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Withhold from Public Disclosure Under 10 CFR 2.390

Bristol-Myers Squibb Company

P.O. Box 191 New Brunswick, NJ 08903-0191

October 20, 2008

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Mr. Dennis Lawyer, CHP
Mail Control No. 142708
U. S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Re: **Radioactive Material License Renewal – Request for Additional Information**
License No. 29-00139-02, Docket No. 030-05222, Mail Control No. 142708

Dear Mr. Lawyer:

In response to your letter dated September 5, 2008 regarding the license application dated August12, 2008 for E. R. Squibb & Sons, LLC, a wholly owned subsidiary of Bristol-Myers Squibb Company, the following additional information is offered as requested:

1. The application is correct, the 750 millicuries of Tc99m is requested for the Lawrenceville facility, not the new Brunswick facility.

2. The amount of unsealed material with a half life greater than 120 days has decreased; the current Certificate of Financial Assurance will overstate the amount of licensed material when the license renewal is granted. The Decommissioning Funding Plan (DFP) and the associated Certificate of Financial Assurance is due to be updated in early 2009, therefore, we request that the Commission allow us to update the Certificate of Financial Assurance when the DFP is updated in 2009.

3. The latest DFP was prepared and submitted to the Commission in March of 2006.

4. Sealed Source data:

Material	Form	Manufacturer	Model	Possession Limit
(b)(4),(b)(7)(F)				
Ni-63	Foil	Agilent	G2397A	15 millicurie
Ni-63	Foil	Barringer	400B-0753	15 millicurie
Ni-63	Foil	Barringer	400B-7169	15 millicurie
Ni-63	Sealed	Smith	ADP2000	10 millicurie

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NMSS/RGN1 MATERIALS-002

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5. Craig Woodard, the Radiation Safety Committee (RSC) Chair, directly reports to Susan Voigt, Vice President, BMS Corporate Environmental, Health & Safety. James Pooler of the RSC directly reports to Mark Speaker, BMS Corporate Vice President and Deputy General Council.
6. With regard to the RSC:

    a. Members are nominated by their management to the RSC for membership. The candidate's resume is submitted with their nomination for review by the RSC. The candidate is assessed based upon their training and experience using radioactive materials, their position in their group and their ability to represent that group's interests, and their ability to devote sufficient time and resources to support the RSC's activities. Candidates must obtain a simple majority of current RSC members to be accepted onto the committee.

    b. The minimum quorum requirements for a meeting of the Radiation Safety Committee is the Chairperson, the RSO and a majority of designated committee members. With the exception of the Chairperson and RSO, committee members are encouraged to provide alternatives, but alternatives are not counted in determining a quorum and cannot vote. If a representative of a department/area, or if a representative with required expertise, is not present at the meeting, the issue requiring their presence will be adjourned for discussion at the next meeting.

7. The criteria for RSC approval of authorized users was discussed on pages 6 and 7 of the renewal application. All authorized users complete the initial radiation safety training and annual refresher provided by EHS – Radiation Safety staff. In addition, the users are expected to have academic training that qualified them to use radioactive material in their work, and the user's supervisor must approve of their request in writing before being considered by the RSC. Requests for large quantities, new processes, or any other non-routine request may require the user to present their request directly to the RSC.

8. Diagrams of the waste management areas in Lawrenceville, New Brunswick, and Pennington and the radio-synthesis suites in Lawrenceville and New Brunswick are attached as requested.

9. With regard to the distribution of radioactive drugs to authorized recipients, pursuant to 10 CFR 30.11, we request an exemption and provide the following information:

    a. Only non-commercial radioactive drugs for which the FDA has accepted an Investigational New Drug (IND) application are manufactured and distributed from the New Brunswick site, and activities concerning their synthesis and formulation will occur at facilities included in this license.

b. The New Brunswick facility is registered with the FDA as a manufacturer under Registration No. 2211101. A copy of the most recent registration is attached.

c. We request an exemption to cover the final preparation and distribution of radioactive drugs to authorized recipients under our broad scope license. This will eliminate the burden for both the Commission and licensee to administer a separate medical distribution license under 10 CFR 32.72 for this specific and limited activity. The manufacture and distribution of clinical drugs for human use containing licensed material occurs infrequently; typically less than ten times per year. These drugs contain less than 500 microcuries of either C-14 or H-3 per dosage and are administered under tightly controlled clinical trial programs.

d. The current FDA mandated controls for the manufacture and distribution of clinical drugs also cover clinical drugs containing licensed material. The facility is subject to inspection by the FDA to ensure compliance with all requirements for clinical drug quality assurance, manufacture and distribution These controls include compliance with two FDA Guidances for Industry that govern the manufacture of clinical supplies:

    i. Guideline on the Preparation of Investigational New Drug Products (March 1991)
    ii. Guidance on CGMP for Phase 1 Investigational Drugs (July 2008)

e. This material is tightly controlled under the broad scope R&D license and the applicable FDA requirements. Obtaining a distribution license for radioactive drugs for human use would present an increased administrative burden with no commensurate enhancement to patient safety or drug quality.

f. The radioactive drugs are labeled as required by 10 CFR 32.72 (a)(4) and packaged in accordance with applicable DOT requirements; typically sealed glass vials overpacked in fiber boxes. Shielding is not required.

