

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.

Licensee		In accordance with the application dated February 18, 1997,	
1. E. R. Squibb & Sons, Inc.		3. License number 29-00139-02 is amended in its entirety to read as follows:	
2. One Squibb Drive P. O. Box 191 New Brunswick, New Jersey 08903-0191		4. Expiration date September 30, 2008	
		5. Docket No. 030-05222 Reference No.	
6. Byproduct, source, and/or special nuclear material		8. Maximum amount that licensee may possess at any one time under this license	
A. Any byproduct material with Atomic Nos. 1-83 except Strontium 90	A. Any	A. 5 curies per radionuclide and 1000 curies total	
B. Iodine 131	B. Any	B. 150 curies	
C. Hydrogen 3	C. Any	C. 20 curies	
D. Carbon 14	D. Any	D. 20 curies	
E. Sulfur 35	E. Any	E. 10 curies	
F. Strontium 90	F. Any	F. 2 millicuries	
G. Any byproduct material with Atomic Nos. 84-103	G. Any	G. 1 millicurie	
H. Nickel 63	H. Plated sources in detector cells	H. Not to exceed 15 millicuries per source and 750 millicuries total	
I. Any byproduct material with Atomic Nos. 1-83 except Strontium 90	I. Any	I. 200 millicuries per radionuclide and 6 curies total	
J. Hydrogen 3	J. Any	J. 7 curies	
K. Carbon 14	K. Any	K. 5 curies	
L. Phosphorus 33	L. Any	L. 1 curie	

UNITED STATES NUCLEAR REGULATORY COMMISSION

Information in this record was deleted in accordance with the Freedom of Information Act.
Exemptions: 208-0063

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PDR ADBCK 03005222
B PDR

FOIPA 208-0063

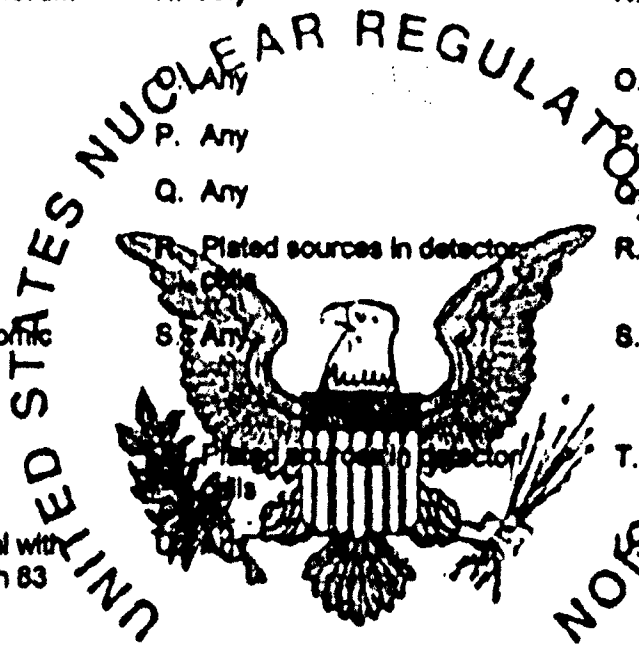
MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number
29-00139-02

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Amendment No. 95

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
M. Sulfur 35	M. Any	M. 10 curies
N. Molybdenum 99/Technetium 99m	N. Any	N. 50 curies
O. Iodine 125	O. Any	O. 500 millicuries
P. Iodine 131	P. Any	P. 500 millicuries
Q. Technetium 99	Q. Any	Q. 200 millicuries
R. Nickel 63	R. Plated sources in detector cells	R. Not to exceed 15 millicuries per source and 750 millicuries total
S. Any byproduct with Atomic Nos. 1-83 except Strontium 90	S. Any	S. Not to exceed 200 millicuries per radionuclide and 6 curies total
T. Nickel 63	T. Plated sources in detector cells	T. Not to exceed 15 millicuries per source and 750 millicuries total
U. Any byproduct material with Atomic Nos. 1 through 83 except Strontium 90	U. Any	U. Not to exceed 10 millicuries per radionuclide and 1 curie total
V. Hydrogen 3	V. Any	V. 100 millicuries
W. Carbon 14	W. Any	W. 100 millicuries
X. Sulfur 35	X. Any	X. 300 millicuries
Y. Phosphorous 32	Y. Any	Y. 100 millicuries
Z. Phosphorous 33	Z. Any	Z. 200 millicuries
AA. Iodine 125	AA. Any	AA. 50 millicuries
BB. Nickel 63	BB. Plated sources in detector cells	BB. Not to exceed 15 millicuries per source and 750 millicuries total



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9. Authorized use:

- A. and B. (1) Research and development as defined in 10 CFR 30.4; animal studies.
(2) For possession, use, and processing incident to the manufacture of radiochemicals and radiopharmaceuticals.
(3) For storage prior to distribution of manufactured radiochemicals and radiopharmaceuticals.
(4) For packaging and distribution of manufactured radiochemicals and radiopharmaceuticals to persons authorized to receive the licensed material pursuant to the terms and conditions of a specific license issued by the Nuclear Regulatory Commission or an Agreement State.
- C. through BB. Research and development as defined in 10 CFR 30.4 including animal studies, calibration of instruments.
- F. and G. Calibration of instruments; interim storage
- H., R., T., and BB. In electron capture detector cells which are distributed under a specific license issued by the U.S. Nuclear Regulatory Commission or any Agreement State.

10. A. Licensed material in Items 6.A through 6.H may only be used at the licensee's facilities located at One Squibb Drive, New Brunswick, New Jersey.
- B. Licensed material in Items 6.I. through 6.R may only be used at the licensee's facilities located at Route 206 and Provincetown Road, Lawrenceville, New Jersey.
- C. Licensed material in Items 6.S. and 6.T may only be used at the licensee's facilities located at 311 Pennington-Rocky Hill Road, Pennington, New Jersey.
- D. Licensed material in Items 6.U. through 6.BB. may only be used at the licensee's facilities located at Three Hamilton Health Place, Hamilton, New Jersey.
11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the licensee's Radiation Safety Committee.
- B. The Radiation Safety Officer for this license is Daniel K. Balkunow.
12. This license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR 31 or to persons exempt from licensing pursuant to 10 CFR 30.18.

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13. The licensee shall not use licensed material in or on human beings.
14. The licensee shall not use licensed material in field applications where activity is released.
15. Experimental animals administered licensed materials or their products shall not be used for human consumption.
16. 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.

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- 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 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.
17. Detector cells containing a titanium trioxide foil or a scandium trioxide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding that specified by the manufacturer.
18. The licensee shall conduct a physical inventory every six months or at other interval approved by NRC, to account for all sealed sources and/or devices received and possessed under the license.
19. The licensee shall not acquire, possess, or use in a sealed source or in a device that contains a sealed source unless the source or device has been registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.
20. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
21. The licensee shall maintain and execute the response measure of his Radiological Emergency Contingency Plan submitted to the Commission on February 18, 1997. The licensee shall also maintain procedures as necessary to implement the plan. The licensee shall make no change in his Radiological Emergency Contingency Plan that would decrease the response effectiveness of the plan without prior Commission approval as evidenced by license amendment. The licensee may make changes to his Radiological Emergency Contingency Plan without prior Commission approval if the changes do not decrease the response effectiveness of the plan, and shall maintain records of changes that are made to the plan without prior approval for a period of two years from the date of the changes and shall furnish the Chief, Nuclear Materials Safety Branch, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, a report containing a description of each change within six months after the change is made.

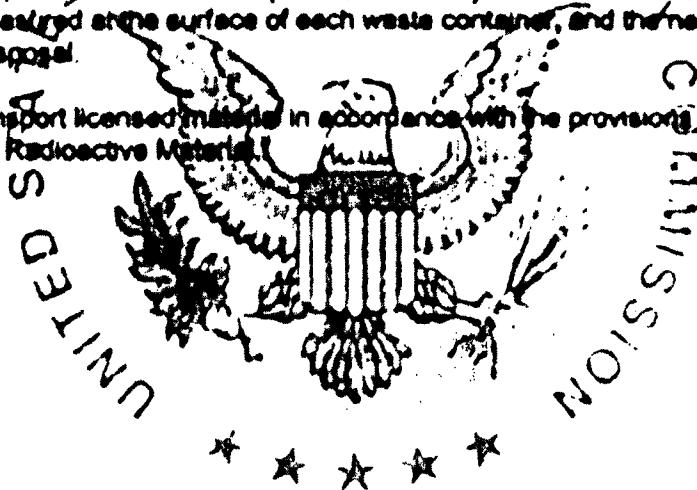
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22. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash, provided:

- 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. The licensee may transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."



**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

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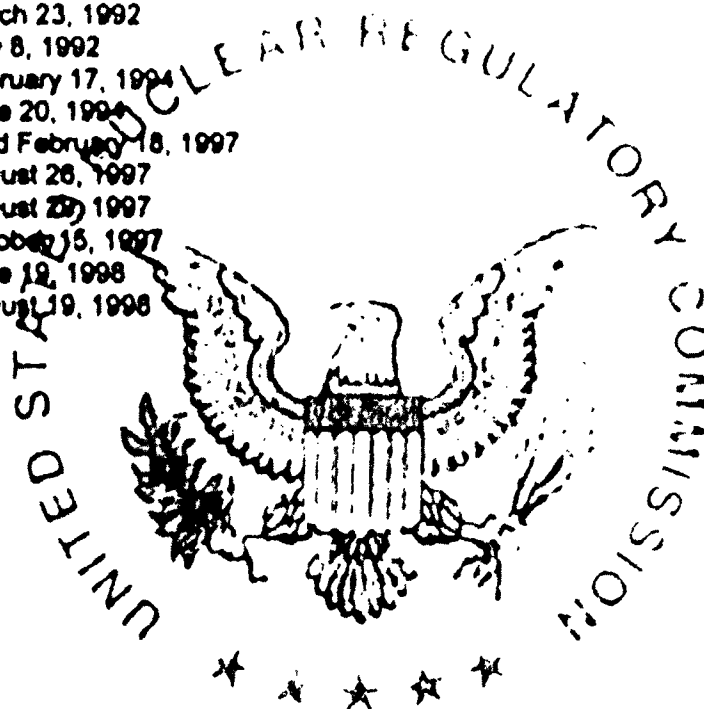
Docket or Reference Number

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24. 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. Letter dated March 23, 1992
- B. Letter dated May 8, 1992
- C. Letter dated February 17, 1994
- D. Letter dated June 20, 1994
- E. Application dated February 18, 1997
- F. Letter dated August 28, 1997
- G. Letter dated August 29, 1997
- H. Letter dated October 15, 1997
- I. Letter dated June 19, 1998
- J. Letter dated August 19, 1998



For the U.S. Nuclear Regulatory Commission

Date September 24, 1998

By

Original signed by Elizabeth Ullrich

Elizabeth Ullrich

Nuclear Materials Safety Branch 2

Division of Nuclear Materials Safety

Region I

King of Prussia, Pennsylvania 19406

September 25, 1988

Docket No. 030-05222

License No. 29-00139-02

Control No. 124288

Thomas M. Primm
Vice President, Facilities, Engineering and Administration
E. R. Squibb & Sons, Inc.
One Squibb Drive
P. O. Box 191

New Brunswick, NJ 08902-0191

Dear Mr. Primm:

This refers to your request for renewal of your NRC license. 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.

The NRC is required to have your Taxpayer Identification Number in order to make payments (refunds). The self-addressed, stamped NRC Form 531, "Request for Taxpayer Identification Number," is enclosed.

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 the NRC no later than 30 days after the mailing address on the license changes (no fee is required if the location of byproduct material remains the same)
3. In accordance with 10 CFR 30.38(d), notify the 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. order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license, or

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T. Primm

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E. R. Squibb and Son, Inc.

- b. add or change the areas of use, or address or addresses of use identified in the license application or on the license
5. Receive written approval from the NRC prior to any change in ownership of your organization, in accordance with 10 CFR 30.34(b)
6. 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. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

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 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 Elizabeth Ullrich

Elizabeth Ullrich
Senior Health Physicist
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

Enclosures.

1. Amendment No. 95
2. 10 CFR Parts 19, 20, 21, 30, 33, 71, 170, and 171
3. NRC Forms 3, 313, and 531
4. Section 206 of the Energy Reorganization Act of 1974

T. Primm
E. R. Squibb and Son, Inc.

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5. NUREG 1600, General Policy and Procedure for NRC Enforcement Actions
(Enforcement Policy)

cc:
Daniel K. Balkunow, Radiation Safety Officer

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OFFICE	DNMS/RI	N	DNMS/RI				
NAME	JBondick <i>JB</i>		EJUNCK				
DATE	09/23/98		09/ /98		09/ /98		09/ /98

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TELEPHONE CONVERSATION RECORD		Date: 9/22/98	Time: 2 p.m.
Mail Control No.: 124288		License No.: 29-00139-02	Docket No.: 030-05272
Person Called: Dan Balkunow, RSO		Organization: <i>and wife</i> E R Squibb & Sons, Inc	Telephone Number: 732-519-2451
Person Calling: J. Bondick		Organization: NRC	Telephone Number: 8951
Subject: Clarification of materials to be used at the New Brunswick site			
<p>Summary: Spoke to Mr. Balkunow regarding the apparent omission of Mo99/Tc99m/any/500 curies that are now on the license for use at the New Brunswick site. Mr. Balkunow verified that the information supplied with the August 19, 1998 letter deliberately deleted the Mo99/Tc99m/any/500 curies from the renewal because they felt that they could handle what they do under Any byproduct materials with atomic nos. 1-83 except Sr-90/any/5 curies per radionuclide and 100 curies total. Mr. Balkunow stated that they expect to be out of the radiopharmaceutical business by the 2000 and this step is leading in that direction. They intend to meet with the NRC in regard to this change sometime in the future regarding decommissioning.</p>			
Action Required/Taken: Note to file; prepare license and cover letter for review.			
Signature: J. Bondick <i>J. Bondick</i>		Date: 9/22/98	



Bristol-Myers Squibb Company

Pharmaceutical Group Technical Operations

One Corporate Drive, P.O. Box 100, New Brunswick, NJ 08903
201-341-1000

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Q-6

August 19, 1998

Dr. John Kinneman
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

DOCKET NO.: 030-05222
CONTROL NO.: 124288
LICENSE NO.: 29-00139-02

Dear Dr. Kinneman,

Enclosed please find two (2) copies of your request for additional information dated July 20, 1998 regarding our license renewal application.

If you have any additional questions, please contact me at 732-519-2451.

Sincerely,

Daniel K. Balkunow

Daniel K. Balkunow
Radiation Safety Officer

DKB bl

Enclosures (2)

cc T Pnmm
S Voigt
C Woodard
RSC*

*Circulation only

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Aug 20 1998

RESPONSE TO NRC REQUEST FOR ADDITIONAL INFORMATION - LICENSE #29-00139-02

Question #1:

The following questions are in regard to the present addresses where licensed material will be used or stored

- a. Since the submission of your application for renewal of License No. 29-00139-02, three amendments have been issued. These are amendments No. 91, 92 and 93. Amendment No. 91 removed the ConvaTec site in Skillman, New Jersey from the license. Amendment No. 92 added the Pennington, New Jersey site to the license. Amendment No. 93 added the Hamilton, New Jersey site. To be consistent with the current authorized locations of use, please revise and resubmit item #2 in your application to reflect the deletion of the ConvaTec site and the addition of the two new locations.
- b. Please revise and resubmit item #5 and item #6 in your application to reflect the deletion of the ConvaTec site in Skillman, New Jersey, and add both the Pennington and Hamilton, New Jersey sites. For these sites, please specify the byproduct materials to be used, the chemical and physical form of the materials, the maximum possession limits, and the requested authorized uses.

Response:

The below information represents BMS activities as of August 5, 1998, in accordance with Amendment #94 of License #29-00139-02. This information supersedes the information submitted in the February 18, 1997 license renewal application.

Item #2: Name and Mailing Address (unchanged)

E. R. Squibb & Sons
One Squibb Drive
P.O. Box 191
New Brunswick, NJ 08903

Item #3: Addresses where licensed material will be used or possessed (modified)

- A. E. R. Squibb & Sons*
One Squibb Drive
P. O. Box 191
New Brunswick, NJ 08903-0191
- B. E. R. Squibb & Sons*
Route 206 & Provincetown Road
Lawrenceville, NJ
P. O. Box 4000
Princeton, NJ 08543 4000
- C. BMS Clinical Research Center
Three Hamilton Health Place
Hamilton, NJ 08690

Question #1 con't:

D. Bristol-Myers Squibb
311 Pennington-Rocky Hill Road
Pennington, NJ 08543

*A wholly-owned subsidiary of Bristol-Myers Squibb Company

Item #4: Contact Person (unchanged)

Mr. Daniel K. Balkunow
Radiation Safety Officer/Department Head - Health Physics
(732) 519-2451

Question #1 cont:

Items #5 and #6: Possession Limits for the Lawrenceville Site, Rt. 206 & Provincetown Road, Princeton, NJ 08540 (modified)

6A. Byproduct, Source, and/or Specific Nuclear Material	5B. Chemical and/or Physical Form	5C. Max. Amount that licensee may possess at any 1 time	6. Authorized Use
Any byproduct material with Atomic Nos. 1 - 83 except Strontium 90	Any	200 millicuries per radionuclide and 6 curies total	Research and development as defined in 10 CFR 30.4
Hydrogen 3	Any	7 curies	Research and development as defined in 10 CFR 30.4; Manufacture of labelled compounds intended for human use and transfer of the compounds to individuals authorized to receive the material by the terms and conditions of a specific license issued by the USNRC or an Agreement State
Carbon 14	Any	5 curies	Same as Hydrogen 3
Phosphorous 33	Any	1 curie	Research and development as defined in 10 CFR 30.4
Sulfur 35	Any	1 curie	Research and development as defined in 10 CFR 30.4
Molybdenum 99 Technetium 99m	Any	50 curies	Research and development as defined in 10 CFR 30.4
Iodine 125	Any	500 millicuries	Research and development as defined in 10 CFR 30.4
Cobalt 60	Any	500 millicuries	Research and development as defined in 10 CFR 30.4
Technetium 99	Any	100 millicuries	Research and development as defined in 10 CFR 30.4
Nickel 63	Plated sources in detector cells	not to exceed 15 millicuries per source and 750 millicuries total	Research and development as defined in 10 CFR 30.4

Question #1 cont:

Items #5 and #6: Possession Limits for the BMS Clinical Research Center, Three Hamilton Health Place, Hamilton, NJ 08690

5A. Byproduct, Source, and/or Specific Nuclear Material	5B. Chemical and/or Physical Form	5C. Max. Amount that licensee may possess at any 1 time	6. Authorized Use
Any byproduct material with Atomic Nos. 1 - 83 except Strontium 90	Any	Not to exceed 10 millicuries per radionuclide and 1 curie total	Research and development as defined in 10 CFR 30.4. Calibration of instruments
Hydrogen 3	Any	100 millicuries	Research and development as defined in 10 CFR 30.4. Calibration of instruments
Carbon 14	Any	100 millicuries	Research and development as defined in 10 CFR 30.4. Calibration of instruments
Sulfur 35	Any	300 millicuries	Research and development as defined in 10 CFR 30.4. Calibration of instruments
Phosphorus 32	Any	100 millicuries	Research and development as defined in 10 CFR 30.4. Calibration of instruments
Phosphorus 33	Any	200 millicuries	Research and development as defined in 10 CFR 30.4. Calibration of instruments
Iodine 125	Any	50 millicuries	Research and development as defined in 10 CFR 30.4. Calibration of instruments
Nickel 63	Plated sources in detector cells	Not to exceed 15 millicuries per source and 750 millicuries total	Research and development as defined in 10 CFR 30.4. Calibration of instruments

Question #1 (cont):

Items #5 and #6: Possession Limits for the Pennington Site 211 Pennington-Rocky Hill Road, Pennington, NJ 08543

5A. Byproduct, Source, and/or Specific Nuclear Material	5B. Chemical and/or Physical Form	5C. Max. Amount that licensee may possess at any 1 time	6. Authorized Use
Any byproduct material with Atomic Nos. 1 - 83 except Strontium 90	Any	200 millicuries per radionuclide and 6 curies total	Research and development as defined in 10 CFR 30.4. Calibration of instruments
Nickel 63	Plated sources in detector cells	Not to exceed 15 millicuries per source and 750 millicuries total	Research and development as defined in 10 CFR 30.4. Calibration of instruments

Question #1 cont:

Items #5 and #6: Possession Limits for the New Brunswick Site (unchanged)

5A. Byproduct, Source, and/or Specific Nuclear Material	5B. Chemical and/or Physical Form	5C. Max. Amount that licensee may possess at any 1 time	6. Authorized Use
Any byproduct material with Atomic Nos 1-83 except Strontium 90	Any	5 Curies per radionuclide and 1000 Curies total	<ol style="list-style-type: none"> 1. Research and development as defined in 10 CFR 30.4 2. For possession, use and processing incident to the manufacture of radiochemicals and radiopharmaceuticals 3. For storage prior to distribution of manufactured radiochemicals and radiopharmaceuticals 4. For packaging and distribution of manufactured radiochemicals and radiopharmaceuticals to persons authorized to receive the licensed material pursuant to the terms and conditions of a specific license issued by the Nuclear Regulatory Commission or an Agreement State
Iodine 131	Any	150 Curies	Same as A. above
Hydrogen 3	Any	20 Curies	Research and development as defined in 10 CFR 30.4, Manufacture of labeled compounds intended for human use and transfer of the compounds to individuals authorized to receive that material by the terms and conditions of a specific license issued by the NRC or an Agreement State
Carbon 14	Any	20 Curies	Same as Hydrogen 3
Sulphur 35	Any	10 Curies	Research and development as defined in 10 CFR 30.4, calibration of instruments
Strontium 90	Any	2 millicuries	For interim storage of waste returned from a processor, calibration of instruments
Any byproduct material with Atomic Nos 84-103	Any	1 millicurie	For interim storage of waste returned from a processor
Nickel 63	Plated Sources in detector cells	Not to exceed 15 millicuries per source and 750 millicuries total	Research and development as defined in 10 CFR 30.4 calibration of instruments

Question #2a:

Item 9 in your application discusses a "built in" area radiation monitoring system. In addition, this section states: "Each filter bank is equipped with before and after continuous tubes used to check charcoal filter efficiencies." "They are changed on a routine basis." Your application also states: "There is no definite filter changer criterion." Please describe the methods you use to determine when the filters in each filter bank are changed.

