in 9.2, the Plant Engineer during the restoration phase would have assessed the damage and made preliminary estimates of the work to be done for full restoration of operations. He would then order the material and schedule the trades. However this does not imply, necessarily that this particular laboratory will be out of service until all the restoration work is completed.

There are spare fume hoods in other laboratories, laboratory apparatus and equipment may be shared or is readily available from local scientific supply houses.

The final decision for a site operation to return to "business as usual" is the responsibility of the Director of the Billerica site in consultation with the Associate Director of Safety and Environmental Engineering and Plant Engineer.

10.0 COMPLIANCE WITH COMMUNITY RIGHT-TO-KNOW ACT

10.1 The attached statement is included in this section to show compliance with Title III of the Superfund Amendments and Reauthorization Act of 1986, Pub. L. 99-499 entitled "Emergency Planning and Community Right-To-Know Act of 1986" with respect to any hazardous materials possessed at the Billerica site.

May 23, 1996.

DUPONT MERCK PHARMACEUTICAL COMPANY
331 Treble Cove Road, North Billerica, MA.

Compliance with Title III of the SARA of 1986, Pub. L. 99-499

This is to certify that the DuPont Merck Pharmaceutical Company facilities at 331 Treble Cove Road, North Billerica, Massachusetts, are in compliance with the Emergency Planning and Community Right-to-Know provisions of Title III of the Superfund Amendments and Reauthorization Act of 1986.

- Notification has been made to the Town of Billerica, to the local Emergency Response Committee and to the State Emergency Response Commission that this facility is subject to the emergency planning requirements.
- Emergency response plans and procedures have been developed for hazardous chemical incidents.
- Training is provided to local emergency response workers regarding handling of emergencies at this facility as described in section 7.2 of this plan.
- Onsite emergency responders are trained in accordance with the provisions of OSHA 1910.120.
- MSDS information is provided as required to the local fire department, LERC, and the SERC under section 311 of Title III of SARA.
- An annual inventory of hazardous materials is provided in March of each year as required under section 312 of Title III of SARA.
- The site is not subject to the reporting requirements under section 313 of Title III of SARA as chemical usage is under the specified threshold limits for reporting.

Dennis Dumas
Associate Director Safety and Environmental Engineering.

Telephone: (508) 671-8669

DUPONT MERCK PHARMACEUTICAL COMPANY
Radiological Emergency Contingency Plan

List of Effective Pages

List of Effective Pages

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03211
STATUS CODE: 2
FEE CATEGORY: 3A 3N 2B
EXP. DATE: 19961130
FEE COMMENTS: 2B ADDED 1/8/94
DECOM FIN ASSUR REQD: Y

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: DU PONT MERCK PHARMACEUTICAL CO.
RECEIVED DATE: 961030
DOCKET NO: 3032013
CONTROL NO.: 123852
LICENSE NO.: 20-28598-01
ACTION TYPE: RENEWAL

2. FEE ATTACHED
AMOUNT: ---
CHECK NO.: ---

3. COMMENTS

SIGNED R. J. Brown
DATE 11/4/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /)

1. FEE CATEGORY AND AMOUNT: ---

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ---
RENEWAL /
LICENSE ---

FEE EXEMPT

1996 NOV 12 PM 2:40

3. OTHER ---

SIGNED ---
DATE ---

RECEIVED BY LFDCB
Date 12/3/96 I (97)
Dec 1
BB
12/3/96

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03211
STATUS CODE: 2
FEE CATEGORY: 3A 3N 28
EXP. DATE: 19961130
FEE COMMENTS: 28 ADDED 1/8/94
DECOM FIN ASSUR REQD: Y

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: DU PONT MERCK PHARMACEUTICAL CO.
RECEIVED DATE: 961030
DOCKET NO: 3032013
CONTROL NO.: 123852
LICENSE NO.: 20-28598-01
ACTION TYPE: RENEWAL

2. FEE ATTACHED
AMOUNT: ---/---
CHECK NO.: ---/---

3. COMMENTS

SIGNED R. J. Brown
DATE 11/4/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /__/)

1. FEE CATEGORY AND AMOUNT: ---

FEE EXEMPT

1996 NOV 12 PM 2:40

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ---
RENEWAL ---
LICENSE ---

3. OTHER ---

SIGNED ---
DATE ---

RECEIVED BY LFMSB
12/3/96
I (97)
Dec 1
BB
12/3/96