If you require any additional information concerning this application, please contact me at michael.vala@bms.com or (732) 227-5096.

Sincerely,

Michael J. Vala

Michael J. Vala, CHP
Radiation Safety Officer

Form Approved: OMB No. 0910-0045. Expiration Date: December 31, 2007. See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **REGISTRATION OF DRUG ESTABLISHMENT/ LABELER CODE ASSIGNMENT** (In accordance with Public Law 92-387)	FDA USE ONLY RE 79,535 113900	FDA USE ONLY 2007 OCT 26 PM 12:48

NOTICE: This report is required by law (21 C.F.R. 207.20). Failure to report can result in imprisonment for not more than one year or a fine of not more than $1,000, or both. (FD&C Act, Section 303).

LABELER CODE: 0000003 REGISTRATION NUMBER: 211101

SECTION A - SITE INFORMATION

REPORTING FIRM NAME	STATE OF INC.
E.R. Squibb & Sons, LLC	Delaware

SITE ADDRESS *(No P.O. Box)*	SITE TELEPHONE NUMBER
1 Squibb Drive, Attention: Vice President Worldwide Quality & Compliance, Building 102	(732) 227-5000

CITY	STATE	ZIP CODE	COUNTRY	BUSINESS CATEGORY:
New Brunswick	NJ	08903	USA	☑ HUMAN ☑ VETERINARY

SITE MAILING ADDRESS *(If different from site address)*				
CITY	**STATE**	**ZIP CODE**	**COUNTRY**	**SITE INTERNET/EMAIL ADDRESS**

DOING BUSINESS AS (DBA) NAME OF FIRM *(if applicable)*

PARENT COMPANY NAME

REASON(s) FOR SUBMISSION

- ☐ Firm Registration
- ☐ Registration of Additional Site
- ☑ Re-Registration
- ☐ LC Assignment
- ☐ Name Change
- ☐ Address Change
- ☐ Merged/Buyout
- ☐ Reentry into Business with Same Name
- ☐ Out of Business

ANNUAL - NO CHANGE

TYPE OF OWNERSHIP

- ☐ Sole Proprietorship
- ☐ Partnership
- ☐ Coop. Assn.
- ☑ Corporation
- ☐ Other _____

PERSON SUBMITTING DATA AND TELEPHONE

BUSINESS TYPE

- ☑ Manufacturer
- ☐ Repacker
- ☐ Relabeler
- ☐ Distributor*
- ☐ Foreign Country
- ☐ Analytical Lab
- ☐ Other _____

SECTION B - FIRM COMPLIANCE MAILING ADDRESS for Annual Listing Report and/or Firm Correspondence

NUMBER AND STREET AND/OR P.O. BOX and ATTENTION LINE and/or Internal Mail Code	TELEPHONE NUMBER
Rt. 206 & Provinceline Road, Attention: Michael Fahmy	(609) 252-4616

CITY	STATE	ZIP CODE	COUNTRY	COMPLIANCE INTERNET/EMAIL ADDRESS
Princeton	NJ	08540	USA	michael.fahmy@bms.com

SECTION C - ADDITIONAL FIRM AND SITE INFORMATION

NAME OF OWNER, PARTNERS OR OFFICERS	TITLE	POSITION

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OTHER FIRMS DOING BUSINESS AT THIS SITE

LABELER CODE	FIRM NAME	LABELER CODE	FIRM NAME
	Bristol-Myers Squibb Co.		

SECTION D - SIGNATURE

SIGNATURE OF AUTHORIZING OFFICIAL	TITLE	DATE *
Donna Gulbinski Donna Gulbinski	Vice President Worldwide Quality & Compliance	10/10/2007

*DISTRIBUTOR'S CERTIFICATION: As a, Distributor, I am submitting product listing information to the FDA on my own behalf. I have provided a copy of this certification (Form FDA 2656) to the registered manufacturer(s). My signature and phone number are listed below.