Response:

The "built in" area radiation monitors do not monitor the ventilation system. They measure ambient radiation levels in operational work areas. The before and after continuous air (sampling) tubes that are used to check charcoal filter efficiencies are collected routinely, typically weekly. Based upon the ratio of the before and after sample tubes, an efficiency for each filter bank is calculated. If a filter bank drops below 80% efficiency and is significantly contributing to the total stack effluent, the filters are replaced.

Question #2b:

From various sections of the text of your submission, and your postulated emergency scenarios, it appears that you depend on area monitors, the analysis of sample tubes, the response of personnel, and fire activated systems in emergency.

Response:

All emergency scenarios have been developed for New Brunswick Building 124 Manufacturing operations. It is these licensed activities that require a Radiological Contingency Plan. Therefore, the responses to Questions 2.b.1 - 2.b.4 will be specific to Building 124 Manufacturing operations.

Question #2b.1:

Provide a schematic diagram of all effluent pathways at each site which includes the identification of the source of the activity, the maximum typical activity at each source, the location of the sampling points in each ventilation pathway, and each contributing and final ventilation flowrates for each pathway.

Response:

All ventilation systems in the manufacturing area are manifolded to a single stack prior to release to the environment. Page 15, paragraph 5 of the February 18, 1997 license renewal application details the sampling of this effluent pathway. The typical flowrate through this stack is approximately 70,000 cfm, seven days a week, twenty-four hours per day. The primary contribution to the effluent is due to hot cell operations where approximately 35 Curies per week of ¹³¹I is processed. Each ventilation pathway is monitored by pre and post air sampling tubes as described in Question 2.a above. A schematic of the Building 124 ventilation system is attached (see Attachments 1 & 2).

Question #2b.2:

Please describe how your present monitoring program emulates a real-time effluent monitoring system in the timely mitigation of releases from a scenario which does not include a fire in the restricted area.

Response:

The radioactive material present in the effluent air stream is constantly monitored by the stack monitor detectors. When these detectors register a count rate above the alarm set point, the stack monitor is designed to trigger an alarm in the Health Physics office. This feature on the stack monitor is currently undergoing modifications to replace aging equipment. The manufacturer's service representative has been contacted and this feature is expected to be upgraded in the near future. Currently, the integrating charcoal sample cartridge is collected and analyzed each business day. Close coordination between Health Physics and manufacturing personnel have ensured that any abnormal occurrences are promptly identified and investigated before any impact on stack effluent occurs.

Question #2b.3:

Include an estimate of the time required to quantify a release, and describe the degree of correspondence you have determined between your "built in" area radiation monitors and the present method for sampling releases.

Response:

If a release is suspected, the charcoal sample cartridge on the stack monitor can be collected and analyzed within fifteen minutes. Subsequent samples could be collected on an hourly basis to continue to assess the stack effluent. Post samples from the filter banks, described in question 2.a, can be collected and analyzed within one hour to determine precisely which hot cell, glove box, or fume hood filter train is contributing to the release. The "built in" area radiation monitors measure ambient radiation levels in operational work areas. Any release in an operation area will result in an elevated radiation level in that area that will be immediately detected by these monitors. As stated previously, these "built in" monitors do not monitor the ventilation system, any correspondence to effluent releases would be qualitative, not quantitative.

Question #2b.4:

Provide the average annual Chi/Q values used for each release site, and the distance to the maximum exposed individual for each site.

Response:

Chi/Q values are not utilized to characterize site effluent. The measured stack concentrations are compared to the limits specified in 10 CFR 20 Appendix B. The effluent concentrations for the previous five years have been 5% or less of the Appendix B limit. This is well within the constraint limit of 10 CFR 20.1101(d) for air releases. If the effluent releases approached 20% of the limit, BMS will calculate the Chi/Q value for the stack release based upon a stack height of 29 meters and the distance to the maximum exposed individual of 5 meters.

Question #3:

The second paragraph in the section "Emergency Procedures" states: "The ConvaTec and Clinical Laboratory facilities have site specific procedures for emergency response." Since the ConvaTec facility was removed from the license, is the Clinical Laboratory facility the only remaining facility to have site specific emergency procedures?

Response:

The Clinical Laboratory at Princeton House has been decommissioned and re-located to Hamilton (see Question #1). Hamilton has site specific emergency procedures and is supported by the Lawrenceville site staff.

Question #4:

Page 22, paragraph 6 states: "Gloves are worn while handling radioactive materials and removed before handling non-radioactive materials." Are gloves the only protective apparel used?

Response:

Page 26, paragraph 5 of the February 18, 1997 renewal application details the protective apparel required by personnel in radiologically restricted areas. Lab coats are required for personnel that are not wearing company issued uniforms. Gloves are required when handling radioactive materials. Additional protective apparel will be used in areas as the situation warrants.

Question #5:

Page 22, paragraphs 12 and 13 discuss surveys and contaminated areas. Paragraph 12 states: "Documentation of such surveys will not be required." "All contaminated areas are cleaned and rechecked." If these surveys are not documented, how are all contaminated areas identified so that all contaminated areas are cleaned and rechecked as stated in your application?

Response:

Page 25, paragraph 3 of the February 18, 1997 renewal application outlines Health Physics contamination surveys and operation contamination surveys. Health Physics surveys are documented, appropriate area personnel are informed of any contamination identified and are responsible for decontamination. Health Physics will verify the decontamination was completed. Operational contamination surveys conducted by personnel in their own work areas, as part of proper handling techniques for radioactive materials, are not required to be documented. If an operational contamination survey identifies contaminated areas or equipment, the item is promptly decontaminated by that person or someone in their group. Personnel that handle radioactive materials are responsible for maintaining their work area free of contamination.

Question #6:

Your application does not have specific details for thyroid bioassays. Describe your bioassay program, including the type of bioassay (thyroid counts, urine counts, whole body counts, etc.), i.e. criteria and the frequency for performing bioassays, and the type of action taken when positive results are obtained. It is recommended that bioassay procedures be considered for personnel using millicurie quantities of treated organic compounds, iodine-131, and iodine-125 in noncontained forms.

Response:

As stated in paragraph 1, page 26 of the February 18, 1997 license renewal application, it is not likely that any employee will exceed 10% of the ALI under anticipated licensed activities. Bioassay by evaluation of the thyroid and urine are available to employees and are performed to verify the adequacy of procedures and engineered controls. Personnel that handle millicurie quantities of unsealed volatile iodine are required to

Question #6 con't:

perform a thyroid bioassay within 72 hours of performing work. Manufacturing personnel who handle iodine typically perform a routine thyroid evaluation weekly. Urine bioassays are conducted on personnel who process ten millicuries or greater of tritium or Carbon-14 on the bench top or 100 millicuries of either isotope in a ventilated enclosure. Urine bioassays are sent to a contract laboratory for analysis (currently, Radiation Science, Inc. License #29-30310-01). Positive results that exceed 0.2% per week of the ALI are investigated with a deviation report. If an employee is expected to exceed 2.5% of the ALI in any quarter, their committed effective dose equivalent is calculated and reported in accordance with 10 CFR 20 requirements.

Question #7:

Your application did not specify the instrument used in your bioassay program for determining activity in the thyroid. Please specify your instrumentation and calibration procedures, including the type of phantom you will use.

Response:

Thyroid evaluations are currently performed utilizing a Model 8501-S2 Thyroid In-Vitro System manufactured by Specialties Electronic Company of Mount Holly, New Jersey. This instrument consists of a collimated 2x2 NaI detector that is connected to a microprocessor unit which calculates and records the thyroid activity for each participant. Each sample is typically collected for two minutes. The instrument is calibrated daily utilizing a mock Iodine-125 (Ba-133) standard or an I-125 standard placed in a tissue equivalent neck phantom.

Question #8:

Specify your criteria for performing internal monitoring which may be required for certain uses of material under your license. Submit a description of procedures, including the methods and instrumentation to be used for sampling and analysis, calibration of equipment, the lower limit of detection for the method and instrumentation, and the action levels for each radionuclide.

Response:

Internal monitoring is not currently required due to the extensive use of engineered controls and administrative procedures. Bioassays are performed to verify the adequacy of procedures and engineered controls. Personnel that handle millicurie quantities of unsealed volatile iodines are required to perform a thyroid bioassay within 72 hours of performing work as described in Question #7. Manufacturing personnel who handle iodine typically perform a routine thyroid evaluation weekly. Urine bioassays are conducted on personnel who process ten millicuries or greater of tritium, Carbon-14, or other beta emitters on the bench top or 100 millicuries in a ventilated enclosure. Urine bioassays are collected and sent to a contract laboratory for analysis (currently, Radiation Science, Inc. License #29-30310-01). Positive results that exceed 0.2% per week of the ALI are investigated. If an employee is expected to exceed 2.5% of the ALI in any quarter, their committed effective dose equivalent is calculated and reported in accordance with 10 CFR 20 requirements on NRC Form 5. Typical lower limits of detection for each isotope are at least 0.1% of the ALI.

Question #9:

Your application states: "The RSC is informed of regulatory requirements and operating procedures through routine meetings and correspondence with the Health Physics Department." At what frequency does the Radiation Safety Committee (RSC) meet?

Response:

Page 7, Item C.7 of the February 18, 1997 renewal application states that the RSC is required to meet quarterly at a minimum.

Question #10:

Page 24, in your application, Item 8, in the section entitled "Safety Evaluations of Proposed Uses and Users" requires that information on the User Form includes, among other things, whether the material will be used in human or animal studies. Please clarify this statement. License No. 29-00139-02 does not authorize use of licensed material in humans or animals. Furthermore, Research and Development, as defined in 10 CFR 30.4, states, in part, "Research and development as used in this part and parts 31 through 35 does not include the internal or external administration of byproduct material, or the radiation therefrom, to human beings."

Response:

New users of radioactive material are queried regarding the use of radioactive material in humans so that the work can be identified before license material is used for activities that are beyond the scope of the license. If a user wishes to use licensed material in humans, the work is done by an outside clinical lab that possess the proper licensing.

The Commission's statement that our license does not authorize the use of licensed material in animals is incorrect. The definition of R&D in 10 CFR 30.4 does not exclude the use of animals. Further, license condition 14 of License Number 29-00139-02 implies the use of animals with licensed material.

Question #11:

Paragraph 6 on page 25 of your application discusses the use of respiratory protection equipment. Please confirm that your program conforms to 10 CFR 20, Subpart H "Respiratory Protection and Controls to Restrict Internal Exposures in Restricted Areas."

Response:

The Bristol-Myers Squibb Respirator Protection Program complies with the requirements of 10 CFR 20, Subpart H.

Question #12:

Provide a copy of senior management's written statement of delegation of authority to the Radiation Safety Officer. This statement should include the requisite authority to communicate with and direct your personnel regarding NRC regulations and license provisions and to enforce these requirements including the ability to terminate any unsafe operation involving the use of licensed material.

Response:

A copy of GRP- 31, Mission Scope and Major Activities of the Radiation Safety Committee and an interoffice memorandum from the President of Technical Operations, are attached for review (see Attachments 3 & 4). This material is submitted for informational purposes only and should not be considered as part of the license renewal application.

Question #12:

Confirm that management will conduct a periodic oversight of the radiation protection program, including interaction with the RSC and RSO.

Response:

Page 7, Items B 1, B 2, and B 4 of the February 18, 1997 renewal application provide the mechanism to ensure that senior management is aware of the activities of the RSC and the RSO. Senior management is copied on the RSC minutes and receives a summary briefing on licensed activities on a biennial basis.

Question #14:

Confirm that the Radiation Safety Committee will conduct safety evaluations of proposed users and uses.

Response:

Page 7, Item C 2 of the February 18, 1997 renewal application specifically states that the RSC is responsible for approving the procurement and use of all sources of licensed material. The information available for review by the committee of a new user is specified on page 24, Safety Evaluations of Proposed Users and Users of the renewal application.

Question #15:

Confirm that the Radiation Safety Committee will develop procedures and criteria for training and testing each category of worker.

Response:

The RSC does not develop procedures and criteria for training and testing each category of worker. The RSO and staff develop these procedures and criteria for comment and approval by the RSC.

Question #16:

Confirm that the Radiation Safety Committee will establish methods for maintaining records of safety evaluations of proposed users and uses of licensed material.

Response:

The RSC is circulated on all routine audits performed by the Health Physics Supervisors. These audits verify approved users are following safety procedures and license requirements.

Question #17:

Please specify the minimum representation which will be required at each Radiation Safety Committee meeting, and the quorum requirement for voting. Confirm that your list of duties and responsibilities of the Radiation Safety Officer will address the following: a) to monitor and maintain absolute and other special filter systems, b) review and determine what radiation protection consulting services may be required, c) ensure the proper receipt, delivery, opening and shipment of radioactive material, d) ensure proper radioactive material storage, e) leak testing program, f) instrument calibration program, g) isotope inventory, h) the RSO can immediately terminate unsafe activities, i) decontamination and recovery operations, and j) the records as required by 10 CFR 30.51

Response:

Each RSC meeting requires a simple majority for a quorum, excluding alternates. There is no minimal representation requirement for a meeting beyond the required quorum.

In addition to the qualifications and responsibilities detailed on pages 7 - 8 of the February 18, 1997 renewal application, the RSO will also address:

- a) Monitoring and maintaining absolute and other filter systems
- b) Review and determine what radiation protection consulting services may be required
- c) Ensure the proper receipt, delivery, and opening and shipment of radioactive materials
- d) Ensure proper radioactive material storage
- e) Maintain leak testing program of sealed sources
- f) Instrument calibration program
- g) Isotope inventory
- h) Immediately terminate unsafe activities
- i) Decontamination and recovery operations
- j) Maintain records required by 10 CFR 30.51

Question #18:

Confirm that the RSO will meet with/report to management and the RSC.

Response:

The RSO has and will continue to meet with and report to management and the RSC regarding licensed activities.

Question #19:

Provide a description of the duties and responsibilities of the radiation safety staff. This should include an assessment regarding staffing levels and qualifications of this support staff. The assessment should be sufficient to demonstrate that the technical staff are adequate to implement, support, and oversee your proposed radiation protection program. If current staffing is not what you consider adequate, a projected timetable when full staffing will be achieved should be included. A projection of future needs would also be useful.

Response:

The duties and qualifications of the Health Physics staff are described in detail on pages 7 - 11 of the February 18, 1997 renewal application. The current staff is technically qualified to implement, support and oversee the radiation protection program. Current staffing levels are adequate.

Question #20:

Describe your program for training and refresher training of all persons who handle licensed material or who frequent areas where licensed material is used. This training program must include a review of emergency procedures and response criteria and include sections that are tailored to various types of radiation and ancillary workers such as authorized users, laboratory supervisors and technicians; incinerator operators, waste compactor operators, and purchasing department personnel receiving licensed material; housekeeping, nursing, security, and other ancillary personnel, and the radiation safety office staff. Confirm that you will maintain records of initial and refresher training, that include a list of topic(s) covered, the amount of time spent and the date, the instructor(s) and student(s) names. The model training program in Appendix I of Regulatory Guide 10.5, Second Proposed Revision 2 (NRC-0005) may be helpful in formulating your response.

Response:

The training program is described in detail on pages 11 - 13 of the February 18, 1997 renewal application. Specific training for various categories of personnel are tailored accordingly to align the topics covered with the department's needs. All initial and refresher training is documented.

Question #21:

Provide a description of the engineered provisions for abnormal operations in which the process systems are intended to provide for the maintenance of primary confinement, protection and control conventional hazards and control of effluents in the event of abnormal occurrences.

Response:

Primary confinement of concentrated solutions of radioactive materials is the purpose of the hot cells and their supporting engineered controls. Access to the interior of the hot cell is interlocked such that the inner door cannot be opened at the same time as the outer door. The ventilation system maintains the hot cell at a constant negative pressure compared to the room pressure. Pressure monitors are installed in each hot cell room and alarm if the hot cells lose pressurization and become positive to the room. The ventilation system is a once through system and is comprised of two parallel redundant filter trains with a fan motor. These filter banks are operated one at a time and are isolated by dampers. If a fan motor or filtration system fails, the second filter train can be manually started to maintain adequate ventilation. The ventilation is supplied with backup electrical power from an on-site generator. In the event of an abnormal occurrence, the hot cell construction and the redundant nature of the ventilation system and power supply provide sufficient confinement of hazardous materials and control of gaseous effluents. Abnormal occurrences resulting in liquid effluents are contained by the holding tank system described on page 14, paragraph 6 of the February 18, 1997 license renewal application.

Question #22:

Provide a description of the intended performance of the alarm systems and equipment provided to prevent releases of hazardous material. Provide a description of the alarm systems intended to alert operators to releases or to otherwise mitigate the consequences of releases. Consider the range of detection of the monitors, the type of alarms, the presence of annunciators, alarm setpoints. Are engineered safety features present to preclude large releases of radioactivity in the event of an accident? Can these engineered safety features be activated both automatically and manually?

Response:

The hot cell negative pressure alarms are discussed above in question #21. Ambient room radiation alarms are discussed on page 14, paragraph 8 of the February 18, 1997 license renewal application. HVAC status is monitored by a panel in the Health Physics Office. This panel indicates which fan motors are currently in operation and alarms if a fan motor fails. Fire alarm panel is also located in the corridor of the first floor of Building 124. This panel monitors the status of all smoke and heat detectors and indicates the location of any alarms. A panel in the south warehouse of Building 124 monitors and controls the holding tank liquid effluent system.

Engineered features that are in place to preclude large releases of radioactivity are summarized in Item #9 of the February 18, 1997 license renewal application. Further detail is given in Question #21 above. These redundant features are always in operation and do not need to be activated in the event of an abnormal occurrence. Specific pieces of equipment (i.e. filter trains, holding tanks) are controlled manually.

Question #23:

Provide a schematic drawing showing the location of the sample cartridge and the stack alarm detector. Paragraph #5 on page 1-8 states: "The radioactivity in the sampler is constantly measured by the stack alarm detector which will sound an alarm in the Health Physics operations area should the integrated activity representing the 24 hour effluent limit for I-131 as specified in Appendix B, Table II, Column I of 10 CFR 20 be exceeded." Provide specific details about the stack alarm detector, and specify whether the alarm setpoint(s) interact with the HVAC system.

Response:

A schematic of the sample cartridge and the stack detector is attached (see Attachment 5). The stack monitor for Building 124 is a Ludlum Model 365 Stack Monitor consisting of two detector assemblies that monitor filters accumulating particulate and gaseous effluents from the stack stream. It is located in the second floor machine room adjacent to the exterior wall. A sample is collected from the stack duct just prior to the stack duct exits the interior of the building. The alarm set points on the stack monitor do not interact with the HVAC system.

Question #24:

Condition I on page 2-2 states: "Remote monitoring detectors located in manufacturing locations would inform Health Physics operational personnel of areas with radiation levels of 50 mR/hr." Describe how these remote monitors interface with the HVAC system.

Response:

The remote monitoring detectors do not monitor the HVAC system nor do they interface with that system. They measure ambient radiation levels in operational work areas.

Question #25:

Item A.3. on page 2-1 describes a scenario where some of the free iodine has a potential to escape to the environment through the cave hallway area and outside door. Provide an estimate of the fraction of the release that might be released from this unmonitored pathway.

Response:

An 8 curie vial containing approximately 1.5 milliliters of sodium iodide is dropped in the hallway outside the hot cell. Approximately 5 curies of sodium iodide is spilled from the vial, 4.5 curies volatilizes in the fire. Approximately 4 curies of this amount is drawn into the air system in the form of smoke and free iodine. The airflow in the area is into the hot cells since they are negative to the hallway. The volatile iodine and smoke is drawn into the hot cell pass through into the ventilation system. Of the remaining 0.5 curies, 90% plates out on the surface in the form of smoke and free iodine. The remaining 0.05 curies migrates into the mechanical area between the ceiling and the second floor, down the hall into the front corridor, and up the hall towards the outside door. The majority (~ 90%) rises to the ceiling due to the heat from the fire. The remaining 45 millicuries is equally split traveling up and down the hallway, plating out as it travels. Approximately 5 millicuries may reach the first of two doors to the environment. These doors are interlocked so that they both cannot be opened at the same time. One millicurie may reach the environment by this pathway for a release fraction of 1.25×10^{-4} . A release to the environment of this type is highly unlikely since all exterior building doors, when opened, would remain negative to the environment.

ATTACHMENTS

1. Bldg. 124 Exhaust Air Flow Study Diagram - South End (D-26984)
2. Bldg. 124 Exhaust Air Flow Study Diagram - North End (D-26985)
3. GRP-31, Mission, Scope, and Major Activities of the Radiation Safety Committee
4. Interoffice Memorandum from the President of Technical Operations
5. Schematic of Bldg. 124 Stack Monitor

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RADIATION SAFETY PROCEDURE

Department: Health Physics		Subject Mission, Scope and Major Activities of the Radiation Safety Committee			
Procedure No: GRP-31	New Procedure <input type="checkbox"/>	Reviewed - No Changes <input type="checkbox"/>	Revised Procedure <input type="checkbox"/>	Replaces Procedure #GRP-31 of 5/13/96	Originator S. Vogt
Reviewed By W. L. McGarry	Approved by Dr. J. L. Hunter H. M. Abdou	Date 5/11/97			Effective Date 5/15/97

I. PURPOSE

The purpose of the procedure is to outline the Mission, Scope and Major Activities of the Central New Jersey Bristol-Myers Squibb Radiation Safety Committee (RSC).

II. RADIATION SAFETY COMMITTEE MISSION AND SCOPE**Mission:**

To protect the radiological health and safety of employees, the public and the environment.

Scope:

The Committee's major responsibilities include the regulation of the procurement, safe use and disposal of all sources of ionizing radiation at the sites specified in licenses issued by the State of New Jersey and the Nuclear Regulatory Commission.

III. MAJOR ACTIVITIES

The major activities of the RSC include, but are not necessarily limited to the following items:

1. Establish and periodically update policy and programs that will maintain radiation doses to all employees and the general public to levels As Low As Reasonably Achievable (ALARA)
2. Approve the procurement and use of all sources of ionizing radiation materials and the users of such materials
3. Ensure that the disposal of radioactive waste meets Federal, State, and local requirements
4. Provide guidance, support and authorization to the Radiation Safety Officer (RSO) in the planning and day administration of the radiation safety program
5. Conduct periodic reviews of the radiation safety program, initiate corrective action based on the findings, verify program implementation and training/retraining of personnel involved with the use of ionizing radiation
6. Review deviations from established procedures and unplanned events to prevent recurrences
7. Meet quarterly, at a minimum
8. Periodically review the member representation of the Committee and formally approve new members. At a minimum, representatives will be the Radiation Safety Officer, a Management representative, and an Administrative member
9. Publish the minutes of each meeting, with copies sent to the current membership roster
10. The periodic review of this radiation safety procedure will be recorded in the Central New Jersey RSC minutes



Bristol-Myers Squibb Company

Pharmaceutical Group

RADIATION SAFETY PROCEDURE

Department: Health Physics		Subject Mission, Scope and Major Activities of the Radiation Safety Committee			
Procedure No. GRP-31	New Procedure <input type="checkbox"/>	Reviewed - No Changes <input type="checkbox"/>	Revised Procedure No. <i>7/15/97</i>	Replaces Procedure #GRP-31 of 8/13/96	Originator S. Vardi
Reviewed By: W. L. McGarry	Approved by: Dr. J. L. Montor <i>J. L. Montor</i> H. M. Abdou <i>H. M. Abdou</i> Date <i>7/15/97</i>				Effective Date 1 1

HISTORY PAGE

1. New procedure.
2. Eliminated "II. Scope"; revised "Radiation Safety Committee Mission and Scope" by removing "listed in Section II above" in the Scope section, added #10 under "Major Activities", describing the recording of the committee review process. Revised 3/28/96
3. Titles changed to replace R. Endries with W. L. McGarry and L. T. De also with H. M. Abdou. Revised 4/1/97



Bristol-Myers Squibb Company

Pharmaceutical Group

ATTACHMENT 4

To Distribution Date March 24, 1994
From L. T. DiFazio CC
Subject RADIATION SAFETY COMMITTEE


The Radiation Safety Committee, presently chaired by Mrs. Susan Voigt, is responsible for establishing Company policy and auditing all Company activities as they relate to the safe use of radiation and radioactive materials at our New Jersey NRC licensed facilities.

I have charged this Committee to uphold the highest standards of safety at Bristol-Myers Squibb. The principles governing their deliberations and decisions are: 1) maintaining employee health and safety; 2) preserving sound environmental controls; and 3) assuring compliance with all governmental regulations.

The Radiation Safety Committee has the authority to approve all uses of radioactive materials and disapprove their use when a potential unsafe condition exists or could exist.

The Health Physics Office, headed by Mr. Dan Balkunow, will carry out the policies of the Radiation Safety Committee and handle all administrative and technical aspects of radiation safety.

Current Radiation Safety Committee members are listed below. I trust you will give the members of this Committee and the Health Physics Office your full cooperation.


L. T. DiFazio
Chairman, Pharmaceutical Group
Environmental Health and
Safety Committee
President, Technical Operations

Radiation Safety Committee.

D. Balkunow	J. Rinchart
H. Bartlett	H. Strauss
R. Endres	C. Today
J. Frankowski	S. Voigt
G. Nicholl	F. Yost

July 20, 1998

Docket No 030-05222
Control No 124288

License No 29-00139-02

Thomas M. Primm
Vice President, Facilities Engineering and Administration
E. R. Squibb & Sons
One Squibb Drive
P. O. Box 191
New Brunswick, NJ 08903-0191

Dear Mr. Primm:

This is in reference to your application dated February 18, 1997 requesting to renew Nuclear Regulatory Commission License No. 29-00139-02. In order to continue our review, we need the following additional information:

1. The following questions are in regard to the present addresses where licensed material will be used or stored:
 - a. Since the submission of your application for renewal of License No. 29-00139-02, three amendments have been issued. These are amendments No. 91, 92, and 93. Amendment No. 91 removed the Convatec site in Stullman, New Jersey from the license. Amendment No. 92 added the Pennington, New Jersey site to the license. Amendment No. 93 added the Hamilton, New Jersey site. To be consistent with the current authorized locations of use, please revise and resubmit item #2 in your application to reflect the deletion of the Convatec site and the addition of the two new locations.
 - b. Please revise and resubmit item #5 and item #6 in your application to reflect the deletion of the Convatec site in Stullman, New Jersey, and add both the Pennington and Hamilton New Jersey sites. For these sites, please specify the byproduct materials to be used, the chemical and physical form of the materials, the maximum possession limits, and the requested authorized uses.
 - c. We have received your letter dated June 19, 1998 in regard to the decommissioning and removal of the Princeton House facility and the other changes requested in the license, and will address these issues in a separate action.

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2 The following questions are in regard to the area radiation monitoring system

- a Item 9 in your application discusses a "built in" area radiation monitoring system. In addition, this section states "Each filter bank is equipped with before and after continuous tubes used to check charcoal filter efficiencies." "They are changed on a routine basis." Your application also states "There is no definite filter change criterion." Please describe the methods you use to determine when the filters in each filter bank are changed.
- b From various sections of the text of your submission, and your postulated emergency scenarios, it appears that you depend on area monitors, the analysis of sample tubes, the response of personnel, and fire activated systems in emergency situations.
 - 1 Provide a schematic diagram of all effluent pathways at each site which includes the identification of the source of the activity, the maximum typical activity at each source, the location of the sampling points in each ventilation pathway, and each contributing and final ventilation flow rates for each pathway.
 - 2 Please describe how your present monitoring program emulates a real-time effluent monitoring system in the timely mitigation of releases from a scenario which does not include a fire in the restricted area.
 - 3 Include an estimate of the time required to quantify a release, and describe the degree of correspondence you have determined between your "built in" area radiation monitors and the present method for sampling releases.
 - 4 Provide the average annual ChvQ values used for each release site and the distance to the maximum exposed individual for each site.
- 3 The second paragraph in the section "Emergency Procedures" states "The ConveTec and Clinical Laboratory facilities have site specific procedures for emergency response." Since the ConveTec facility was removed from the license, is the Clinical Laboratory facility the only remaining facility to have site specific emergency procedures?
- 4 Page 22, paragraph 6 states "Gloves are worn while handling radioactive materials and removed before handling non radioactive materials." Are gloves the only protective apparel used?
- 5 Page 22, paragraphs 12 and 13 discuss surveys and contaminated areas. Paragraph 12 states "Documentation of such surveys will not be required." "All contaminated areas are cleaned and rechecked." If these surveys are not documented, how are all contaminated areas identified so that all contaminated areas are cleaned and rechecked as stated in your application?

T. Primm

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6. Your application does not have specific details for thyroid bioassays. Describe your bioassay program, including the type of bioassay (thyroid counts, urine counts, whole body counts, etc), the criteria and the frequency for performing bioassays, and the type of action taken when positive results are obtained. It is recommended that bioassay procedures be considered for personnel using millicurie quantities of treated organic compounds, Iodine-131, and Iodine-125 in noncontained forms.
7. Your application did not specify the instrument used in your bioassay program for determining activity in the thyroid. Please specify your instrumentation and calibration procedures, including the type of phantom you will use.
8. Specify your criteria for performing internal monitoring which may be required for certain uses of material under your license. Submit a description of procedures, including the methods and instrumentation to be used for sampling and analysis, calibration of equipment, the lower limit of detection for the method and instrumentation, and the action levels for each radionuclide.
9. Your application states "The RSC is informed of regulatory requirements and operating procedures through routine meetings and correspondence with the Health Physics Department. At what frequency does the Radiation Safety Committee (RSC) meet?"
10. Page 24, in your application, item 8, in the section entitled "Safety Evaluations of Proposed Uses and Users" requires that information on the User Form includes, among other things, whether the material will be used in human or animal studies. Please clarify this statement. License No. 29-00139-02 does not authorize use of licensed material in humans or animals. Furthermore, Research and Development, as defined in 10 CFR 30.4, states, in part, "Research and development as used in this part and parts 31 through 35 does not include the internal or external administration of byproduct material, or the radiation therefrom, to human beings."
11. Paragraph 6 on page 25 of your application discusses the use of respiratory protection equipment. Please confirm that your program conforms to 10 CFR 20, Subpart M "Respiratory Protection and Controls to Restrict Internal Exposures in Restricted Areas".
12. Provide a copy of senior management's written statement of delegation of authority to the Radiation Safety Officer. This statement should include the requisite authority to communicate with and direct your personnel regarding NRC regulations and license provisions and to enforce these requirements including the ability to terminate any unsafe operation involving the use of licensed material.
13. Confirm that management will conduct a periodic oversight of the radiation protection program, including interaction with the RSC and RSO.
14. Confirm that the Radiation Safety Committee will conduct safety evaluations of proposed users and uses.

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15. Confirm that the Radiation Safety Committee will develop procedures and criteria for training and testing each category of worker
16. Confirm that the Radiation Safety Committee will establish methods for maintaining records of safety evaluations of proposed users and users of licensed materials
17. Please specify the minimum representation which will be required at each Radiation Safety Committee meeting, and the quorum requirement for voting. Confirm that your list of duties and responsibilities of the Radiation Safety Officer will address the following: a) to monitor and maintain absolute and other special filter systems, b) review and determine what radiation protection consulting services may be required, c) ensure the proper receipt, delivery, opening and shipment of radioactive material, d) ensure proper radioactive material storage, e) leak testing program, f) instrument calibration program, g) isotope inventory, h) the RSO can immediately terminate unsafe activities, i) decontamination and recovery operations, and j) the records as required by 10 CFR 30.51.
18. Confirm that the RSO will meet with report to management and the RSC
19. Provide a description of the duties and responsibilities of the radiation safety staff. This should include an assessment regarding staffing levels and qualifications of the support staff. The assessment should be sufficient to demonstrate that the technical staff are adequate to implement, support, and oversee your proposed radiation protection program. If current staffing is not what you consider adequate, a projected timetable when full staffing will be achieved should be included. A projection of future needs would also be useful.
20. Describe your program for training and refresher training of all persons who handle licensed material or who frequent areas where licensed material is used. This training program must include a review of emergency procedures and response criteria and include sections that are tailored to various types of radiation and ancillary workers such as authorized users, laboratory supervisors and technicians, incinerator operators, waste compactor operators, and purchasing department personnel receiving licensed material, housekeeping, nursing, security, and other ancillary personnel, and the radiation safety office staff. Confirm that you will maintain records of initial and refresher training, that include a list of topic(s) covered, the amount of time spent and the date, the instructor(s) and student(s) names. The model training program in Appendix I of Regulatory Guide 10.5, Second Proposed Revision 2 (DG-0005) may be helpful in formulating your response.
21. Provide a description of the engineered provisions for abnormal operations in which the process systems are intended to provide for the maintenance of primary confinement, protection and control conventional hazards and control of effluents in the event of abnormal occurrences.

T. Primm

8

E. R. Squibb & Sons

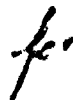
22. Provide a description of the intended performance of the alarm systems and equipment provided to prevent releases of hazardous material. Provide a description of the alarm systems intended to alert operators to releases or to otherwise mitigate the consequences of releases. Consider the range of detection of the monitors, the type of alarms, the presence of annunciators, alarm setpoints. Are engineered safety features present to preclude large releases of radioactivity in the event of an accident? Can these engineered safety features be activated both automatically and manually?
23. Provide a schematic drawing showing the location of the sample cartridge and the stack alarm detector. Paragraph 85 on page 1-8 states: "The radioactivity in the sampler is constantly measured by the stack alarm detector which will sound an alarm in the Health Physics operations area should the integrated activity representing the 24 hour effluent limit for I-131 as specified in Appendix B, Table II, Column I of 10 CFR 20 be exceeded." Provide specific details about the stack alarm detector, and specify whether the alarm setpoint(s) interact with the HVAC system.
24. Condition 1 on page 2-2 states: "Remote monitoring detectors located in manufacturing locations would inform Health Physics operational personnel of areas with radiation levels of 50 mR/hr." Describe how these remote monitors interface with the HVAC system.
25. Item A 3 on page 2-1 describes a scenario where some of the free iodine has a potential to escape to the environment through the cave hallway area and outside door. Provide an estimate of the fraction of the release that might be released from this unmonitored pathway.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control No. 124288. If you have any questions regarding this deficiency letter, please call James M. Bondick at (610) 337-6951.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Original signed by Elizabeth Ulrich



John D. Kinnaman, Chief
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

Enclosures

10 CFR Parts 19, 20, and 30

cc:

Daniel K. Balkunow, Radiation Safety Officer

T. Primm

E. R. Squibb & Sons

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Bristol-Myers Squibb Company

Pharmaceutical Group Technical Operations

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

908 519 2000

97

April 24, 1997

Mr. Keith Brown
US Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406 1415

RE: LICENSE #29 00139 02
MAIL CONTROL #124288

Dear Mr. Brown:

- Currently all NRC correspondence regarding E. R. Squibb & Sons' radioactive material license is being sent to the attention of

Dr. Joseph P. Nirschl
Vice President, US Manufacturing
One Squibb Drive
P.O. Box 191
New Brunswick, NJ 08903 0191

Due to recent organizational changes, all future correspondence regarding license #29 00139-02 should be sent to the attention of:

Mr. Thomas M. Primm
Vice President, Facilities, Engineering and Administration
One Squibb Drive
P.O. Box 191
New Brunswick, NJ 08903 0191

- Currently the text of "Item 7: Individuals Responsible for Radiation Safety Program and Their Training and Experience" of E. R. Squibb & Sons' license application reads as follows:

"Senior management...for licensed activities. This is the responsibility of the Vice President, US Manufacturing;..."

This text should be revised to read as follows:

"Senior management...for licensed activities. This is the responsibility of the Vice President, Facilities, Engineering and Administration;..."

124288

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Mr. Keith Brown
Page 2

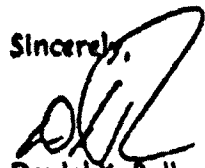
April 24, 1997

The title change should also be reflected in the following section of E. R. Squibb & Sons' license application:

- Page 6, Item #7 A.

Should you have any questions or require additional information please call. I can be reached at 908-519-2451.

Sincerely,



Daniel K. Balkunow
Radiation Safety Officer

DKB:bl

RECEIVED

cc J. Nirschl
T. Primm
H.P. Staff
RSC



Bristol-Myers Squibb Company

Pharmaceutical Group Technical Operations

One Squibb Drive P.O. Box 191 New Brunswick, NJ 08901-0191
908 519 2000

03-05122

April 8, 1997

Mr. Duncan White
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

RE: LICENSE #29-00139 02 -
BRISTOL-MYERS SQUIBB RADIATION SAFETY COMMITTEE CHANGES

Dear Mr. White:

This letter is to inform you of recent changes that have occurred in the Bristol Myers Squibb Radiation Safety Committee. The changes are:

- New Members

Gary R. Matsueda, Ph.D. and Brian J. Gavin, Ph.D. have become members of the Radiation Safety Committee. Included for your records are copies of their resumes.

Sincerely,

Daniel K. Balkunow
Radiation Safety Officer

DKB:bl

Enclosures (2)

cc: B. Gavin*
G. Matsueda*
RSC*

100-001100

*Cover IOM only

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RADIATION SAFETY COMMITTEE

D. Balkunow
H. Bartlett
J. Frankowski
B. Gavin
D. Johnson
G. Matsueda
K. Rinehart
C. Tudey
S. Voigt
C. Woodard
F. Yost

CURRICULUM VITAE

Brian J. Gavin

Date of Birth

Current Address

Telephone

(609) 252-6388 (Bus.)