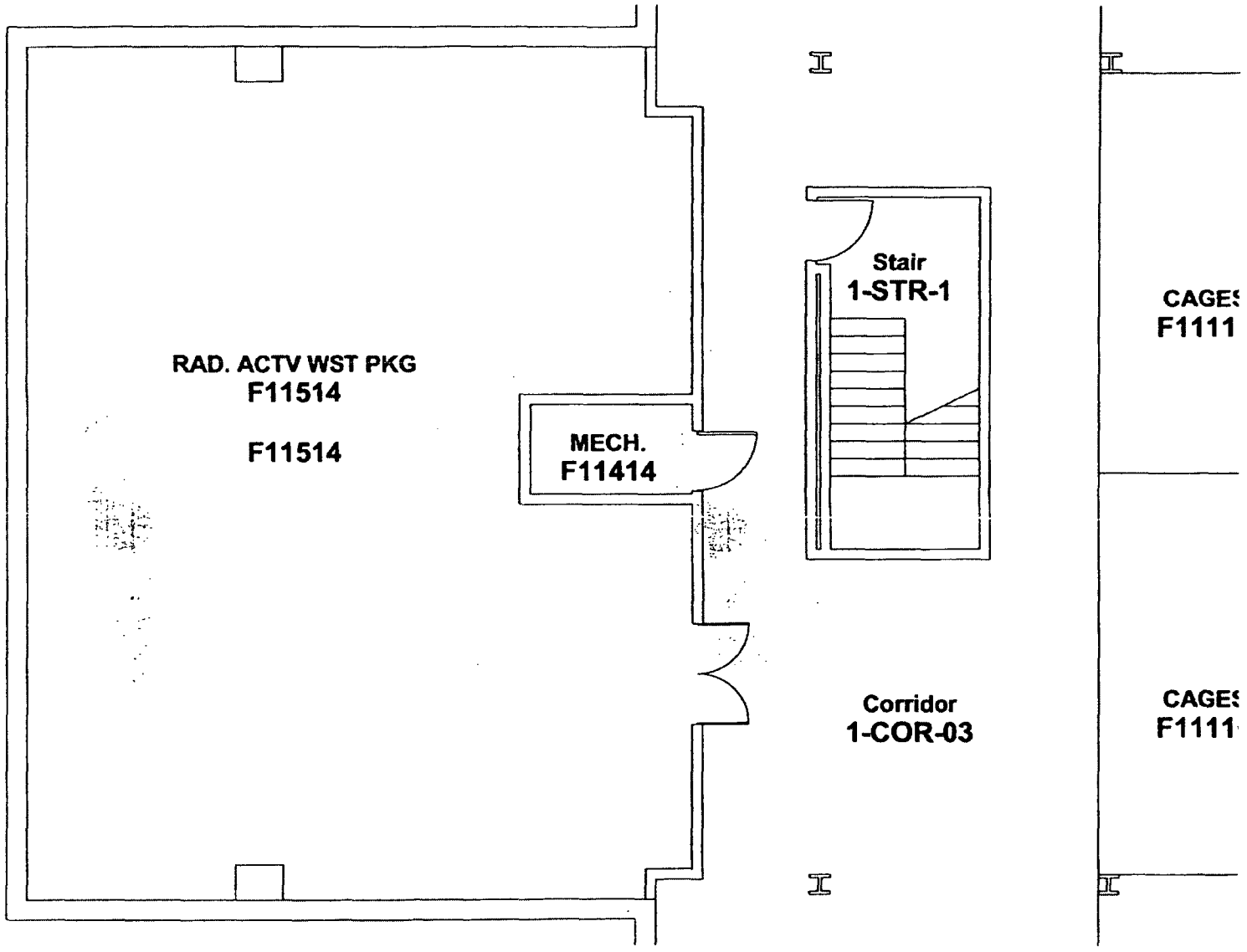
RETURN THIS FORM TO: FOOD AND DRUG ADMINISTRATION CDER/DRUG REGISTRATION AND LISTING (HFD-337) 5600 FISHERS LANE ROCKVILLE, MD 20857 INTERNET: DRLS@FDA.HHS.GOV	SIGNATURE OF DISTRIBUTOR DISTRIBUTOR'S TELEPHONE NUMBER ( )