Education

(b)(6)

Ph.D., Human Genetics
Yale University
New Haven, CT

(b)(6)

M. Phil., Human Genetics
Yale University
New Haven, CT

(b)(6)

B.S., Biology
Muhlenberg College
Allentown, PA

Professional Experience

1997 - present

Head, Genetic Modeling
Bristol-Myers Squibb
Pharmaceutical Research Institute
Department of Cardiovascular Drug Discovery
Princeton, NJ 08543

1996 - 1997

Senior Research Investigator I
Bristol-Myers Squibb
Pharmaceutical Research Institute
Department of Cardiovascular Drug Discovery
Princeton, NJ 08543
Development of transgenic models of cardiac arrhythmias

1993 - 1996

Research Investigator II
Bristol-Myers Squibb
Pharmaceutical Research Institute
Department of Oncology Drug Discovery
Princeton, NJ 08543
Development of novel transgenic mouse models of carcinogenesis

Curriculum Vitae: Brian J. Gavin
Page 2

1991 - 1993

Assistant Fellow (Senior Scientist)
Sandoz Research Institute
Department of Receptor Mechanisms
Sandoz Pharmaceuticals Corporation
East Hanover, NJ 07936
Construction and characterization of high diversity random peptide libraries expressed on the surface of bacteriophage

1989 - 1991

Postdoctoral Research Fellow
Laboratory of Dr. Andrew McMahon
Roche Institute of Molecular Biology
Department of Cell and Developmental Biology
Nutley, NJ 07110
Functional analysis of the Wnt-1/int-1 gene family in mouse mammary gland and fetal development

1984 - 1989

Thesis Research
Dr. David C. Ward
Yale University
Transcriptional control of the mouse parvovirus, MVM

1983 - 1984

Laboratory Rotations
Drs. Bernard Forget and Daniel DiMaio
Yale University

1980 - 1983

Laboratory Technician
Dr. Debra J. Wolgemuth
Columbia University
Molecular analysis of mouse gametogenesis and early development

Teaching Experience

Summer 1987

Co-instructor, "The Impact of Genetics on Today's Society",
Albertus Magnus College, New Haven, CT

Spring 1986

Assistant Discussion Leader, "Medical Genetics",
Yale University School of Medicine

1985

Teaching Assistant, Graduate Student Microcomputer,
Department of Human Genetics, Yale University

Publications

1. Wolgemuth, D.J. and B.J. Gavin "Ultrastructural and Biochemical Characterization of Gene Expression in Follicular Oocytes in Neonatal and Prepubertal Rats" In: Development and Function of the Reproductive Organs, pp. 289-298. Bykov, A.E. and H. Peters, eds. Elsevier Medica, Amsterdam (1981).
2. Wolgemuth, D.J., Givang-Ginsberg, E., Engelmeier, E., Gavin, B.J. and Ponsetto, C. "Separation of Mouse Testis Cells on a Celscp Apparatus and Their Usefulness as a Source of High Molecular Weight DNA or RNA" Gamete Res., 12: 1-10 (1985)

3. Kasher, M.S., Kumar, O., Pittluk, Z., Gavin, B.J. and Ward, D.C. "Identification and Purification of Transcription Factor Proteins Using Defined DNA Probes." In: *Current Communications in Molecular Biology: DNA Probes - Applications in Genetic and Infectious Disease and Cancer*, pp. 101-105. Lerman, L.S., ed. Cold Spring Harbor Laboratory, NY (1986).
4. Ahn, J.K., Gavin, B.J., Kumar, O. and Ward, D.C. "Transcriptional Analysis of Minute Virus of Mice P₃ Promoter Mutants." *J. Virol.* 63: 5425-5439 (1989).
5. Gavin, B.J. and Ward, D.C. "Positive and Negative Regulation of the Minute Virus of Mice P₃ Promoter." *J. Virol.* 64: 2057-2063 (1990).
6. Gavin, B.J., McMahon, J.A. and McMahon, A.P. "Expression of Multiple Novel *Wnt-1/int-1*-related genes during Fetal and Adult Mouse Development." *Genes & Dev.* 4: 2319-2332 (1990).
7. Christian, J.L., Gavin, B.J., McMahon, A.P. and Moon, R.T. "Isolation of cDNAs Partially Encoding Four *Xenopus Wnt-1/int-1* Related Proteins and Characterization of Their Transient Expression during Embryonic Development." *Dev. Biol.* 143: 230-234 (1991).
8. Gavin, B.J. and McMahon, A.P. "Differential Regulation of the *Wnt-1/int-1* Gene Family During Pregnancy and Lactation Suggests a Role in Normal Mammary Gland Growth." *Mol. Cell. Biol.* 12: 2418-2423 (1992).
9. McMahon, A.P., Gavin, B.J., Parr, B., Bradley, A. and McMahon, J. "The *Wnt*-family of Cell Signaling Molecules in Post-implantation Development of the Mouse." In: *CIBA Foundation Symposia* 165, pp. 199-218. Wiley and Sons, Chichester (1992).
10. Gavin, B.J. and McMahon, A.P. "Cloning of Developmentally Regulated Gene Families using Degenerate PCR." *Methods in Enzymology* 225: 653-663 (1993).
11. Zimmerman, L., Lendahl, U., Cunningham, M., McKay, R., Parr, B., Gavin, B., Mann, J., Vassileva, G., and McMahon, A. "Independent Regulatory Elements in the Nestin Gene Direct Transgene Expression to Neural Stem Cells or Muscle Precursors." *Neuron*, 12: 11-24 (1994).
12. Wong, G.T., Gavin, B.J., and McMahon, A.P. "Differential Transformation of Mammary Epithelial Cells by *Wnt* Genes." *Mol. Cell. Biol.* 14: 6278-6286 (1994).
13. Gavin, B.J., Gao, J., Andahazy, M.L., Dhamija, S., Seizinger, B.R. and Kley, N. "Targeted Inactivation of the Mouse von Hippel-Lindau Disease Gene results in Mid-Gestational Embryonic Lethality". Submitted for Publication.

Patents

1. Gavin, B.J., Gao, J., Kley, N. and Seizinger, B.R. "Mice Deficient in the von Hippel-Lindau Gene". Application Submitted (1996).

CURRICULUM VITAE

Name Gary R. Matsueda

Address

Date of Birth

Place of Birth

Education

(b)(6)

B.S. Chemistry, University of California, Berkeley
Ph.D. Biochemistry, University of Hawaii, Manoa

*Exemption 6
PII
TJH*

Employment

1971-73

1973-76

UNIVERSITY OF COLORADO SCHOOL OF MEDICINE, Denver
National Institutes of Health Postdoctoral Fellow
Instructor, Department of Biochemistry.

1976-77

1977-80

1980-86

1986-89

HARVARD MEDICAL SCHOOL, Boston, Massachusetts
Research Fellow in Medicine,
Instructor in Pathology
Assistant Professor of Pathology
Associate Professor of Pathology

1976-78

1978-88

1989

MASSACHUSETTS GENERAL HOSPITAL, Boston
Research Fellow in Medicine
Assistant in Biochemistry
Associate in Biochemistry

1989-94

PRINCETON UNIVERSITY, Princeton, New Jersey
Visiting Biologist, Department of Biology

1989-96

1996-

BRISTOL-MYERS SQUIBB PHARMACEUTICAL
RESEARCH INSTITUTE, Princeton, New Jersey
Director/Sr. Res. Fellow, Macromolecular Structure
Sr. Res. Fellow, Cardiovascular Drug Discovery

Memberships

American Chemical Society
American Association for the Advancement
of Science
American Society for Biochemistry and Molecular Biology

Major Research Interests

Fibrinolysis and Thrombosis
Chemical synthesis of peptides
Immunochemistry

Publications

ORIGINAL REPORTS

1. Benson A, Tomoda K, Chang J, Matsueda G, Lode ET, Coon MJ, Yasunobu KT. Evolutionary and phylogenetic relationships of rubredoxin-containing microbes. *Biochem Biophys Res Commun* 1971;42:640-646.
2. Tanaka M, Hantu M, Matsueda G, Yasunobu KT, Himes RH, Akagi JM, Barnes EM, Devanathan T. The primary structure of the *Clostridium tartarivorum* ferredoxin, a heat-stable ferredoxin. *J Biol Chem* 1971;246:3953-3960.
3. Tanaka M, Hantu M, Matsueda G, Yasunobu KT, Mayhew S, Massey V. Amino- and carboxyl-terminal amino acid sequences of the *Peptostreptococcus avident* and *Clostridium pasteurianum* flavodoxins. *Biochemistry* 1971;10:3041-3046.
4. Wingard M, Matsueda G, Wolfe RS. Myxobacter AL-1 protease II: Specific peptide bond cleavage on the amino side of lysine. *J Bacteriol* 1972;112:940-949.
5. Cann JR, Stewart JM, Matsueda GR. A circular dichroism study of the secondary structure of bradykinin. *Biochemistry* 1973;12:3780-3788.
6. Stewart JM, Freer RJ, Rezende L, Pena C, Matsueda GR. A pharmacological study of the angiotensin receptor and tachyphylaxis in smooth muscle. *Gen Pharmacol* 1976;7:177-183.
7. Pulg MM, Gascon P, Craviso GL, Bjur RA, Matsueda G, Stewart JM, Musacchio JM. The effect of enkephalin and enkephalin analogs on the guinea-pig ileum and rat brain opiate receptor. *Arch Int Pharmacodyn Ther* 1977;226:69-80.
8. Ehrlich PH, Matsueda GR, Margolies MN, Haber E. Preparation of an active Fd fragment by cyanogen bromide cleavage of an IgG heavy chain from a homogeneous rabbit antibody. *Immunochemistry* 1978;15:937-940.
9. Matsueda GR, Margolies MN. Increased efficiency in solid-phase Edman degradation of synthetic peptidyl-resins using an oxymethylphenylacetamidomethyl-linkage. *FEBS Lett* 1979;106:89-92.
10. Ehrlich PH, Matsueda GR, Haber E, Margolies MN. Isolation and characterization of an active variable domain from a homogeneous rabbit antibody light chain. *Biochemistry* 1979;18:4411-4418.
11. Matsueda GR, Haber E. The use of an internal reference amino acid for the evaluation of reactions in solid-phase peptide synthesis. *Anal Biochem* 1980;104:215-227.
12. Ehrlich PH, Matsueda GR, Margolies MN, Husain SS, Haber E. Isolation of an active heavy-chain variable domain from a homogeneous rabbit antibody by cathepsin B digestion of the aminoethylated heavy chain. *Biochemistry* 1980;19:4091-4096.
13. Matsueda GR, Haber E, Margolies MN. Quantitative solid-phase Edman degradation for the evaluation of extended solid-phase peptide synthesis. *Biochemistry* 1981;20:2471-2480.

14. Matsueda GR, Stewart JM. A p-methylbenzhydrylamine resin for improved solid-phase synthesis of peptide amides. *Peptides* 1981;2:45-50.
15. Matsueda R, Kimura T, Kaiser ET, Matsueda GR. 3-Nitro-2-pyridinesulfonyl group for protection and activation of the thiol function of cysteine. *Chem Lett* 1981;737-740.
16. Gashde SA, Matsueda GR. Synthesis of N-tert-butoxycarbonyl-(α -phenyl)aminomethylphenoxycetic acid for use as a handle in solid-phase synthesis of peptide α -carboxamides. *Int J Pept Protein Res* 1981;18:451-458.
17. Katus HA, Hurrell JG, Matsueda GR, Enrich P, Zurewski VR Jr, Khew BA, Haber E. Increased specificity in human cardiac-myosin radioimmunoassay utilizing two monoclonal antibodies in a double sandwich assay. *Mol Immunol* 1982;19:451-455.
18. Ridge RJ, Matsueda GR, Haber E, Matsueda R. Sulfur protection with the 3-nitro-2-pyridine sulfonyl group in solid-phase peptide synthesis. *Int J Pept Protein Res* 1982;19:490-498.
19. Matsueda GR. Deprotection of Nin-formyl tryptophan using 1,2-ethanedithiol in liquid hydrogen fluoride. Deformylation upon HF treatment of Merrifield peptidyl-resins. *Int J Pept Protein Res* 1982;20:26-34.
20. Pacella BL Jr, Hul KY, Haber E, Matsueda GR. Induction of fibrin-specific antibodies by immunization with synthetic peptides that correspond to amino termini of thrombin cleavage sites. *Mol Immunol* 1983;20:521-527.
21. Young JD, Costello CE, Van Langenhove A, Haber E, Matsueda GR. Synthesis of a cyclic fibrin-like peptide and its analysis by fast atom bombardment mass spectrometry. *Int J Pept Protein Res* 1983;22:374-380.
22. Nussberger J, Matsueda GR, Re R, Haber E. Selectivity of angiotensin II antisera. *J Immunol Meth* 1983;56:85-96.
23. Hul KY, Haber E, Matsueda GR. Monoclonal antibodies to a synthetic fibrin-like peptide bind to human fibrin but not fibrinogen. *Science* 1983;222:1129-1132.
24. Nussberger J, Re R, Matsueda GR, Haber E. A simplified radioimmunoassay for physiologically active angiotensin peptides [(1-8) octa- and (2-8) heptapeptides]. *Horm Metab Res* 1984;16:606-610.
25. Nussberger J, Mudgett-Hunter M, Matsueda G, Haber E. A monoclonal antibody specific for the carboxy-terminus of angiotensin II. *Hybridoma* 1984;3:373-376.
26. Steiman DM, Ridge RJ, Matsueda GR. Synthesis of side chain-protected amino acid phenylthiohydantams and their use in quantitative solid-phase Edman degradation. *Anal Biochem* 1985;145:91-95.

27. Nussberger J, Matsueda G, Re RN, Haber E. Recognition of peptide orientation: Studies with angiotensin II in the guinea-pig. *Mol Immunol* 1985;22:619-621.
28. Bode C, Matsueda GR, Hui KY, Haber E. Antibody-directed urokinase: A specific fibrinolytic agent. *Science* 1985;229:765-767.
29. Allen PM, Matsueda GR, Haber E, Unanue ER. Specificity of the T cell receptor: Two different determinants are generated by the same peptide and the I-Ak molecule. *J Immunol* 1985;135:368-373.
30. Hui KY, Haber E, Matsueda GR. Immunodetection of human fibrin using monoclonal antibody-64C5 in an extracorporeal chicken model. *Thromb Haemostasis* 1985;54:524-527.
31. Babbitt BP, Allen PM, Matsueda G, Haber E, Unanue ER. Binding of immunogenic peptides to Ia histocompatibility molecules. *Nature* 1985;317:359-361.
32. Bernalowicz MS, Matsueda GR. The N-hydroxysuccinimide ester of Boc-[S-(3-nitro-2-pyridinesulfonyl)]-cysteine: A heterobifunctional cross-linking agent. *Biochem Biophys Res Commun* 1985;132:1046-1050.
33. Bloch KD, Scott JA, Zisfein JB, Fallon JT, Margolies MN, Seidman CE, Matsueda GR, Homcy CJ, Graham RM, Seidman JG. Biosynthesis and secretion of proatrial natriuretic factor by cultured rat cardiocytes. *Science* 1985;230:1168-1171.
34. Fluckiger JP, Waeber B, Matsueda G, Delabroye B, Nussberger J, Brunner HR. Effect of atriopeptin III on hemolysis and volume of nephrectomized rats. *Am J Physiol* 1986;251:H880-883.
35. Babbitt BP, Matsueda G, Haber E, Unanue ER, Allen PM. Antigenic competition at the level of peptide-Ia binding. *Proc Natl Acad Sci USA* 1986;83:4509-4513.
36. Bernalowicz MS, Matsueda R, Matsueda GR. Preparation of Boc-[S-(3-nitro-2-pyridinesulfonyl)]-cysteine and its use for unsymmetrical disulfide bond formation. *Int J Pept Protein Res* 1986;28:107-112.
37. Hui KY, Haber E, Matsueda GR. Monoclonal antibodies of predetermined specificity for fibrin: A rational approach to monoclonal antibody production. *Hybridoma* 1986;5:215-222.
38. Matsueda GR, Margolies MN. Structural basis for the species selectivity of a fibrin-specific monoclonal antibody. *Biochemistry* 1986;25:1451-1455.
39. Bernalowicz MS, Matsueda GR. Preparation of peptide-protein immunogens using N-succinimidyl bromoacetate as a heterobifunctional crosslinking reagent. *Anal Biochem* 1986;155:95-102.
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- and regulation of its biosynthesis with volume depletion. *J Mol Cell Cardiol* 1986;18:917-929.
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44. Runge MS, Bode C, Matsueda GR, Haber E. Antibody-enhanced thrombolysis: Capture of tissue plasminogen activator by a bispecific antibody and direct targeting by an antifibrin-tissue plasminogen activator conjugate in vivo. *Trans Assoc Am Physicians* 1987;100:250-255.
45. Runge MS, Bode C, Matsueda GR, Haber E. Antibody-enhanced thrombolysis: Targeting of tissue plasminogen activator in vivo. *Proc Natl Acad Sci USA* 1987;84:7659-7662.
46. Allen PM, Matsueda GR, Evans RJ, Dunbar JB Jr, Marshall GR, Unanue ER. Identification of the T-cell and Ia contact residues of a T-cell antigenic epitope. *Nature* 1987;327:713-715.
47. Bode C, Runge MS, Newell JB, Matsueda GR, Haber E. Thrombolysis by a fibrin-specific antibody Fab'-urokinase conjugate. *J Mol Cell Cardiol* 1987;19:335-341.
48. Llau CS, Haber E, Matsueda GR. Evaluation of monoclonal antifibrin antibodies by their binding to human blood clots. *Thromb Haemost* 1987;57:49-54.
49. Bode C, Runge MS, Newell JB, Matsueda GR, Haber E. Characterization of an antibody-urokinase conjugate. A plasminogen activator targeted to fibrin. *J Biol Chem* 1987;262:10819-10823.
50. Schnee JM, Runge MS, Matsueda GR, Hudson NW, Seldman JO, Haber E. Quaternary T. Construction and expression of a recombinant antibody-targeted plasminogen activator. *Proc Natl Acad Sci USA* 1987;84:6904-6908.
51. Fluckiger JP, Waeber B, Nussberger J, Matsueda G, Brunner HR. Effect of indomethacin and propranolol on the blood pressure and renin response to atriopeptin III in conscious rats. *Regul Pept* 1987;17:277-284.
52. Vieira JG, Federico P, Matsueda G, Neer RM. Monoclonal antibodies to bovine parathyroid hormone: Production and characterization. *Braz J Med Biol Res* 1988;21:1005-1011.
53. Nawroth P, Handley D, Matsueda G, De Waal R, Gertach H, Blohm D, Stern D. Tumor necrosis factor/cachectin-induced intravascular fibrin formation in meth A fibrosarcomas. *J Exp Med* 1988;168:637-647.

54. Charpie JR, Haber E, Matsueda GR. A sequence-dependent monoclonal antibody specific for single-chain urokinase. *Biochem Biophys Res Commun* 1988;152:910-915.
55. Fischman AJ, Wildey GM, Matsueda GR, Margolies MN, Zisfein JB, Homcy CJ, Graham RM. Specificity of serine proteases for cleavage sites on proatrial natriuretic factor. *Peptides* 1988;9:1275-1283.
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57. Reed GL III, Matsueda GR, Haber E. Acceleration of plasma clot lysis by an antibody to α_2 -antiplasmin. *Trans Assoc Am Physicians* 1988;101:250-256.
58. Runge MS, Bode C, Matsueda GR, Haber E. Conjugation to an antifibrin monoclonal antibody enhances the fibrinolytic potency of tissue plasminogen activator in vitro. *Biochemistry* 1988;27:1153-1157.
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Joseph P. Haeckl, Ph.D.
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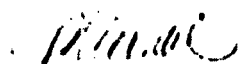
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LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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 I
101 MARSHALL STREET NW, SUITE 300
ATLANTA, GA 30333-0100

IF YOU ARE LOCATED IN

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION REGION II
801 WASHINGTON ST.
LAKE E. GENEVE, IL 60155-4101

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

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION REGION IV
811 BYAN PLACE DRIVE, SUITE 400
MILWAUKEE, WI 53211-0000

030-05222
X

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 box) <input type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input checked="" type="checkbox"/> C. RENEWAL OF LICENSE NUMBER <u>29-00119-02</u>		2. NAME AND MAILING ADDRESS OF APPLICANT (Include full name) E. R. Squibb & Sons One Squibb Drive P.O. Box 191 New Brunswick, NJ 08903-0191	
3. ADDRESS IN WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED See Item 3) in attachment		4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION Mr. Daniel K. Balkunow TELEPHONE NUMBER 908-519-2451	
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 symbol; physical form and c. maximum amount which will be possessed at any one time		6. PURPOSES 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. LICENSE FEES (See 10 CFR 170.10 and Section 170.20) FEE CATEGORY <u>3A</u> AMOUNT ENCLOSED \$550.00	
13. CERTIFICATION (Must be completed by signing the applicant UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. 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, 30.34, 30.36, 30.38 AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 10 U.S.C. SECTION 1001 ACT OF JUNE 26, 1948 IS 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 - TYPEPRINTED NAME AND TITLE Joseph P. Nirschl, Ph.D., VP US Manufacturing		SIGNATURE <u>[Signature]</u> DATE <u>2-18-97</u>	
FOR NRC USE ONLY			
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED
			\$
APPROVED BY	DATE	124288	

NRC LICENSE RENEWAL APPLICATION - 2/18/97
#29-00139-02

Item #1: Application

Renewal of License #29-00139-02

Item #2: Name and Mailing Address

E. R. Squibb & Sons
One Squibb Drive
P.O. Box 191
New Brunswick, NJ 08903

Item #3: Addresses where licensed material will be used or possessed:

- A. E. R. Squibb & Sons***
One Squibb Drive
P. O. Box 191
New Brunswick, NJ 08903-0191
- B. E. R. Squibb & Sons**
Route 206 & Provinceline Road
Lawrenceville, NJ
P. O. Box 4000
Princeton, NJ 08543-4000
- C. E. R. Squibb & Sons**
Bristol-Myers Squibb Clinical Laboratory
905 Hemmantown Road
Princeton, NJ 08540
- D. ConvaTec***
200 Headquarters Park Drive
Skillman, NJ 08558

***A wholly-owned subsidiary of Bristol-Myers Squibb Company**

Item #4: Contact Person

Mr. Daniel K. Balkunow
Radiation Safety Officer/Department Head - Health Physics
(908) 519-2451

Items #5 and #6: Possession Limits for the Lawrenceville Site, Rt. 206 & Princelina Road, Princeton, NJ 08540

5A. Byproduct, Source, and/or Specific Nuclear Material	5B. Chemical and/or Physical Form	5C. Max. Amount that licensee may possess at any 1 time	6. Authorized Use
Any byproduct material with Atomic Nos. 1 - 83 except Strontium 90	Any	200 millicuries per radionuclide and 6 curies total	Research and development as defined in 10 CFR 30.4
Hydrogen 3	Any	6 curies	Research and development as defined in 10 CFR 30.4; Manufacture of labelled compounds intended for human use and transfer of the compounds to individuals authorized to receive the material by the terms and conditions of a specific license issued by the USNRC or an Agreement State.
Carbon 14	Any	4 curies	Same as Hydrogen 3
Phosphorous 33	Any	1 curie	Research and development as defined in 10 CFR 30.4
Sulfur 35	Any	1 curie	Research and development as defined in 10 CFR 30.4
Molybdenum 99/ Technetium 99m	Any	5 curies	Research and development as defined in 10 CFR 30.4
Iodine 125	Any	500 millicuries	Research and development as defined in 10 CFR 30.4
Iodine 131	Any	500 millicuries	Research and development as defined in 10 CFR 30.4
Technetium 99	Any	500 millicuries	Research and development as defined in 10 CFR 30.4
Nickel 63	Plated sources in detector cells	not to exceed 15 millicuries per source and 750 millicuries total	Research and development as defined in 10 CFR 30.4

Items #5 and #6: Possession Limits for the Bristol-Myers Squibb Clinical Laboratory Site, 805 Hamontown Road, Princeton, NJ 08540

5A. Byproduct, Source, and/or Specific Nuclear Material	5B. Chemical and/or Physical Form	5C. Max. Amount that licensee may possess at any 1 time	6. Authorized Use
Any byproduct material with Atomic Nos. 1 - 83 except Strontium 90	Any	Not to exceed 10 millicuries per radionuclide and 1 curie total	Research and development as defined in 10 CFR 30.4
Hydrogen 3	Any	100 millicuries	Research and development as defined in 10 CFR 30.4
Carbon 14	Any	100 millicuries	Research and development as defined in 10 CFR 30.4
Sulfur 35	Any	300 millicuries	Research and development as defined in 10 CFR 30.4
Phosphorous 32	Any	100 millicuries	Research and development as defined in 10 CFR 30.4
Phosphorous 33	Any	200 millicuries	Research and development as defined in 10 CFR 30.4
Iodine 125	Any	50 millicuries	Research and development as defined in 10 CFR 30.4
Nickel 63	Plated sources in detector cells	Not to exceed 15 millicuries per source and 750 millicuries total	Research and development as defined in 10 CFR 30.4

NRC License Renewal Application - 2/18/97 - #29-00139-02

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Items #5 and #6: Possession Limits for the ConvaTec Site, 200 Headquarters Park Drive, Skillman, NJ 08558

5A. Byproduct, Source, and/or Specific Nuclear Material	5B. Chemical and/or Physical Form	5C. Max. Amount that licensee may possess at any 1 time	6. Authorized Use
Any byproduct material with Atomic Nos. 1 - 83 except Strontium 90	Any	Not to exceed 10 millicuries per radionuclide and 1 curie total	Research and development as defined in 10 CFR 30.4
Hydrogen 3	Any	50 millicuries	Research and development as defined in 10 CFR 30.4
Carbon 14	Any	50 millicuries	Research and development as defined in 10 CFR 30.4
Iodine 125	Any	50 millicuries	Research and development as defined in 10 CFR 30.4
Nickel 63	Plated sources in detector cells	Not to exceed 15 millicuries per source and 750 millicuries total	Research and development as defined in 10 CFR 30.4

Items #5 and #6: Possession Limits for the New Brunswick Site, 1 Squibb Drive, New Brunswick, NJ 08903

5A. Byproduct, Source, and/or Specific Nuclear Material	5B. Chemical and/or Physical Form	5C. Max. Amount that licensee may possess at any 1 time	6. Authorized Use
Any byproduct material with Atomic Nos. 1-83 except Strontium 90	Any	5 Curies per radionuclide and 1000 Curies total	<ol style="list-style-type: none"> 1. Research and development as defined in 10 CFR 30.4 2. For possession, use and processing incident to the manufacture of radiochemicals and radiopharmaceuticals 3. For storage prior to distribution of manufactured radiochemicals and radiopharmaceuticals 4. For packaging and distribution of manufactured radiochemicals and radiopharmaceuticals to persons authorized to receive the licensed material pursuant to the terms and conditions of a specific license issued by the Nuclear Regulatory Commission or an Agreement State
Iodine 131	Any	150 Curies	Same as 1-4 above
Hydrogen 3	Any	20 Curies	Research and development as defined in 10 CFR 30.4; Manufacture of labelled compounds intended for human use and transfer of the compounds to individuals authorized to receive the material by the terms and conditions of a specific license issued by the USNRC or an Agreement State.
Carbon 14	Any	20 Curies	Same as Hydrogen 3
Sulphur 35	Any	10 Curies	Research and development as defined in 10 CFR 30.4; calibration of instruments
Strontium 90	Any	2 millicuries	For interim storage of waste returned from a processor, calibration of instruments
Any byproduct material with Atomic Nos. 84-103	Any	1 millicurie	For interim storage of waste returned from a processor
Nickel 63	Plated Sources in detector cells	Not to exceed 15 millicuries per source and 750 millicuries total	Research and development as defined in 10 CFR 30.4, calibration of instruments

Item # 7: Individuals Responsible for Radiation Safety Program and Their Training and Experience

An optimum level of performance in radiation protection is accomplished by the establishment of high radiological protection standards by senior management, by communicating these standards to personnel involved in manufacturing and research, by providing sufficient resources to the Health Physics Department to implement these standards, and by holding all personnel accountable for their performance in radiological protection

Senior management establishes radiological protection policies for licensed activities. This is the responsibility of the Vice President, US Manufacturing; Vice President, Administration and Finance, PRI; and Senior Director, Pharmaceutical Group Environmental Health & Safety (PG/EHS). In addition to this managerial control, a Radiation Safety Committee (RSC) has been established to ensure development of radiation protection policy and implementation of the Radiation Protection Program. Ms. Susan Voigt, the Senior Director PG/EHS is the chair of the RSC. The scope and mission of the RSC is outlined in an operating procedure that is endorsed by Pharmaceutical Group Technical Operations senior management. Membership of the RSC consists of, but is not limited to, the Radiation Safety Officer (RSO), the chairperson, and representation from Administration, Facilities, Manufacturing, Research & Development (R&D), and EHS. A simple majority of current RSC members, excluding alternates, is required for a quorum. The current membership of the RSC and their respective resumes are included in Addendum III of this application.

The responsibility for management of the Radiation Protection Program and the day to day coordination of all radiological related activities lies with the RSO, who reports to the Director, Environmental Health & Safety, PRI. To assist in the administration of radiological activities and to implement the program, the RSO, who is also the Health Physics Department Head, has a staff of supervisors and technicians for carrying out the related Health Physics functions. An organizational chart is included in Addendum III.

Specific radiation protection responsibilities for each position described above are as follows:

- A. The Vice President, US Manufacturing, Vice President, Administration and Finance, PRI, and Senior Director, PG/EHS are responsible for
 - 1. Ensuring sufficient facilities and equipment are provided to effectively manage the radiation protection program and to evaluate radiological conditions in all areas where radioactive materials and radiation producing machines are in use
 - 2. Ensuring sufficient personnel are provided to effectively implement the Radiation Protection Program.
 - 3. Ensuring appropriate responses are made to Nuclear Regulatory Commission (NRC) and New Jersey State inquiries or inspections
- B. The Director of Environmental Health & Safety, PRI is responsible for
 - 1. Ensuring the senior management is cognizant of all Health Physics operations
 - 2. Providing the liaison between the Health Physics Group and the senior management
 - 3. Providing direction and supervision to the Radiation Safety/Department Head of Health Physics
 - 4. Reporting to the senior management on all aspects of the Health Physics program

C. The Radiation Safety Committee is responsible for:

1. Establishing and periodically updating policy and programs that will maintain radiation doses to all employees and the general public to levels As Low As Reasonably Achievable (ALARA).
2. Approving the procurement and use of all sources of ionizing radiation materials and the users of such materials.
3. Ensuring that the disposal of radioactive waste meets Federal, State, and local requirements.
4. Providing guidance, support and authorization to the RSO in the planning and daily administration of the radiation safety program.
5. Conducting annual reviews of the radiation safety program, initiating corrective action based on the findings, verifying program implementation and training/retraining of personnel involved with the use of ionizing radiation.
6. Reviewing deviations from established procedures and unplanned events to prevent recurrences.
7. Meeting quarterly, at a minimum.
8. Periodically reviewing the member representation of the Committee, and formally approving new members. At a minimum, representatives will be the RSO, a Management representative, and an Administrative member.
9. Publishing the minutes of each meeting, with copies sent to the current membership roster.

D. Health Physics Department

1. Radiation Safety Officer/Health Physics Department Head

The Radiation Safety Officer/Health Physics Department Head is currently Daniel K. Balkunow, who, by virtue of education and experience in Health Physics is qualified to oversee the functions of the Health Physics Department. Mr. Balkunow's résumé is included in Addendum III of this application. The Health Physics Department Head maintains his qualifications by keeping abreast of current developments in the field of Health Physics, by attendance at professional meetings, refresher training courses, and review and study of articles published in professional journals of Health Physics. He oversees the development and the conduct of the training and refresher training course for all personnel throughout the manufacturing, production and R&D facilities. In addition, this individual ensures emergency response training is provided.

The Health Physics Department Head is knowledgeable of all the facility systems used for manufacturing and handling radioactive materials. This individual is familiar with the design parameters and capabilities of these systems and conducts design reviews and makes recommendations for all new facilities and modifications to older facilities that may affect the operation or release of radioactive materials to the environment. The Radiation Safety Officer/Department Head of Health Physics is responsible for:

- a. Ensuring compliance with all applicable regulations of the NRC, the State of New Jersey, and the conditions of all licenses.
- b. Managing the implementation of all aspects of the radiation protection program
- c. Ensuring there is adequate staff to perform all radiation protection tasks.
- d. Preparing or reviewing safety evaluations prepared by members of his staff of all proposed uses of radioactive materials.
- e. Temporarily approving new uses and users of radioactive materials for requests of less than ten millicuries of total activity. This approval is valid for ninety days and contingent upon final approval of the RSC.
- f. Ensuring procedures are prepared for conducting selected aspects of the radiation protection program.
- g. Administering the radioactive waste disposal program
- h. Administering the radiological training program for all occupational radiation workers
- i. Ensuring the ALARA principles are incorporated into the radiation protection program.
- j. Administering the contingency plan and conducting exercises as required
- k. Ensuring contingency plan off-site support services personnel are adequately trained.

2. Health Physics Supervisors

Health Physics Supervisors are professionals who are qualified by education and/or experience to perform their duties. The minimum education and experience requirements of the Health Physics management staff are:

- A college degree and/or equivalent training and experience in the physical or biological sciences, or in engineering.
- A minimum of (40) hours of training in the occupational and environmental radiation protection.
- A minimum of (4) four years of experience in the safe handling and/or management of radioactive materials. Handling and management could include but is not necessarily limited to the following activities:
 1. Operational Health Physics
 2. Radioactive Waste Management
 3. Research and Development
 4. Production and/or Distribution of Radiopharmaceuticals

All of the current Health Physics management staff meet the above criteria. These individuals assist the Radiation Safety Officer in all day-to-day activities essential for the administration of the Type A Broad Scope License. An organizational chart of the current Health Physics staff is attached (See Addendum III). The supervisors have experience in the operation of all counting equipment used for evaluating radiological conditions and provide training to the technicians in the operation of this equipment. They have performed the survey and sampling functions for which they provide this training. In addition they possess the theoretical background pertinent to the operation and capabilities of the equipment. The supervisors have experience in the use of computers for the maintenance of personnel dosimetry and other Health Physics records.

The Health Physics management staff maintain their qualifications by attending professional meetings and refresher training courses and reviewing related articles in professional journals. They develop and conduct training for all manufacturing, research and development, contractors and ancillary personnel. They also assist in the development and conduct emergency response training. The Health Physics Supervisors are responsible for.

- a. Supervising the day to day activities of the radiation protection program.
- b. Supervising and evaluating the performance of the radiation protection technicians.
- c. Conducting training of all potential users of radiation or radioactive materials.
- d. Evaluating potential uses of radioactive materials for safety and ALARA considerations.
- e. Ensuring survey instruments are calibrated as necessary.
- f. Maintaining an inventory of radioactive materials to ensure license limits are not exceeded.
- g. Ensuring bioassays are performed on personnel as required.
- h. Ensuring personnel monitoring is provided as necessary to all personnel entering high or very high radiation areas or who work with radioactive materials and are likely to receive a dose in excess of ten (10 %) percent of any applicable limit.
- i. Maintaining records associated with the radiation protection program.
- j. Evaluating any unusual exposures or conditions involving radioactive materials.
- k. Preparing reports for submittal to the regulatory agencies as required.
- l. Auditing all facilities and users of radioactive materials for compliance with procedures and regulations.
- m. Evaluating the use of radiation producing machines for radiological safety.
- n. Ensuring radiation producing machines are registered as required.
- o. Ensuring all areas containing radiation or radioactive materials are properly posted or available.
- p. Ensuring all notices to employees required to be posted by the regulations are posted.

- q. Preparing and reviewing procedures for the conduct of the radiation protection program.
- r. Ensuring all laboratory equipment is appropriate for the task and the equipment is properly calibrated.
- s. Ensuring the radiation protection technicians are trained for the job functions they will perform.
- t. Maintaining current their knowledge of the regulations, license conditions, and Health Physics concepts.
- u. Ensuring the proper storage and control of radioactive materials.
- v. Administering the procurement and receipt program for radioactive materials, including temporarily approving new uses and users of radioactive materials for requests of less than ten millicuries of total activity. This approval is valid for ninety days and contingent upon final approval by the RSC.
- w. Evaluating the radiation exposure records as needed to maintain doses ALARA
- x. Evaluating equipment and facilities such as glove boxes and fume hoods to ensure their acceptability for the quantities and kinds of radioactive materials that will be used within.
- y. Conducting and participating in emergency exercises.
- z. Ensuring sealed source leak tests are performed on schedule.

3. Health Physics Technicians

Upon appointment to the position of Health Physics Technician, they are required to qualify in that position within a specified time period. They are required to demonstrate proficiency in the performance of the necessary functions for that job category. Those individuals who have been in the position for some time received training through a laboratory training program which qualified them in the various aspects of Health Physics. The newer Health Physics technicians are required to possess an AA degree in science or technology. In addition to the refresher training that all personnel receive on an annual basis the technicians receive specific training in the performance of their functions. This specific training is conducted by the Health Physics Supervisors. Additional training may be provided by outside consultants on specific topics in Health Physics. The Health Physics Technicians are responsible for:

- a. Performing all functions as directed by Health Physics supervision.
- b. Making routine and special radiation surveys as required by procedures and/or as directed by the RSO and/or Health Physics Supervisors.
- c. Making routine and special smear surveys for contamination as required by procedures and/or as directed by the RSO and/or Health Physics Supervisors.
- d. Taking routine and special air samples as required by procedures.
- e. Counting samples on laboratory equipment as required.

- f. Bringing to the attention of Health Physics supervision any unusual conditions pertaining to radiological safety.
- E. The Supervisors of the Radiopharmaceutical Production facility and their management are responsible for:
1. Ensuring all personnel working in his or her department abide by the Health Physics rules and regulations.
 2. Enforcing the Health Physics requirements.
 3. Ensuring all personnel are cognizant of the policies established by the RSC.
- F. Research Scientists and their management are responsible for:
1. Ensuring all assistant or associate scientists are aware of the limitations regarding the quantities of radioactive materials with which they may work.
 2. Ensuring the segregation and minimization of waste as required by Health Physics.
 3. Ensuring all biohazardous materials are autoclaved as needed.
 4. Ensuring the policies of the RSC are disseminated among their employees.
 5. Ensuring all personnel working in his or her department abide by the Health Physics rules and regulations.

Item # 8: Training for individuals working in or frequenting restricted areas.

It is the policy of E. R. Squibb & Sons management to provide a safe working environment for the use of radiation and radioactive materials in the conduct of manufacturing and research applications, to ensure the protection of its employees, ancillary personnel and others, as well as ensuring releases to the environment are As Low As Reasonably Achievable (ALARA). All persons who work with radioactive materials are required to be trained in the safe handling of the materials and in maintaining their exposure as low as reasonably achievable.

A. Employee Training and Retraining

Employee training is provided to all newly hired personnel or transfers. This includes manufacturing production, laboratory supervisors, research personnel, Health Physics staff, and auxiliary personnel. These personnel are provided with information concerning the general safety rules and regulations and specific procedures for working in a radiation environment. Annual retraining is also provided. The generic contents for the above training may include, but is not limited to, the following:

1. Health Physics Initial and Refresher Training
 - Purpose
 - User registration and responsibilities
 - Radioactive materials licenses and regulations
 - Laboratory postings
 - Hazards associated with radioactive material
 - Radiation Safety Committee
 - Role of Health Physics

- Regulatory exposure limits and information
- Dosimetry issuance, use and return policy
- General radiation safety rules
- Radioactive waste collection, segregation, consolidation and disposal procedures
- Radiation detection equipment, types of instruments and their use
- Exposure reduction by time, distance and shielding
- The ALARA concept
- Radioactive contamination and control measures
- Personal Protective Equipment (PPE) requirements
- Federal and State posting requirements
- Emergency procedures
- Reporting unsafe conditions to Health Physics
- Radioactive materials purchase, receipt and transfer

2. Emergency Training

- Notification/evacuation
- Personal Protective Equipment (PPE)
- Emergency contacts
- Site specific procedures
- Contamination control
- Re-entry

3. Department of Transportation/Hazardous Materials Training

Training is required for all persons who handle radioactive materials for transport. This training is specific to hazardous material employees. The generic contents for the above training requirements may include, but is not limited to, the following:

- Introduction
- Hazardous materials table
- Shipping papers
- Markings
- Labeling
- Placarding
- Emergency Response
- Training
- Function specific training and safety

B. Contingency Plan Training

Personnel assigned to the manufacturing facility, emergency support, and ancillary personnel receive annual training on the emergency procedures and the Radiological Contingency Plan. In addition to on-site personnel, there are off-site response agencies who are invited to participate in emergency exercises every two years. Training requirements necessary to support the Contingency Plan may include, but is not limited to, the following:

1. The Plant Emergency Response Group and any individuals responsible for preparing, maintaining and implementing the emergency plan participate in training drills annually. Material covered includes:
 - a. Portable radio use and proper protocol

- b. Classification of incidents
 - c. Planning sessions and drills
 - d. Review of Radiological Contingency Plan organization and responsibilities
 - e. Offsite organization communication drills and table top exercises
2. Emergency Monitoring Teams receive periodic training. Specific groups receive training specific to the response of hazardous material incidents. Material covered may include, but is not limited to, the following:
- a. Site control
 - b. Response procedures
 - c. Review of the Radiological Contingency Plan
 - d. Responsibilities of the Emergency Monitoring Teams
 - e. Restricted area control
 - f. Personnel protective equipment
 - g. Measurement and control of contamination
 - h. Evacuation, control and accountability
 - i. Radiation safety
 - j. Instrumentation
 - k. Use of portable radios and protocols
 - l. Assembly of emergency response equipment
 - m. Coordination with First Aid, Fire and Security personnel
 - n. Onsite emergency exercise
 - o. Full scale emergency exercise, including off-site response personnel
 - p. Respirator training
3. The Plant Emergency Response Group plans and coordinates annual radiological emergency exercises. Off-site organizations are invited to participate in exercises every two years.

Item # 9: Facilities & Equipment

FACILITIES

New Brunswick Site

Radiopharmaceuticals are manufactured by E. R. Squibb and Sons, Inc. in New Brunswick, New Jersey. This manufacturing facility (Building 124) includes provisions for the storage of raw materials, intermediate products and finished products. Sterile areas are provided for all aseptic operations and sanitary areas are provided for all nonaseptic phases of operation.

This facility (see Attachment #1, Figure #1) was specifically designed and constructed for the handling of radiopharmaceuticals. Processing of radioactive materials is carried out in gloveboxes equipped with leaded glass windows. In all cases, shielding is adequate to prevent exposure of operating personnel to excessive radiation levels. Rooms and gloveboxes are provided with forced ventilation to protect operators from volatile radioactive materials.

Each hot cell and glovebox is equipped with a damper which will prevent the spread of a fire through the ventilation system. Any smoke or water vapor released by the fire and not stopped by the local fire damper will be contained in the glovebox. In addition, smoke detectors have been encased in the ducts of each filter bank system. When activated, valves located on each side of the filter bank will close automatically, and releases of airborne activity would be contained within the ducts of the ventilation system.

The hot cells are constructed of steel and concrete equivalent to four inches of lead for I-131 iodine and eight inches of lead for the Sr-82/Rb-82 operations. The steel and concrete used in the walls, flooring and ceiling of the hot cells range from 14 inches to more than three feet in thickness.

The facility layout is such that movement of supplies, equipment and materials into processing areas does not interfere with adjacent work areas. The layout provides for easy access for purposes of maintenance and efficiency of operation. No unnecessary movement of materials is permitted through areas in which exposure to radiation could occur. Personnel movement in the facility does not require passage through radiation areas to gain access to non-radioactive materials areas.