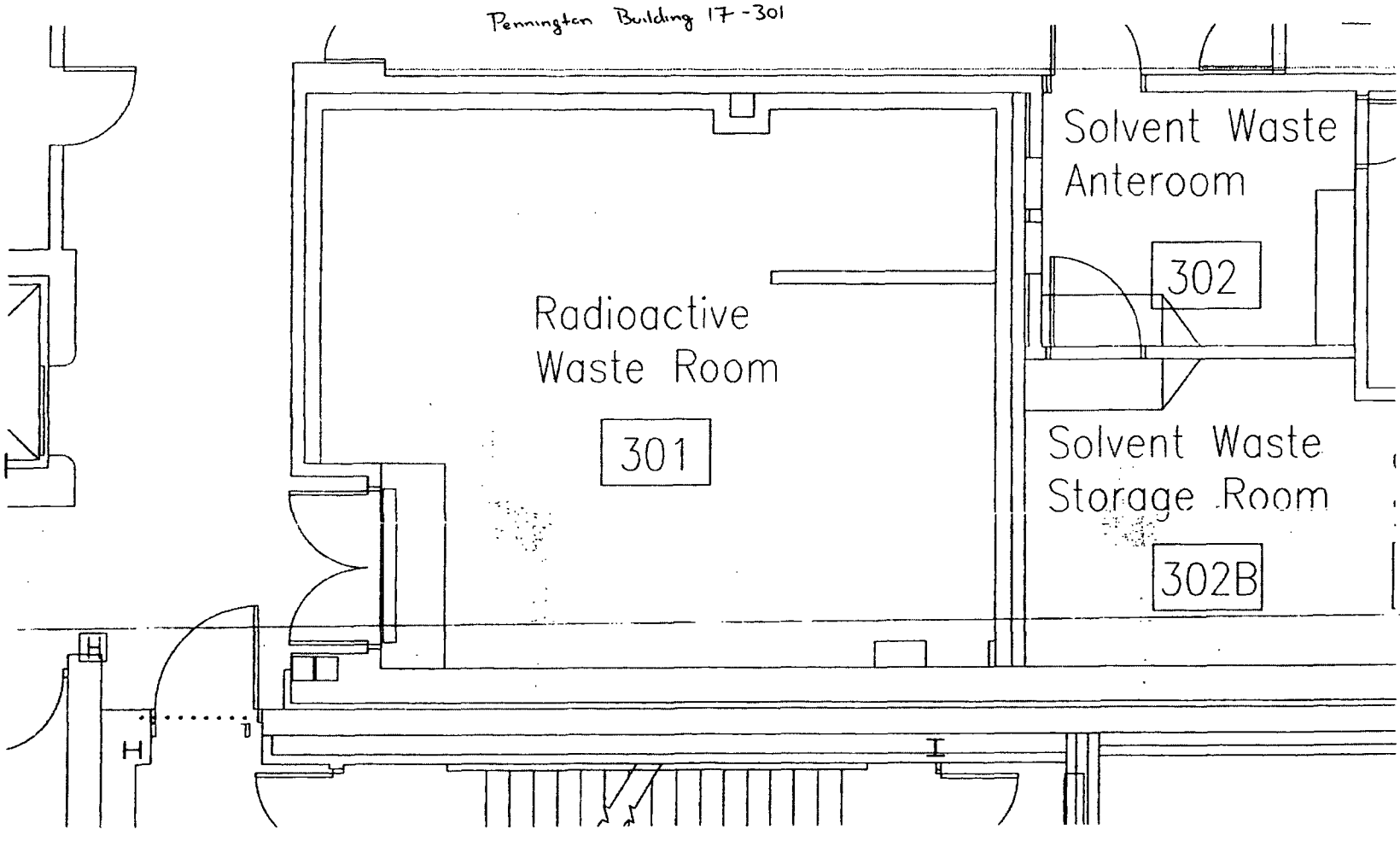
FORM FDA 2656 (8/07) (FRONT) NOTE: Validation of this form is not to be construed as FDA approval of the establishment or its products.