Holding tanks and storage facilities for the radioactive materials to decay are remotely located, and are not in the normal path of travel of personnel or equipment. There are four (4) tanks located at the south end of the building and are in an enclosed area. Each tank has a capacity of $3.8E+4$ liters (10,000 gal.) that collect the liquid from the low level radioactive liquid processing, glassware washing and sinks. These tanks are sampled as necessary, evaluated and eventually discharged.

Clean areas, radiation areas and high radiation areas are situated and segregated so that no unnecessary exposure is received by personnel. This layout also provides for contamination control. A personnel monitoring area and a protective clothing change room is located adjacent to the radioactive materials area. Shower and locker room facilities are also provided. The layout of the facility is such that the products progress in sequence of operations from the manufacturing, filling and packaging areas to the final holding area for shipment. The loading dock is adjacent to the holding area. By use of conveyor belts and by judiciously locating the various stations in the complete manufacturing process, contact with and handling of any radioactive material is minimal.

Selected portions of the production and storage areas are monitored by use of a "built in" area radiation monitoring system. An indicating and alarm panel is located in the Health Physics Office, thus assuring access to information regarding any unusual dose rates in the monitored areas and rapid response with corrective actions. The instrument ranges from 0.1 mR/hr to 200 mR/hr. Local alarms are provided with visual and

audible alarms to alert persons entering these areas of any abnormal condition. The instrumentation provided has the capability of detecting the highest anticipated radiation levels with positive readout at the lowest possible levels. To assure optimum coverage of all areas, the detector locations have been chosen with great care.

The manufacturing areas are served by a non-recirculating air conditioned supply system utilizing all outside air introduced through a prefilter and high efficiency particulate filter. A general system exhausts the various spaces through filtration equal to that of the supply system. Fume hoods, wherein particulate matter is the expected contaminant, are exhausted through an F-85 and a High Efficiency Particulate Air (HEPA) filter followed by a 1" high efficiency carbon filter to arrest any possible gaseous contaminant. The Sr-82/Rb-82 cave is exhausted through an F-85, a HEPA filter and three 1" charcoal filters. The combination of particulate and gaseous filters described serves to reduce the effluent of other radionuclides such as Sr-82, etc. to the lowest practicable level. Other manufacturing gloveboxes, where less volatile radionuclides are processed, are exhausted through an F-85 and a HEPA filter followed by two 1" high efficiency carbon filters.

Each of the twelve fume hood system filter banks service from one to five fume hoods or other ancillary equipment. Each fume hood system has a manual air bypass to be used during filter changes.

Each glovebox filter bank services up to five glovebox units or similar equipment. Each glovebox system has access to an auxiliary system offering identical filtration. There are no bypasses to allow passage of unfiltered exit air. There are eleven glovebox systems and six auxiliary systems available for use during filter changes or maintenance.

Filtration for three hot cells is accomplished by employing two identical exhaust systems. One is in continuous operation, while the other exhaust system serves as an auxiliary system when the primary is shut down for decay prior to filter changes or maintenance. Each system is filtered by three Flanders roughing (or equivalent), three Flanders HEPA (or equivalent) and nine 1" Flanders V-Bed Carbon Adsorber Cells (or equivalent) activated charcoal filters. There are no bypasses to allow passage of unfiltered cave system air.

Each filter bank is equipped with before and after continuous sample tubes used to check charcoal filter efficiencies. They are changed on a routine basis. The sample tubes are counted and an evaluation is made as to which bank should be changed, if applicable. There is no definite filter change criterion. Each system is examined individually to provide the most effective reduction in effluent.

All exhaust systems are discharged to the effluent exhaust stack. The system used for sampling exit air from the stack is comprised of six 1" lines within the exit duct. Each of these hold six pitot tubes facing upstream. The 1" lines connect to two 2" lines that pass through the main exhaust duct, then combine to another 6" line. The system is drawn by a fan that exhausts to another exit duct prior to entry back to the main duct exhaust. The effluent air sample drawn from the 6" line post fan, runs continuously at 1.85 cubic feet per minute and is changed each work day. The radioactivity collected in the air sampler is constantly measured by the stack alarm detector.

Fire protection is provided at each branch connection to gloveboxes and fume hoods, etc. by means of a spring-loaded fusible link fire damper. Carbon filters are protected by means of ionization-type detectors in the duct work. Generally, detectors will isolate a filter fire from the air stream by closing metal-seated shutoff valves and transfer the effluent to the standby filters, or stop the fan, depending on the type system involved.

The manufacturing facility is also equipped with an auxiliary generator which will automatically engage in the event of an electrical power failure. The generator is capable of maintaining the air systems and emergency lighting for the plant.

Additional facilities at the New Brunswick site include laboratories for sterility and quality control testing, and research and development (R&D) laboratories. All ventilation is supplied by non-recirculating air. Low density shielding is used in areas housing significant quantities of Phosphorous P-32.

Carbon filtration is utilized in areas where unbound Iodine is processed. See Attachment #1, Figure #2 for the diagram of the Iodination laboratory: Room 207A, Building 80. Effluent air from the Iodination laboratory is continuously monitored. Air concentrations in areas housing unbound Iodine are also continuously monitored. No more than 20 millicuries of unbound Iodine are processed at one time at this Iodination laboratory.

A laboratory suite in Building 107 was specifically designed for the radio synthesis and labeling of compounds, primarily with millicurie quantities of C-14 and H-3. See Attachment #1, Figure #3 for a diagram of this suite. Entrance to this suite is controlled by card key access. All ventilation is supplied by non-recirculating air and exhausted through HEPA and carbon filtration. The effluent air is monitored during all syntheses.

Building 81 is the Interim Waste storage facility for the New Brunswick, Lawrenceville, Bristol-Myers Squibb Clinical Laboratory, and ConvaTec sites. It is used for waste consolidation prior to shipment, storing waste for decay, and long term storage if a disposal option is not available. The facility is located in a 14,000 square foot building on the New Brunswick site. This facility is capable of being expanded if additional space is needed. It is anticipated that E. R. Squibb and Sons can store up to 15,000 ft³ of low-level radioactive waste if a disposal option is not available. See Attachment #1, Figure #4 for a diagram of the facility. An existing one-story structure was specifically renovated in accordance with the specification of the NRC Regulatory Guide 90-09, to include storage areas for the following: dry waste storage, liquid waste storage, animal or biological waste freezer storage, mixed waste storage. In addition, a waste sorting and processing area that includes an in-drum waste compactor is located at the facility. Personnel and materials access into the building is controlled with magnetic card personnel access system. All doors are properly identified with appropriate radiation decals. All entrances and emergency doors are equipped with alarms. These alarms are monitored by the site's Security department during off-hours.

The 14,000 ft² structure is heated, has reinforced concrete floor slab and an insulated metal roof and siding. It has been provided with the following to assure low-level radioactive waste containment:

- a) A perimeter containment concrete curb to contain any spilled liquids and fire sprinkler water within the building.
- b) Patched concrete floor slab that have been epoxy sealed to eliminate cracks and porosity.
- c) Concrete masonry interior partition walls.

The low-level radioactive waste storage HVAC ventilation and air distribution system has been designed and incorporated into the building's existing heating and air condition systems. This system include:

- a) A recirculated air distribution system with a 20-30% fresh air makeup services the main storage areas. The return air will pass through a HEPA/charcoal recirculation filter unit prior to dehumidification cooling or heating. The air handling system has been designed to supply and circulate 100% fresh air on demand by activation of a by-pass damper.
- b) Once-through ventilated air is supplied to the mixed waste storage area and the waste processing areas. Its return air is directly exhausted through a HEPA/charcoal filter unit.
- c) All effluent from the HVAC system is continuously monitored.

The facility's mechanical and HVAC system is designed to provide uniform temperature and humidity ranges with adequate ventilated air to avoid subjecting waste containers to extreme temperatures. The building's mechanical and HVAC systems supply the storage areas with a year-round central refrigerated air conditioning and heating system. The HVAC system is designed to maintain a summer condition of 78°F at 55% to 60% relative humidity range and a winter heating design condition of 55°F at ambient relative humidity range. The storage ventilation and air circulation rates are in accordance with Building Officials and Code Administrators (BOCA) and American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) codes to inhibit metal container external surface corrosion.

The fire protection and suppression system is designed and installed as follows:

- a) The low-level radioactive waste storage area is protected with an overhead fire sprinkler system. The sprinkler system complies with all requirements of the National Fire Protection Association (NFPA), local code requirements and the insuring agent.
- b) The drum compaction area is protected with a fire water sprinkler system that complies with NFPA, local code requirements and the insuring agent.
- c) Fire detection sensors are installed in selected areas of this facility and report to the New Brunswick central in-plant fire alarm panel.
- d) A fire water perimeter concrete curb has been installed around the low-level radioactive waste storage area to contain contaminated fire water from draining out of the building.

Waste containers are stacked in a pallet rack system to provide easy accessibility for inspection. Animal and biological waste is stored in a walk-in freezer storage unit. A separated mixed low-level radioactive/hazardous waste storage area that meets EPA/NJDEP RCRA requirements is also located in this facility. The mixed waste area is secured from the main storage area and is protected by curbing to prevent any spills or leaks from the mixed waste area from migrating to the main storage area. This area is currently operating under an interim RCRA permit for the storage of hazardous waste for greater than ninety days. Daily hazardous waste inspections are performed when waste is present in the permitted area.

Lawrenceville Site

The Lawrenceville facility is the main R&D campus for licensed activities. Laboratory facilities in Lawrenceville are quite extensive. Significant amounts of radioactive materials may be used in these laboratories, therefore, special design features are incorporated into some labs depending on the type of research being conducted. All laboratories utilize non-recirculating ventilation in the areas that process licensed material.

Unbound iodine is used in three laboratories at this facility. These three laboratories were specifically designed for the use of volatile iodine. All ventilation is supplied by non-recirculating air. Carbon filtration is utilized in areas where unbound iodine is processed. See Attachment #1, Figures #5-7 for the diagrams of the three iodination laboratories: Room H.4613, K.3622, and K.4319. Effluent air is continuously monitored in these three laboratories. Air concentrations in areas housing unbound iodine are also continuously monitored. No more than 20 millicuries of unbound iodine are processed at one time in any one iodination laboratory. No unbound iodine is processed outside of these three laboratories at the Lawrenceville facility.

Low density shielding is used in areas housing significant quantities of Phosphorous P-32.

The central waste collection and consolidation area for the Lawrenceville site is located in the F1 basement. At this controlled area, waste from the site is collected and consolidated into containers for shipment off site. Non-recirculating ventilation exhausted through HEPA and charcoal filtration and continuous room and effluent air sampling services the waste area. This area is locked when not occupied by authorized personnel. This area is currently operating under an interim RCRA permit for the storage of hazardous waste for greater than ninety days. Daily hazardous waste inspections are performed when waste is present in the permitted area.

Bristol-Myers Squibb Clinical Laboratory and ConvaTec

Laboratories for R&D activities are located at the Bristol-Myers Squibb Clinical Laboratory and ConvaTec facilities. These laboratories utilize non-recirculating ventilation in the areas that process licensed material. Unbound iodine is not processed at these sites. At the Bristol-Myers Squibb Clinical Laboratory site, waste is stored prior to shipment in a secure, designated area.

EQUIPMENT

Laboratory Equipment

Various types of equipment are required to perform the necessary surveillance, counting and monitoring functions throughout the E. R. Squibb and Sons facilities. Sufficient laboratory and field instrumentation is available for this purpose.

Laboratory counting equipment is used to quantify the results of samples taken throughout the facilities to ensure compliance with the regulations and the safety of personnel. The primary laboratory counting equipment consists of gamma counters and liquid scintillation counters. The liquid scintillation counters are used for the counting of "smears" used for contamination surveys. This counter is also used for the analysis of various samples containing H^3 , C^{14} , and other low energy beta emitters. The gamma counters are used for the analysis of sampling tubes used for determination of filter efficiencies, effluent releases, and room air concentrations. Other samples are analyzed for gamma radiation as required. In addition, sodium iodide crystals are used for thyroid counting for the determination of iodine uptake.

All laboratory instrumentation is calibrated on a routine basis and documented. During operation of the laboratory equipment, background samples and standard samples are counted without the background automatically subtracted from the sample and standard counts. However, background is entered into the computer manually. Source checks on selected instruments are performed daily. The thyroid counter is normally calibrated on a daily basis in New Brunswick and on an as-needed basis in Lawrenceville, and is configured such that the counter must be calibrated before it can be used.

Portable Survey Instrumentation

Field survey instruments consist of geiger-mueller tubes, ionization chambers and a variety of solid state detectors. These detectors are connected to various types of scalars or ratemeters and can detect very low levels of radiation at low dose rates or very high levels of radiation at high dose rates (hundreds of R/hr). There is no neutron or alpha radiation present at E. R. Squibb and Sons, therefore the only concern is with beta and gamma radiation. There are sufficient amounts of beta-gamma survey instruments available for use by Health Physics personnel. The majority of the instruments are manufactured by Eberline, Ludlum or Victoreen, and consist of pancake type thin window detectors for low levels of contamination, ion chambers for low to high levels of radiation, and other G-M tubes and ion chambers for ranges of dose and dose rates encountered. The detectors are connected to either scalars or ratemeters depending on their use.

All portable survey meters used by Health Physics are calibrated on a six month interval. Calibrations are performed by The NDL Organization (New York State License # 1959-1422) or any other vendor specifically authorized by the NRC or an Agreement State to perform instrument calibrations. Operational checks are performed the first time an instrument is used in any given week. This includes every detector, scalar, and ionization chamber that will be used by Health Physics Operations. These checks are performed with standard sources appropriate for the radioisotopes to be detected by the specific instrument.

Additional instruments, similar to those utilized by the Health Physics Department, are available within the individual laboratories and manufacturing areas. These portable survey meters are used by manufacturing and R&D personnel and are calibrated on an annual basis or after repair by The NDL Organization (New York State License # 1959-1422) or any other vendor specifically authorized by the NRC or an Agreement State to perform instrument calibrations.

Area Monitors

Area monitors are designed to provide a continuous indication of the ambient radiation levels within an area. They are placed in areas of Building 124 in New Brunswick where the potential exists for radiation levels to change. These monitors have local readout and alarm capability in addition to having remote readouts and alarms. Area radiation monitors are normally set to alarm at a preset dose rate. The detectors are chosen to respond primarily to gamma radiation, but can also be adjusted to respond to high energy beta particles. These monitors serve to warn personnel in the area that radiological conditions have changed and the area should be immediately evaluated. As with all Health Physics instrumentation the area radiation monitors are calibrated on a routine basis; normally at six month intervals and after repair. They are calibrated over the full range of dose rates that may be encountered. Calibration is performed by The NDL Organization (New York State License #1959-1422) or any other vendor specifically authorized by the NRC or an Agreement State to perform instrument calibrations.

Air Sampling Equipment

There are several different types of air sampling equipment available for use. These include grab samplers, fixed air samplers (continuous monitors), personal air samplers or breathing zone samplers, and stack effluent monitors. Each sampler is designed to fulfill a particular need. The airborne contamination is usually very low so care must be exercised to ensure a representative sample is taken to accommodate the sensitivity of the equipment used for analysis. Air sampling equipment is appropriately calibrated against a primary or accurate secondary standard.

Portable air samplers or grab samplers consist of an air suction pump and sample collection media and are used for rapid assays after radioactive spills or inadvertent releases of radioactive particulate into the air. The quantity of air sampled is determined by measurement of the flow and the length of time the sample is taken. Portable air samplers are calibrated primarily by ensuring the flow measurements are accurate by placing a rotameter in the sample line and adjusting the flow to the flow meter accordingly. Most rotameters are calibrated against a primary standard with corrections made for temperature and pressure.

Fixed air samplers are used for routine monitoring in areas where there may be a potential for airborne radioactive material. The sampler is operated continuously with the filters changed at a pre-established frequency consistent with the anticipated levels of air contamination. Fixed air samplers consist of a vacuum source, a flow meter, and a fixed filter paper holder and other filters or sample collection media such as charcoal filters, silica gel, etc. depending on the activity being sampled. Fixed air samplers with removable charcoal and paper filters are also used to sample the air effluents from designated release points.

Personal air samplers may be used for non-routine tasks which may generate airborne radioactivity and for which other sampling devices may not provide a representative sample. Personal air samplers or breathing zone samplers are small devices which can be attached to a worker's clothing with the air intake placed near the breathing zone. This method samples the air most representative of that which the worker is breathing. Flow rates of the order of 5 liter per minute (LPM) are typical for these samplers.

Effluent monitoring is used at the New Brunswick and Lawrenceville facilities to monitor stack releases to the environment. These monitors are specific to the radionuclide(s) of interest in the effluent stream. The monitors consist of a stream of air extracted from the duct or stack just prior to its exit into the environment, this air

stream is then passed through a collection media and analyzed. The collection media may consist of filter paper, activated charcoal, or a bubbling system. The collection media is then counted on a calibrated instrument to determine the total radioactivity present. The stack monitor in Building 124 in New Brunswick also has the capability to alarm if the activity on the collection media reaches a pre-set value. The stack monitors are calibrated by measuring the air flow through the collection media with a calibrated flow device such as a rotameter.

Ventilation Equipment

Ventilation systems within the facilities are all designed to ensure the working area is provided with suitable breathing air. This is accomplished by filtration of the incoming air, once through air moving systems, and bypass lines to divert the air if necessary. Facility design is such that the air flows from clean areas to areas where the potential for contamination exists in increasingly higher levels. The ventilation systems also ensure air is maintained at a negative pressure within hoods, glove boxes, and hot cells.

Fume hoods are enclosures which have a moveable window which can be raised or lowered to obtain the proper position for the work being conducted. The main function of fume hoods is to dilute and remove airborne contaminants. Hoods are designed to control the sources of radioactive materials from entering the general laboratory area by the air flow entering the front of the hood. The air flow at the face of fume hoods is measured using a calibrated thermoanemometer at a minimum of five points over the face of the opening. The values are averaged and if the average air flow is < 100 feet per minute the hood is taken out of service until sufficient air flow can be established in accordance with Regulatory Guide 8.21.

Glove boxes are enclosures similar to the fume hoods described above. The main purpose of glove boxes is to isolate the contaminant from the environment by confining it to the enclosed volume. Glove boxes are more secure in the sense they have no window or opening that can be adjusted. Glove boxes usually have a door or a small air lock on the side of the box through which materials and equipment are placed inside. The individual works in the box through gloves that are attached to ports in the front part of the box. The gloves form a seal to prevent any leakage of radioactive materials into the room. The glove box is maintained at a negative pressure relative to the room in which it sits.

Hot cells are utilized for handling high levels of radioactive materials, i.e., materials that result in high dose rates in the area. The hot cells at E. R. Squibb and Sons are constructed of steel and concrete equivalent to either four or eight inches of lead depending on the materials that were processed within. The cells with the greater thickness are used for processing strontium (Sr-82), while the others are used for processing iodine (I-131). The thickness of the floor, ceiling, and walls of the hot cells range from 14 inches to more than three (3) feet in thickness. Entrance to the cells, for placing materials and equipment inside, is through a door in the rear of the cell. Material is handled inside the cells by remote manipulators that are located on the front part of the cell. A leaded glass window in the front allows direct observation of the work in progress inside the cell. The air exhausted from the hot cells is filtered by roughing filters, high efficiency particulate (HEPA) filters, and activated charcoal filters. The air is also sampled prior to exiting through the stack to the environment.

Item #10: Radiation Safety Program

Previous Licenses

This application requests a continuation of activities that are presently conducted under license # 29-00139-02

Administrative Procedures

Procedures for Control of Procurement and Use

The Radiation Safety Committee is responsible for assuring that all operations involving radioactive materials are carried out in conformance with our overall radiation safety program which is administered and enforced by the RSO and his staff. The committee has the authority and responsibility for the approval or disapproval of all proposals for radioactive material use prior to the purchase of the materials. That is, the committee reviews all facilities and generic uses of material prior to their use. The committee has delegated the RSO and his designees the responsibility and authority to temporarily approve individual uses and users of radioactive material up to ten millicuries for up to ninety days.

All purchases of radioactive material are reviewed and approved by Health Physics prior to processing. The review and approval process includes verifying that the person is authorized to use this material.

Emergency Procedures

All occupational employees are trained in emergency procedures as part of their initial and refresher radiation safety training. Emergencies may include equipment failures, fires, spills, and site incidents. Emergency procedures for minor spills, major spills and site incidents are posted in areas where licensed material is used. The license also has a comprehensive Radiological Contingency Plan (RCP), see Addendum II, for manufacturing operations.

Minor spills, typically less than a millicurie in a controlled area, are addressed by the user. Health Physics is notified by the user to provide assistance if needed, and to verify the decontamination effort. Major spills, typically greater than a millicurie in a controlled area, a spill in an uncontrolled area or a spill that results in personnel contamination require immediate notification of Health Physics and/or the site emergency response number. The remediation of a major spill is managed by the Health Physics department. If the spill also involves other hazards, such as hazardous chemicals or fire, the Health Physics department will act as advisors to the site emergency response teams in dealing with the radiological hazards present. Notifications to the NRC of an incident as required by 10 CFR 20.2202 is the responsibility of the RSO or his designee. The NRC and other outside agency contacts are listed in the RCP.