PREVIOUS EDITION IS OBSOLETE

PSC Graphics (301) 443-1090 DF

Lawrenceville F Module F11514

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Solvent Waste
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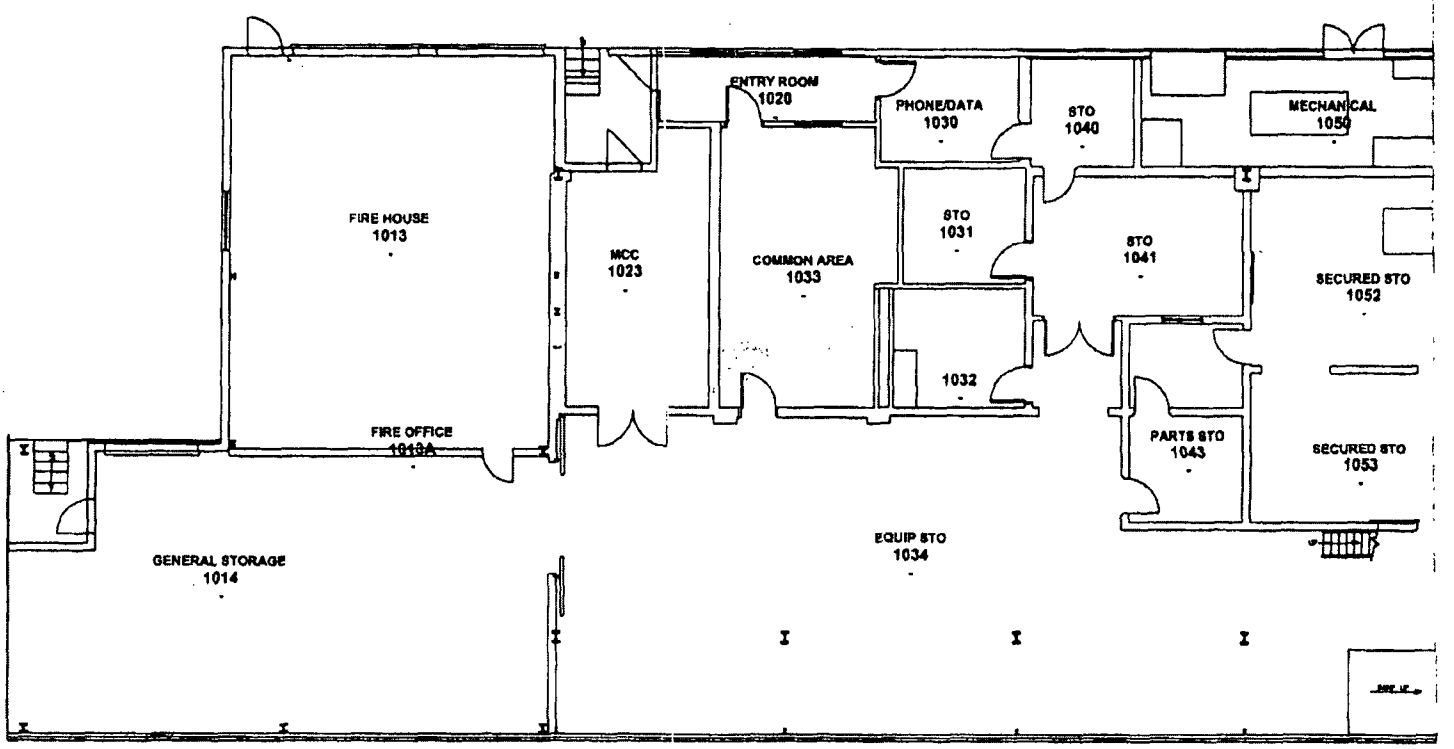
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FIRE OFFICE
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GENERAL STORAGE
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EQUIP STO
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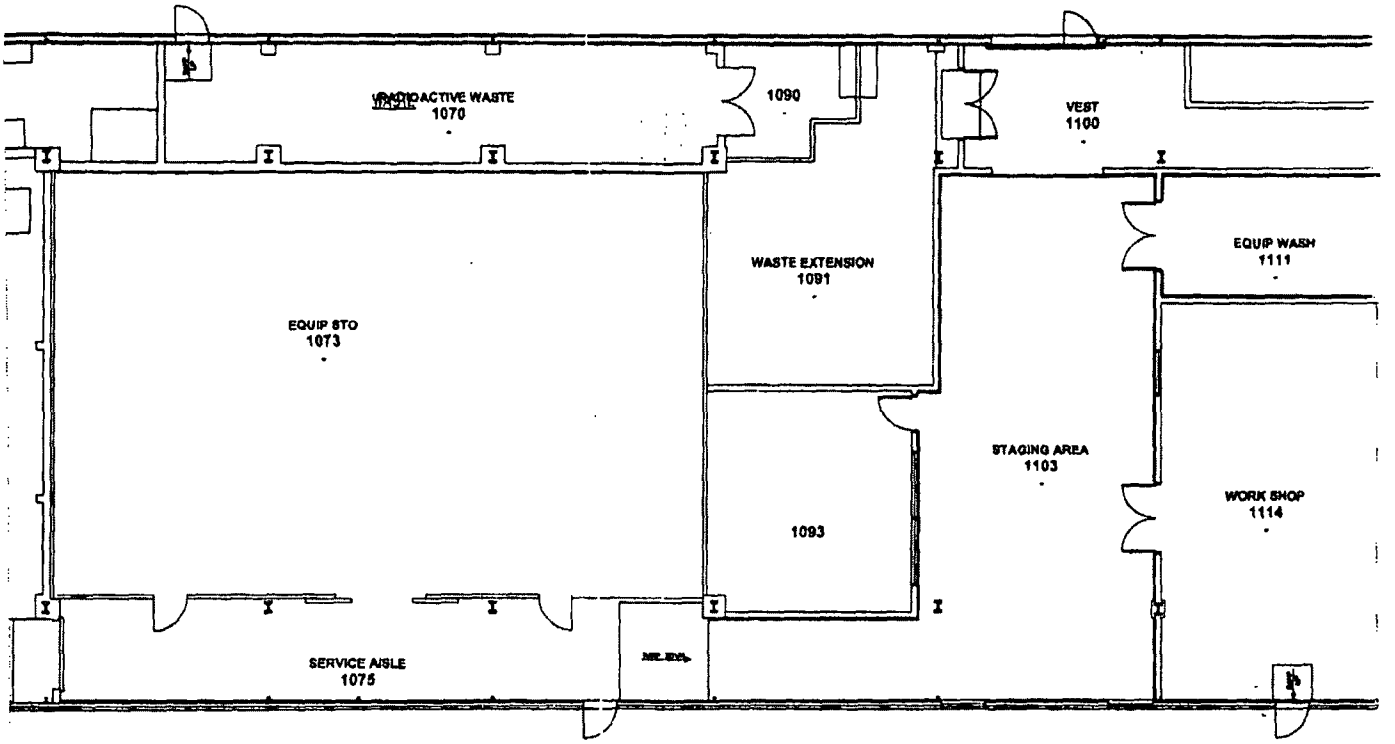
New Brunswick Waste Storage

Building 81



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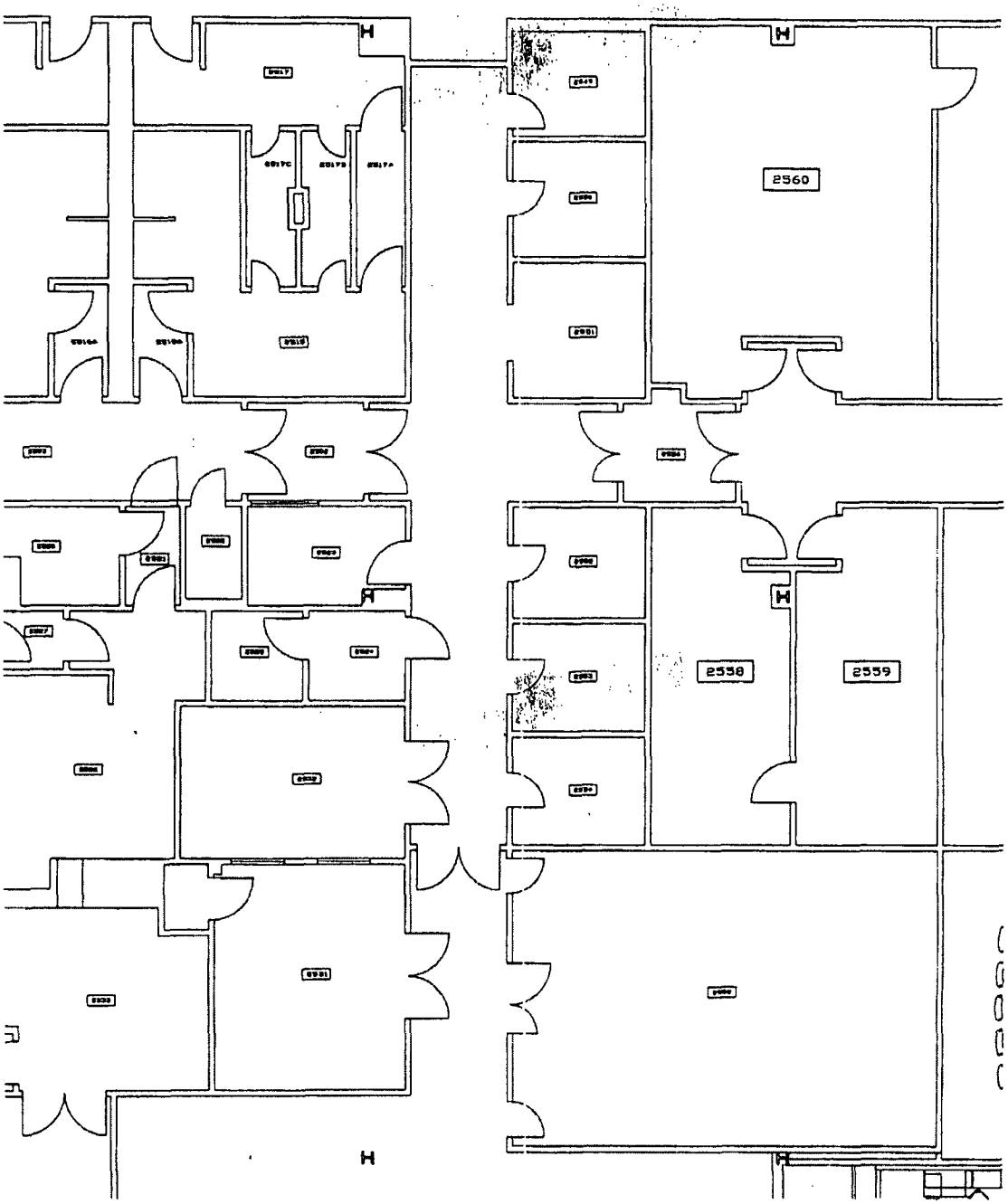