The Security Department monitors the New Brunswick, and Lawrenceville sites twenty-four hours a day, seven days a week. The ConvaTec and Clinical Laboratory facilities have site specific procedures for emergency response. Staff from the Lawrenceville facility also provide support to these two facilities if needed. In the event of an emergency during off hours at a facility, the Security department has the home phone numbers of the RSO and Health Physics Supervisors. The Health Physics staff can assist the Security staff over the phone to assess or stabilize a situation and if necessary, respond to the site.

New Brunswick and Lawrenceville sites have comprehensive emergency response teams made up of employees from fire, safety, industrial hygiene and volunteers from other departments. These teams are trained to respond to medical, fire, and hazardous spills at their facilities. The Lawrenceville team also supports the Clinical Laboratory in Princeton. The emergency response teams are activated by Security in conjunction with the team leader.

Operating and Handling Procedures

Each occupational worker is trained on the appropriate procedures in radiation safety for that persons job function before they work with radioactive material. In addition, ancillary personnel attend training and may be issued temporary dosimetry.

The radioactive material waste disposal program is coordinated through the Health Physics department. All gaseous and liquid effluents are monitored by the Health Physics staff.

Radioactive material not in current use, including waste, is stored with appropriate markings of isotope, date and activity. Exposure rates are monitored by the Health Physics staff to assure that proper shielding and/or distance is used for achieving ALARA.

The Health Physics department will determine what personal monitoring equipment must be worn while in a controlled area. Film badges or TLD's will be issued in accordance to 10 CFR 20

No eating, storage of food, drinking, smoking or application of cosmetics is permitted in a controlled area

Pipetting by mouth is prohibited in controlled areas

Handling radioactive materials with an open sore or cut below the wrist is not permitted unless the wound is adequately bandaged.

Gloves are worn while handling radioactive materials and removed before handling non-radioactive materials

Radioactive waste or cartons bearing the marking "Radioactive" are not be discarded into non-radioactive waste containers unless properly surveyed and labeled

No radioactive liquid waste is placed in the Publicly Owned Treatment Works (POTW) unless authorized by the Health Physics department

All purchases of radioactive material are approved by the Health Physics department

All spills involving radioactive material are reported to the Health Physics department

Refrigerators are not used jointly for food and radioactive material

Operational contamination surveys in R&D areas will be performed daily, as practical, by researchers when unsealed sources of radioactive materials are used. Documentation of such surveys will not be required

For Manufacturing activities, work areas should be surveyed by workers for radiation and contamination before commencing, during the processing and after the completion of assignment. Documentation of such surveys will not be required. All contaminated areas are cleaned and rechecked

Any radiation control, monitoring device or permanent shield is not to be removed or altered without the Health Physics departments approval.

Carts are used to transport radioactive material, as appropriate

Film badges and TLD's should be promptly returned to the Health Physics Department, as required

All work with open vessels of volatile radioactive material is done in properly ventilated areas

All radioactive material bears a radiation warning label specifying isotope, date, and approximate amount of activity when required by appendix C of 10 CFR 20

Radioactive waste is discarded in accordance with the radioactive waste disposal procedure

The Health Physics department is notified when any occupational worker is hired, transferred or terminated

The Health Physics department is notified when new procedures that involve new isotopes or added risk of contamination, volatilization or exposure are instituted

Appropriate protective work clothing and safety shoes are worn while working with radioactive material

It is the prerogative of a female radiation occupational worker to notify the company through her Supervisor Medical department or Health Physics department, if she becomes pregnant

Other Procedures

All sealed sources containing licensed materials or their products will be tested for leakage and/or contamination at intervals not to exceed six months by the Health Physics staff. Records of leak test results will be kept in units of microcuries and be maintained for inspection by the commission. All repairs, alterations or removal of a source from its enclosure will only be performed by persons specifically licensed by the commission or an agreement state

Thyroid bioassays are routinely performed for occupational personnel assigned to the controlled area of the manufacturing facility (Building 124 in New Brunswick, NJ). All other personnel monitor their thyroids after handling significant quantities of potential volatile iodine

Carbon filter systems are employed wherever iodination procedures are performed as described in Facilities and Equipment

Health Physics coordinates the calibration of all portable radiation monitoring equipment with a licensed contractor. Instruments in use are calibrated on an annual basis or after repair by The NIXL Organization (New York State License # 1959-1422) or any other vendor specifically authorized by the NRC or an Agreement State to perform instrument calibrations. They are marked with a calibration date and calibration certificates are reviewed and kept by Health Physics

Licensed Material Inventory and Accountability

The external surfaces of all incoming packages containing radioactive material will be monitored for radioactive contamination. In addition, all incoming packages labelled with a radioactive White I, Yellow II, Yellow III, or labelled as LSA will be monitored for radiation levels

Radioactive materials are controlled by maintaining records and procedures to ensure accountability at all times. All receipts of radioactive material are logged into the site's inventory. All site radioactive material inventories are maintained by the Health Physics staff. Records indicate total site possession, responsible person, location of material, date delivered, and date and method of material disposition

Management and Radiation Safety Committee Audits

Periodic audits of the radiation safety program will be conducted by the RSC. The findings will be reviewed by the Radiation Safety Committee. The audit consists of a review of the activities of the RSO and the records required by the rules, regulations and internal procedures. The audit results will be reviewed by the RSO, RSC and management. Modification to the radiation safety program based upon the audit results will be made as appropriate.

The RSC is informed of regulatory requirements and operating procedures through routine meetings and correspondence with the Health Physics Department. Minutes of each meeting are recorded and distributed to each member.

RSO and Staff Audits

The RSO or Health Physics Supervisors perform unannounced audits of radiation safety practices in areas where radioactive material is used. These audits are performed approximately monthly and the results are recorded. The purpose of the audit is to ensure users are handling radioactive material safely and are complying with all terms and conditions of our NRC license and standard operating procedures. This is accomplished by observing users work practices while handling radioactive material, and reviewing independent surveys of user work areas performed by Health Physics staff.

The frequency of monitoring performed by the Health Physics staff is based upon the radionuclides, amount and activities in accordance with Regulatory Guide 8.21. The monitoring entails surface contamination monitoring and field surveys where appropriate. Smear surveys are quantified using instrumentation suitable for the radionuclides being used.

Safety Evaluations of Proposed Users and Users

Before any use of radioactive material is approved for R&D use, a user must complete an information form that identifies how the material will be used. The form is filled out by the Principal Radiation User (PRU) who is typically the laboratory supervisor, senior scientist or group leader. Coworkers are included on the form as additional radioactive material users and usually report directly to the PRU. All users of radioactive material are required to participate in the initial Health Physics training. Any additional training may be provided to Users as appropriate; for example, Users that perform iodinations are required to review procedures specific to the iodination suite.

Information on the User Form includes the following:

- Radionuclides used
- Chemical and physical form
- Total activity per experiment
- Total activity per purchase
- Total possession limit
- Storage location of licensed material
- Whether the material will be transferred to another facility or authorized user
- Whether the material will be used in human or animal studies
- Non-radiological hazards (i.e., chemical, biological or cytotoxic)
- Physical conditions under which the material will be processed (i.e., room temperature in a ventilated area or benchtop)
- Safety and ancillary equipment that is available
- Radiation detection equipment
- Specific types of waste generated
- Solubility of liquid waste

After the PRU has completed the form, the department head must review and approve the PRU's request. The form is then forwarded to the Health Physics department for review. For quantities up to 10 millicuries, the RSO or a member of Health Physics management may grant temporary approval. After the PRU receives temporary approval, the form is brought before the RSC within ninety days for final approval. If the quantity is greater than 10 millicuries, approval can only be granted by the RSC. In this situation, a PRU can not begin work until the RSC has granted approval. Approval is valid for two years.

Dose Control and Monitoring

The dose an occupational worker could receive is controlled by various methods including establishing administrative limits, engineered controls, use of special work permits in radiological areas, posting of areas with radiation and contamination levels, labeling containers, training personnel to ensure their awareness of potential radiological hazards, etc. Health Physics provides the information and equipment to accomplish this, but each individual is responsible for maintaining their dose ALARA.

Radiation surveys are performed for the purpose of identifying areas that may represent a potential for exposure and/or contamination of individuals to radiation or licensed materials. Surveys are performed by the Health Physics staff at routine frequencies in radiation controlled areas in accordance with Regulatory Guide 8.21. Operational contamination surveys in R&D areas will be performed daily, as practical, by researchers when unsealed sources of radioactive materials are used. Documentation of such surveys will not be required. For Manufacturing activities, work areas should be surveyed by workers for radiation and contamination before commencing, during the processing and after the completion of assignment. Documentation of such surveys is not required. All contaminated areas are cleaned and rechecked.

Personnel monitoring devices are required to be provided to all persons who are likely to receive a dose equivalent in one year in excess of ten (10 %) percent of the applicable limits in 10 CFR 20 or for anyone who enters a high or very high radiation area. Only a NNLAP approved contractor can be used to provide dosimetry services. Landauer is currently used as our dosimetry contractor. Personnel monitoring is performed through the use of film badges or TLDs worn by each individual who works with radioactive materials or frequents the radiologically restricted area. In addition to film or TLD badges worn on the upper portion of the torso for determining "whole body dose (deep dose) equivalent", personnel may also be required to wear dosimetry on their extremities, normally on their hands. This is necessary when persons handle radioactive materials during the manufacturing process or for certain high level experimental procedures. The film badges or TLDs are replaced on a routine basis and sent to the badge processor for evaluation. Reports of the exposure of individuals are sent to Health Physics who review and maintain records on each individual.

In addition to the personnel monitoring performed by the use of film or TLD badges as noted in the previous section, personnel may also be monitored for contamination. This is performed by the use of either hand held detectors which the individual slowly moves over the hands, feet, and the rest of his/her body or by the use of a hand and foot counter. Contamination monitoring is conducted to ensure persons do not accidentally ingest radioactive materials that may be on their hands and to ensure the contamination is not spread out of the radiologically restricted area. In addition, eating, drinking, smoking, and application of cosmetics is not permitted in the radiological restricted areas.

Respiratory protection equipment may be required to reduce the possibility of individuals inhaling radioactive materials. Respiratory protection equipment is not normally used but is available in the event of emergencies requiring access to areas in which radioactive material may have become airborne. Work on highly contaminated equipment may also require the use of respirators. Respiratory protection devices may consist of half face masks, full face masks, or supplied air breathing apparatus. Use of such equipment is determined by either Health Physics or Industrial Hygiene. Persons must be trained and also be medically certified that they are physically fit prior to the use of these devices.

In accordance with 10 CFR 20, intakes of radioactive material are monitored if adult workers are likely to receive, in one year, an intake in excess of ten (10 %) percent of the applicable Annual Limits on Intake (ALIs) given in Appendix B of 10 CFR 20, or if minors and declared pregnant women are likely to receive, in one year, a committed effective dose equivalent in excess of 50 millirem. It is not likely that employees will exceed 10% of the ALI under anticipated licensed activities. A bioassay program that requires the calculation of the Committed Effective Dose Equivalent (CEDE) will only be conducted if the Health Physics department determines that an individual may exceed ten percent of the ALI for any given year. The types of bioassays available to employees are thyroid and urine evaluation. Other techniques, such as whole body counting, can be considered if required.

In areas where uptakes may occur that are below the level the ten percent limit of the regulations, bioassay results are routinely performed and used to verify the adequacy of radioactive material handling procedures, engineered controls and other radiation safety components.

Air sampling is conducted in areas where the potential for airborne radioactive material is present. These samples are collected routinely in the manufacturing areas, the waste consolidation areas, and in iodination laboratories. These samples are typically analyzed in-house and results are compared to the appropriate limits. These air sample results will be used for calculation of the CEDE only if there is no bioassay data available.

The ALARA philosophy is a policy of the management of Bristol-Myers Squibb. Management requires all personnel to be aware of these concepts and to implement them in their daily work activities. The concepts have been incorporated into the design of the facility and in the procedures used for working with radioactive materials. The ALARA concepts are presented in the training courses provided to personnel prior to their working in the radiologically restricted area. Each person is expected to minimize their exposures and the exposure of their fellow workers in the performance of their duties. The Health Physics and manufacturing departments prepare procedures for the various processes regarding handling, use, and disposal of radioactive materials. Through the use of and adherence to these procedures individual doses to radiation are maintained ALARA.

Protective apparel is worn by all personnel who enter a radiologically restricted area. The clothing may be a lab coat, safety shoes and safety glasses, or could consist of head covers, gloves, and shoe covers. Health Physics determines protective apparel that will be required but the supervisors within the individual departments are responsible for its issuance and control.

Fume hoods, glove boxes, and other ventilated enclosures are used wherever potentially airborne licensed material is processed to minimize the potential for inhalation by occupational workers. Filter systems are utilized where appropriate to minimize releases to the environment. This equipment is discussed in detail in Item #9 Facilities & Equipment.

Areas adjacent to radiation controlled areas are monitored for contamination on a routine basis. Environmental TLDs are placed around the perimeters of Buildings 81 and 124 at the New Brunswick site to monitor radiation levels.

The general public and environment is protected from radiation resulting from activities in a facility by reducing the potential for exposure at all stages of design and operation. This is done by ensuring the ALARA concepts are incorporated into the original design of the facility, by use of additional engineered controls for operations, by maintaining the radioactivity in the effluents ALARA, by use of proper procedures, by trending data and evaluating the effluent concentrations on a routine basis, and by additional preparation for handling emergency situations should they arise.

As indicated previously, the engineered controls have been incorporated into the design of the various facilities. These engineered controls consist of the heavy shielding provided for the hot cells, the shielding provided for the glove boxes and hoods, the ventilation system specific for those systems containing roughing filters, high efficiency particulate (HEPA) filters and charcoal filters. The HEPA filters eliminate essentially all (99.97 % efficient for 0.3 micron particles) particulate matter that could be released to the environment while

the charcoal filters remove the major portion of the iodine that is released into the ventilation system. The manufacturing areas are provided with non recirculating outside air introduced through a prefilter and a high efficiency particulate filter. In some cases redundant systems are used to ensure continuous availability in the event malfunctions occur. A backup generator is dedicated to the manufacturing ventilation system to ensure operation in the event of loss of off-site power.

Item #11: Waste Management

E.R. Squibb & Sons generates radioactive waste resulting from its use of licensed material. This waste is typically in the form of dry trash, aqueous liquids, animal/biological wastes, scintillation fluids, mixed hazardous/radioactive waste (mixed wastes), and sealed sources.

Waste management options that are utilized by E. R. Squibb & Sons include, storage for decay, on-site compaction, off-site processing, disposal at a licensed radioactive waste disposal facility, disposal under 10 CFR 20.2003 and 2005, and extended interim waste storage, if warranted. On-site incineration is not a current waste management practice. Radioactive waste that is not managed at an E. R. Squibb & Sons licensed site is transferred to a waste broker/processor that is licensed to perform these activities by the NRC or an Agreement State. E. R. Squibb & Sons utilizes the services of The NDL Organization (New York State License #1726-1422) and the Scientific Ecology Group (Tennessee State Licenses #R-73008-F94 and #R-73013-F91) to transfer process and ship for final disposal radioactive waste that is managed off-site. Other licensed waste brokers/processors may also be used by E. R. Squibb & Sons to transfer radioactive waste if required.

Waste Segregation

Radioactive waste is sorted at the point of generation for proper storage and/or disposal. Wastes that are generated in a radioactive material area are surveyed by the occupational worker to determine if the waste can be disposed as non-radioactive. This method is used in areas that utilized radioactive materials that are readily detectable with portable survey instruments. In areas that used low energy beta/gamma emitters, all waste that had the potential to be contaminated is packaged as radioactive waste. Wastes that are known to be radioactive by the user (i.e. buffer solutions mixed with radioactive material, etc.) are packaged as radioactive waste without survey. Laboratory wastes that are determined to be radioactive are sorted according to half life, processing method, waste form, and hazard class. Waste is sorted by isotope and/or half life to allow storage for decay. If waste is to be processed, the waste is sorted according to the type of expected processing technology: compactable wastes from non-compactable and incinerable wastes from non-incinerable, etc. Waste is also sorted by hazard class to ensure regulatory compliance and proper handling of mixed wastes, such as lead or organic solvents.

All containers for radioactive waste that are located at the point of waste generation are labeled appropriately. Liquid waste containers are typically double walled to guard against potential leakage. Biological waste is packaged in a container that will minimize the potential for personnel exposure to pathogenic or putrid materials.

Storage for Decay

Radioactive waste may be packaged for storage for decay if its half life is less than 120 days. All radiation labels are removed or obliterated from the waste. All waste held for decay is stored for a minimum of ten half lives. The storage location is a secured area protected from the weather, extremes in temperature, and vermin. R&D waste is typically stored in Building 81 and Manufacturing waste is stored in Building 122, both at the New Brunswick site. However, it may also be stored locally in laboratories or waste consolidation areas if the volume of the material and the half life are manageable in that area and the storage location meets the criteria mentioned.

After ten half lives have elapsed, the unshielded waste container is surveyed with a radiation detection instrument appropriate to the radiation present. If the instrument response can not be distinguished from background, the waste is disposed as non radioactive. Detailed record keeping is maintained for storage for decay of radioactive materials. The following information is maintained: date of initial storage, isotopes and

activity in waste, date surveyed for release, person performing the survey, instrument used, background readings, survey results of each waste container. Depending upon the isotope in the waste, the contents of the container may be removed to be adequately surveyed.

Interim Waste Storage

Due to disposal facility restrictions, there may be extended periods of time when a disposal facility is not available to E. R. Squibb & Sons. When this occurs, all waste generated by the licensee is held in interim storage in Building 81 at the New Brunswick site. This facility was specifically designed for this purpose in accordance with the criteria in Regulatory Guide 90-09. If a disposal option becomes available, the waste held in interim storage will be shipped for disposal as soon as practical with consideration given to scheduling, manpower, budgeting, and contract approval.

Specific information on extended interim storage and Building 81 is listed below.

Identification of Waste to be Stored

- 1) It is estimated that approximately 15,000 ft³ of low-level radioactive waste can be stored by the licensee during extended interim storage.
- 2) The maximum activity to be stored is estimated to be 20.5 Curies.
- 3) The estimated activity will include but not be limited to the following radionuclides:

Nuclide	Activity
¹⁴ C	5.7 Ci
³ H	3.0 Ci
¹³⁷ Cs	0.1 Ci
¹⁰⁹ Ag	0.1 Ci
⁹⁰ Sc	0.1 Ci
⁹⁰ Sr	0.1 Ci
¹⁰⁹ Sn	0.1 Ci
⁶⁰ Co	0.1 Ci
¹⁵³ Gd	0.1 Ci
³⁵ S	0.5 Ci
¹²⁵ I	0.2 Ci

Radionuclides with atomic numbers 1-83 will also be stored in activities that are estimated to be 10.0 Curies.

All low-level radioactive waste stored during the extended interim storage period will be Class A unstable or Class B Stable. The primary physical waste form to be held during the extended interim storage period will be dry solids and animal/biological waste. Bulk liquids, solidified liquids, and mixed waste in small quantities will

also be stored. A designated freezer area will be used for the storage of containers of animal/biological waste. All of the waste forms will be packaged in strong, tight containers. Compaction will be performed to reduce the volume of dry solid materials. In addition, storage and decay of dry solids will be employed. The facility will house mixed waste. An interim hazardous waste permit for the storage of mixed wastes beyond ninety days has been filed with the NJ DEP. Air permits for the Building 81 extended interim storage facility HVAC system have been obtained from the NJ DEP.

Radioactive waste generated by E. R. Squibb & Sons that has been shipped off site for processing may also be returned from the processing facility for interim storage. Only waste generated by the E. R. Squibb & Sons sites covered under this application will be accepted from the processor. This waste may be in the form of supercompacted dry material or processed incinerator ash. The ash will be rendered non-dispersable exclusive of packaging prior to receipt of this waste from the processor. The ash may also contain trace amounts of fission products, including Sr-90, and other radioisotopes of elements 84-103 due to cross contamination from the processor's incinerator. The total quantity of Sr-90 in the processed waste will not exceed two millicurie and the total quantity of radioisotopes of elements 84-103 will not exceed one millicurie.

Pending the decision of South Carolina to accept low-level radioactive waste from out-of-region generators and the efforts of the Northeast Compact to provide disposal capacity, on-site storage can begin at any future date. The licensee is expected to ultimately dispose of its low-level radioactive waste in the Northeast Compact disposal facility. It is projected that this facility will be located in New Jersey and be operational by the year 2001. The licensee expects to commence shipping low-level radioactive waste to the Northeast Compact facility when it is authorized to accept waste from generators. The time required for the licensee to dispose of its estimated storage inventory varies. Every effort will be made to reduce storage inventory as soon as practical.