o Synthesis Suite
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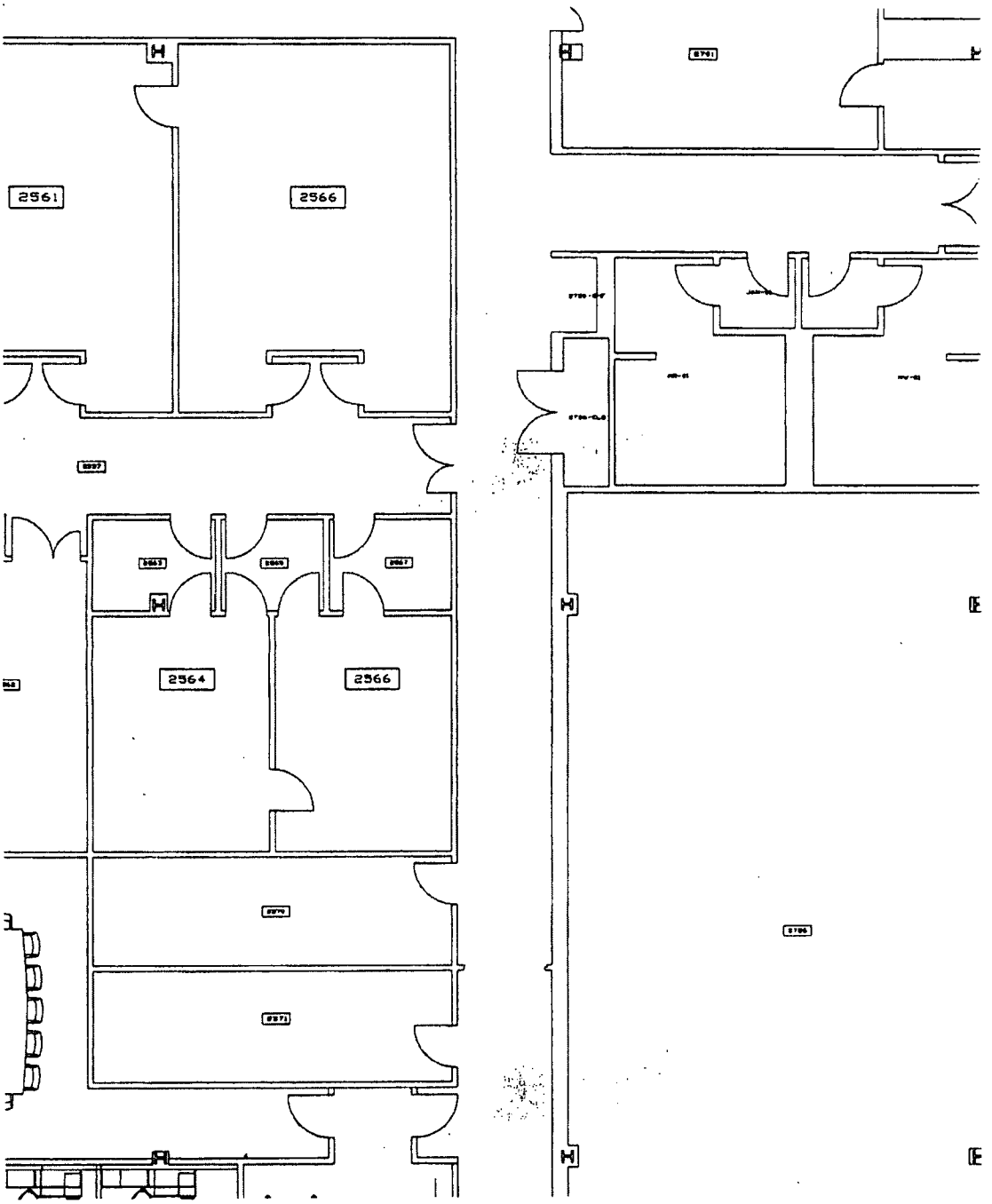
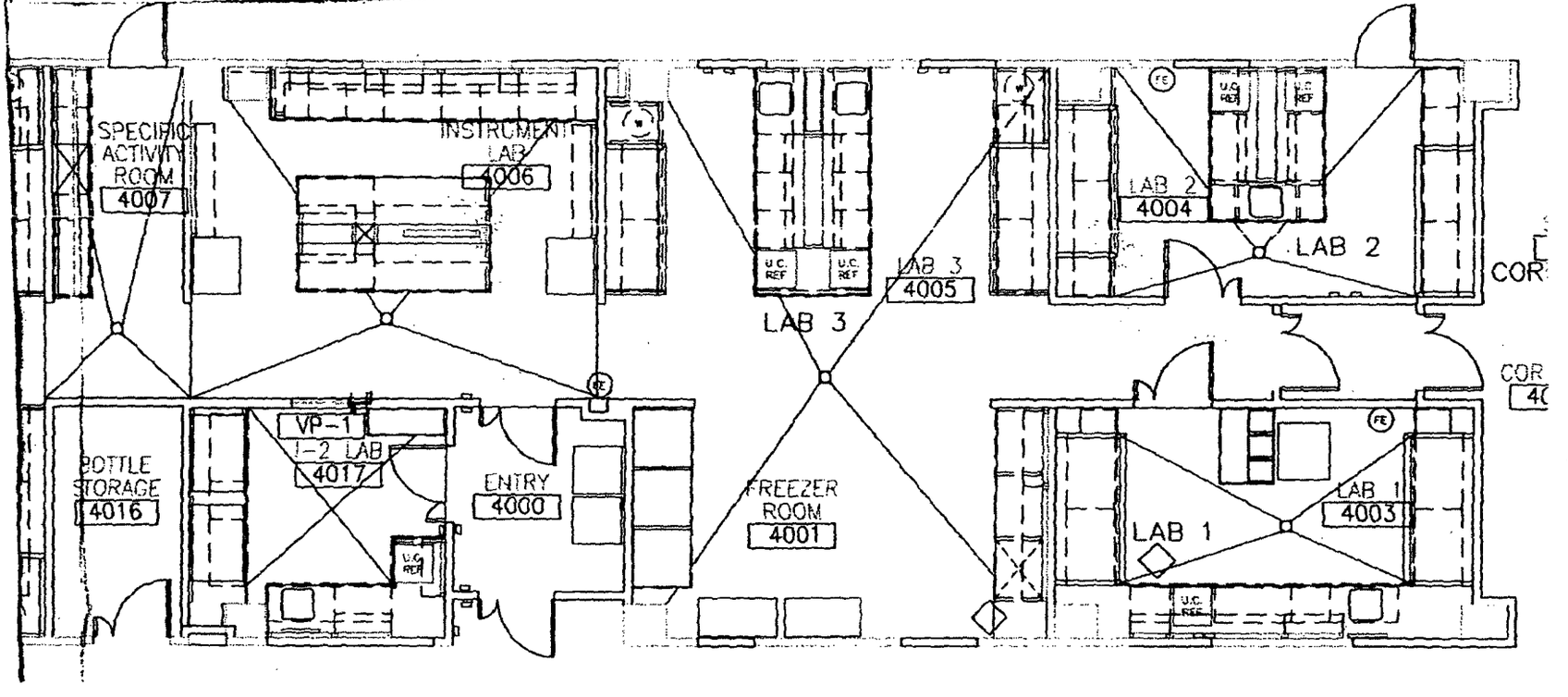
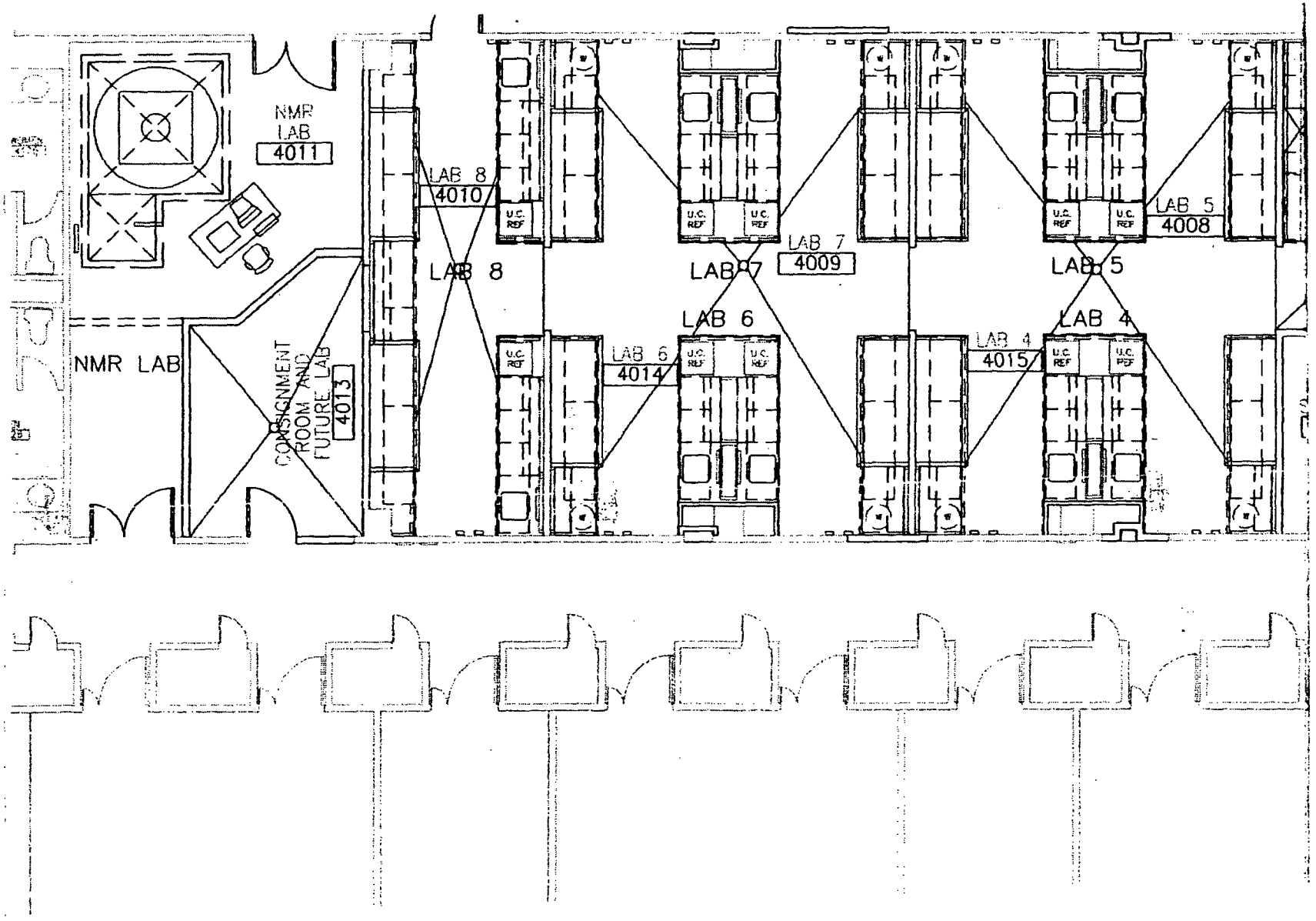


Lawrenceville Radiosynthesis Suite
Module H4

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