The E. R. Squibb & Sons low-level radioactive waste storage facility is located in Building 81, a 14,000 square foot building on the New Brunswick site. This facility has the capability of being expanded if additional space is needed. See Item 9, Facilities and Equipment for a description of the facility.

Low-level radioactive waste shall be packaged in strong, tight containers so there will be no leakage of radioactive materials under conditions normally incident to transportation and storage. These containers will be compatible to the waste material being stored and should not have an effect on the container's integrity. It is projected that the storage life of the container will be at least 15 years. Quarterly inspections of low-level radioactive waste packages will be performed to insure that they retain their integrity and containment of radioactive waste. Mechanical and/or electrical lifting equipment is available for stacking drums in storage racks. Any damaged or leaking waste containers will be repacked in an isolated area using protective equipment and guidelines that are conducive to such operation.

Radioactive containers will be stored on pallet racks that are separated by sufficient aisle space to allow easy direct inspection on a routine basis. Since the primary radionuclides that will be stored in the facility will be low energy beta emitters, storage containers will provide the shielding necessary to minimize personnel radiation exposures. Additional shielding will be used if necessary to maintain occupational exposures ALARA, but the need is not anticipated. The storage area is posted in accordance with 10 CFR 20.1902. Radiation and contamination surveys of the storage area and individual packages and/or containers are conducted on a routine basis. The exposure rates for the majority of the packages stored by the licensee during interim storage will be in less than 5 mR/hr at the surface and 1 mR/hr at a meter. The existing method used for monitoring personnel exposures and E. R. Squibb & Sons radiation protection program will not be changed or degraded as a result of waste storage.

Records of waste in storage are maintained in a manner similar to our existing inventory procedures. Specifically, all waste receipts are recorded according to category, radionuclides, activity and date of receipt. Containers are placed in designated storage locations and their activities adjusted for decay. Any waste removed from the facility is subtracted from the inventory records.

All occupational workers assigned to the interim storage facility will receive instructions in the packaging, handling and inspection of radioactive waste. In addition survey techniques and emergency response training will be provided. Refresher training will be provided every two years.

Emergency response measures will be in accordance with the site's Radiological Contingency Plan detailed in Addendum II of this application.

Processing

The only method of on-site waste processing is open drum compaction. Compaction of waste is performed with an open head drum compactor in the manufacturing area, Building 122 (Consolidated Bailing Machine Company, Model DOS-RAW-CB1) and Building 81 (Ram Flat drum compactor, Model #55E) at the New Brunswick site. The location of this equipment can be identified on Diagrams #1 and #3 in the Item #9, Facilities and Equipment of this application. Dry radioactive waste consisting of paper, plastic, glass and metal in plastic liners is compacted into fifty-five gallon steel drums. Approximately five drums per quarter are compacted. Liquid, biological, and mixed waste are not compacted. Each compactor ventilation system draws air through the unit and away from the operator's breathing zone. The ventilated air is drawn through an F-85 HEPA and charcoal filtration as described in Item #9, Facilities and Equipment. If volatile iodine is compacted, the operator is required to perform a thyroid bioassay within twenty-four hours of using the compactor. Contamination surveys are performed on a routine basis in accordance with Item #10, Radiation Safety Program. Operators are instructed in radiation safety and contamination control. Work clothes or lab coat and gloves are required when handling the open containers of waste or operating the compactor. When a drum is full, it is inspected for damage resulting from the compaction procedure and then closed. Empty drums are surveyed for residual contamination, decontaminated if needed, inspected, and are either re-used or discarded as scrap.

Releases to the Environment

The release of radioactive material to the environment through air emissions within the limits specified in 10 CFR 20.1302 is not a method of waste minimization currently used at E. R. Squibb & Sons. Air emissions are maintained ALARA through the use of filtration and procedural controls. Should this method be utilized in the future, it would require the approval of the Radiation Safety Committee and the implementation of a sampling program to document conformance with 20.1302.

The release of aqueous, soluble liquid radioactive waste to the POTW is under the control of the Health Physics Department. The solubility characteristics of the waste is based upon generator knowledge of the waste stream. Non biological suspended solids are not released to the POTW.

The New Brunswick manufacturing facility utilizes holding tanks to control radioactive waste releases to the POTW from this area. Liquid is collected in one of the four holding tanks until the tank is full, the facility effluent flow is then switched to an empty holding tank. The full tank is allowed to decay for a period of time that is determined by the total capacity of the four tanks and the building effluent. Before a tank is released, its contents are agitated to ensure a uniform mixture and then sampled. The sample is analyzed by gamma counting and/or liquid scintillation counting to quantify and identify the radionuclides present. This data is compared to the effluent limits in 20.2003 and the total site effluent. Upon approval of the area Health Physics Supervisor, the contents of the tank is then released to the POTW. Records of the radioactivity released, the date, volume, and an annual activity total are maintained as required.

At release points that do not have or utilize a holding tank, liquid waste is collected in containers prior to release to the POTW. Prior to release, each container is sampled and analyzed as noted above. If the contents of a container conforms with 20.2003, it is released to the POTW upon approval of the area Health Physics Supervisor. Records of the radioactivity released, the date, volume, and an annual activity total are maintained as required. Individual laboratories are not permitted to release any radioactive waste to the POTW from their laboratory sinks. If an authorized user requested permission to release liquid waste directly from their laboratory instead of from a centralized release point, the request would have to be approved by the Radiation

Safety Committee. The authorized user would be required to implement a sampling program that complies with the Health Physics Department's program. The Health Physics Department would audit the sampling program and release records on a routine basis to ensure continued compliance with 20 2003

Item #12: Licensee Fee

Fee category: 3A

Amount Enclosed: \$550.00

ADDENDUM I

Financial Assurance for Decommissioning

A "Parent Company Guarantee" was submitted to the Commission in April, 1994 for this license to comply with the financial assurance requirements specified in 10 CFR 30.35. That document is still valid with the following modifications:

- The original Cost Estimate for Decommissioning assumed that the Building 81 Interim Waste Storage Facility was full to capacity at the time of decommissioning. Since disposal is currently available and it is expected to be available for several years, this assumption is no longer valid and the estimated cost for disposal of 448.7 cubic meters of waste has been removed. The estimated cost associated with this waste disposal was \$5.7 million.
- The new radiosynthesis suite in Building 107 in New Brunswick has been added to the Cost Estimate for Decommissioning. The estimated cost for decommissioning of this laboratory suite is approximately \$450,000.00. In addition, other laboratories have been decontrolled since 1994.
- The Financial Assurance documents submitted in 1994 were based upon December 1993 dollars. From December 1993 to December 1996, the Consumer Price Index has risen by 9.1%.

The effect of these changes results in a revised estimated decommissioning cost of \$27.7 million. This amount is 13% below the original amount assured. Therefore, the 1994 amount is still valid. The financial standards required under a parent company guarantee are verified on an annual basis to ensure that this method of financial assurance meets the requirements specified in Regulatory Guide 3.66.

ADDENDUM II

Radiological Contingency Plan

RADIOLOGICAL CONTINGENCY PLAN

NRC LICENSE # 29-00139-02

DANIEL K. BALKUNOW

RADIATION SAFETY OFFICER

E. R. SQUIBB & SONS, INC.

ONE SQUIBB DRIVE

NEW BRUNSWICK, NJ 08903-0191

A WHOLLY-OWNED SUBSIDIARY OF
BRISTOL-MYERS SQUIBB COMPANY

Rev. January 15, 1997

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EMERGENCY NOTIFICATION LIST			
GROUP/PERSON	EMERGENCY CLASSIFICATION		
	LEVEL 1 CMP	ALERT	SITE AREA EMERGENCY
Emergency Director	Yes	Yes	Yes
Alternate	Yes	Yes	Yes
Emergency Monitoring Team	Yes	Yes	Yes
Emergency Response Leader 1	Yes	Yes	Yes
Emergency Response Leader 2	Yes	Yes	Yes
Fire Protection & Prevention	Opt.	Yes	Yes
Alternate	Opt.	Yes	Yes
Environmental Health & Safety	Opt.	Yes	Yes
Alternate	Opt.	Yes	Yes
Maintenance	Opt.	Yes	Yes
Alternate	Opt.	Yes	Yes
Utility Services	Opt.	Yes	Yes
Alternate	Opt.	Yes	Yes
Radiodiagnostics Operations	Yes	Yes	Yes
Alternate	Opt.	Yes	Yes
Plant Security	Opt.	Yes	Yes
Fire	N/A	Through Plant Security if needed	
First Aid	N/A	Through Plant Security if needed	
Robert Wood Johnson University Hospital	N/A	Through Plant Security if needed	
New Brunswick Police Dept.	N/A	Through North Brunswick Police Dept.	
New Brunswick Fire Dept.	N/A	Through North Brunswick Police Dept.	
North Brunswick Police Dept.	N/A	Through Plant Security if needed	
North Brunswick Fire Dept.	N/A	Through Plant Security if needed	
HAZ MAT	N/A	Yes	Yes
NBOEM	N/A	Yes	Yes
EPA	N/A	Yes	Yes
NJDEP	N/A	Yes	Yes
NJSPOEM	N/A	Yes	Yes
USNRC	N/A	Yes	Yes

QUARTERLY CHECK OF EMERGENCY RESPONSE PHONE NUMBERS

SERVICE/LOCATION	PHONE NUMBER	DATE OF VERIFICATION			
		1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.
FIRE:					
New Brunswick	Will be contacted by North Brunswick (908-745-6200)				
North Brunswick	911				
POLICE:					
New Brunswick	Will be contacted by North Brunswick				
North Brunswick	Emergency 911				
N.J. State Police (Sgt. John Connolly)	609-636-6069				
NJ State Police	609-882-2000*				
FIRST AID:					
New Brunswick	Will be contacted by North Brunswick				
North Brunswick	911				
HAZMAT:					
Middlesex County	908-727-6626				
	908-727-6622*				
OFFICE OF EMERGENCY MANAGEMENT:					
Middlesex County	908-727-9000				
	908-727-6622*				
North Brunswick	908-247-0922 X367				
MEDICAL SERVICES:					
Robert Wood Johnson Hospital	908-937-6089				
St. Peter's Medical Center	908-745-8600				
REGULATORY:					
U.S. N.R.C.	301-816-5100* (primary) 301-951-0550* (secondary) 301-816-5151 (fax)				
N.J. D.E.P.	609-984-5462 609-292-7172*				
E.P.A.	908-548-8730*				
ON-SITE SERVICES:					
Security	X4444				
First Aid	X4444				
Medical	X4444				
Safety	X4444				
Utilities	X4444				

*24 Hour Hotline

SECTION I

GENERAL DESCRIPTION OF PLANT/
LICENSED ACTIVITY

1.0 Facility Description

E. R. Squibb & Sons, Inc. owns and operates a pharmaceutical manufacturing and research facility located in Middlesex County, New Jersey. The site occupies approximately 96.2 acres primarily in the township of North Brunswick, at the crossroads of Route 1 and Squibb Drive.

Geographically, the site can be represented at 40 degrees, 28 minutes, and 25 seconds North; and 74 degrees, 28 minutes, and 25 seconds West.

The topography of the site is relatively flat. Elevations near the center of the site are close to 120 feet above sea level, while elevations near either end of the site are approximately 105 feet above sea level.

There are approximately 40 individual structures, ranging in height from 10 feet to 75 feet above grade. Structure sizes are variable but can be considered to contain between 5,000 and 150,000 square feet. Uses include warehousing of raw materials and finished products, animal facilities, analytical and pilot plant laboratories, bulk chemical processing, finished product and packaging, and utilities, maintenance and administrative services.

Parking facilities cover about 17% of the entire site. Approximately 5 1/2 acres, at the southern end of the site, are set aside as a picnic grove and recreational area.

1.1 Description of Licensed Activities

E. R. Squibb and Sons, Inc. of New Brunswick, New Jersey is the holder of a Type A Broad Scope License No. 29-00139-02 issued by the Nuclear Regulatory Commission. With the exception of research activities utilizing small quantities of radionuclides, the radiopharmaceutical manufacturing plant (Building 124) and its storage facility (Building 122) are utilized for the processing, storage and decay of radioactive materials generated during the manufacture of radiopharmaceuticals. Both structures are located at the southwest end of the 96.2 acre site and occupy approximately 1.75 acres.

Only small quantities of hazardous chemicals are utilized in the processing and testing of radiopharmaceuticals in Building 124. Approved areas have been designated for the allocation and storage of such chemicals. Eyewash stations and showers are also provided near areas where hazardous chemicals are used.

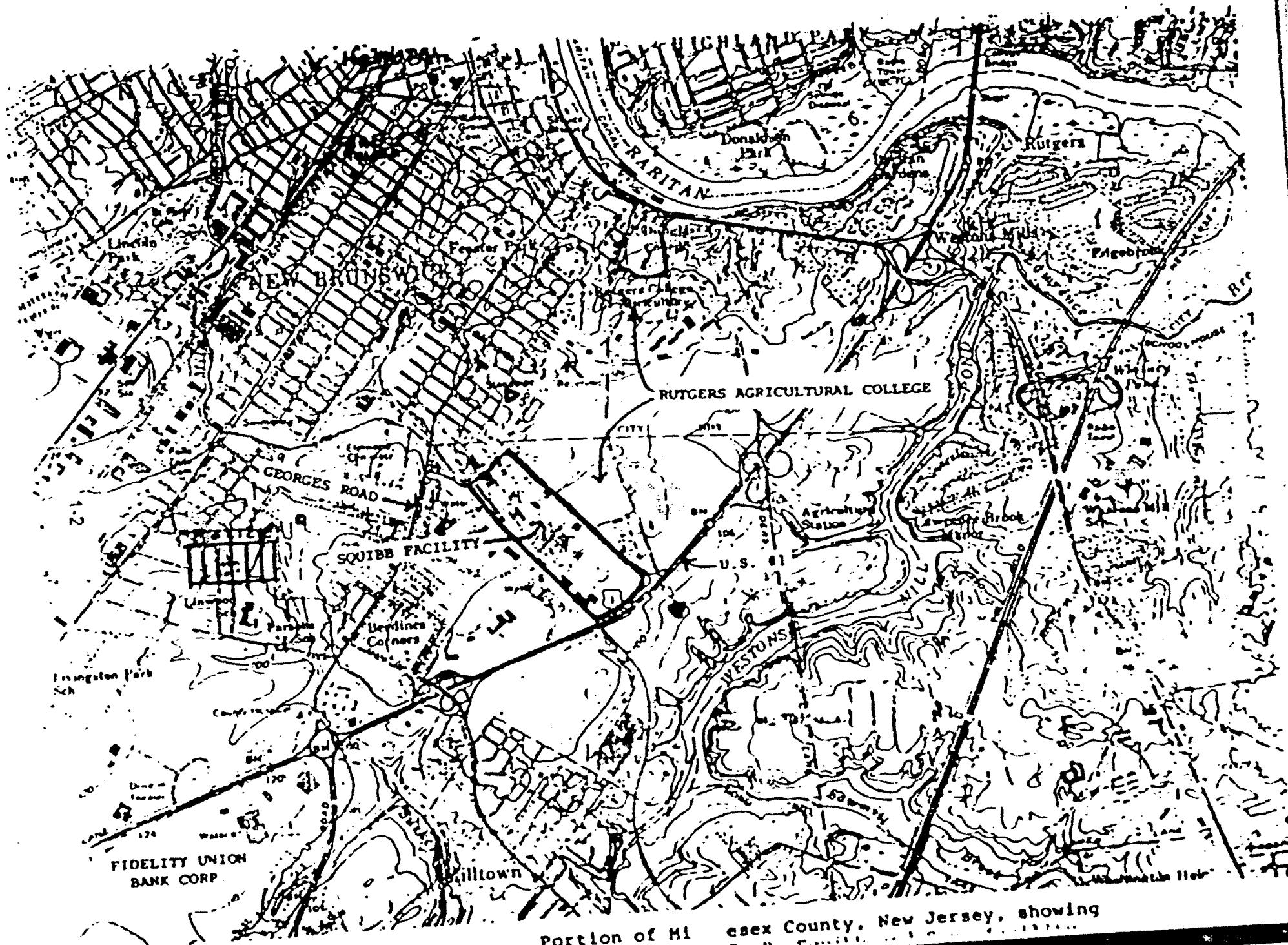
Building 81 is the interim waste consolidation and storage facility for R&D waste. This 14,000 square foot facility is the central waste storage facility for five (5) Bristol-Myers Squibb sites in central New Jersey, and is also a "Permitted Part B" storage facility whose number is 1214KIHP01. This facility includes a waste sorting and processing area, a large freezer for biological waste, a mixed hazardous waste storage area and a dry waste storage area.

Buildings 105 and 107 contain R&D laboratories, including a radiosynthesis suite that utilizes millicurie quantities of C¹⁴ and H³. It is located on the 2nd floor of Building 107.

1.2 Description of Area Near the Site

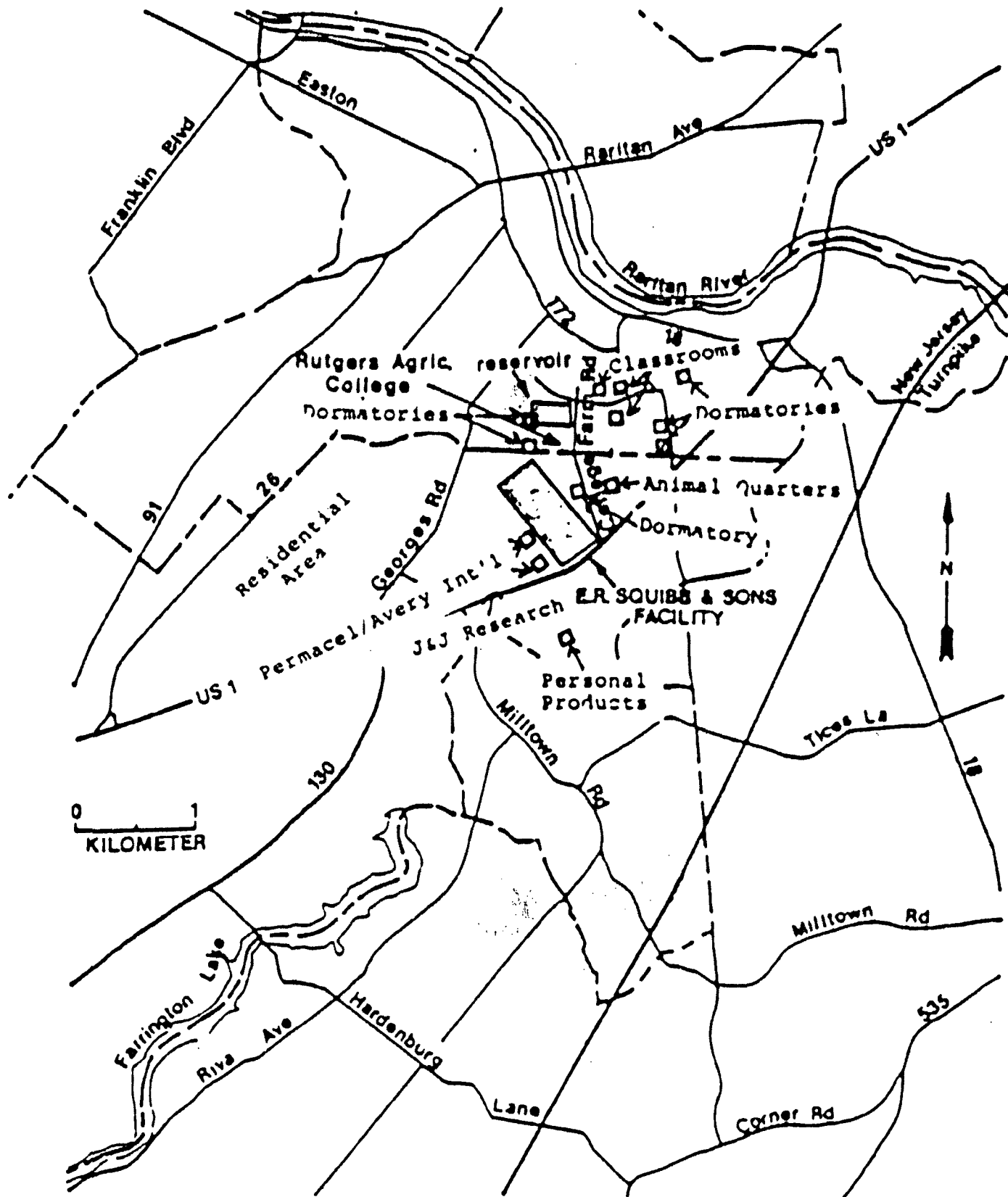
Included is a map of the New Brunswick, New Jersey area (Figure 1-A) which indicates the location of office buildings, school dormitories, classrooms and primary routes for access of emergency equipment or for evacuation.

Population centers are identified by ☐ on the map labelled Figure 1-A.

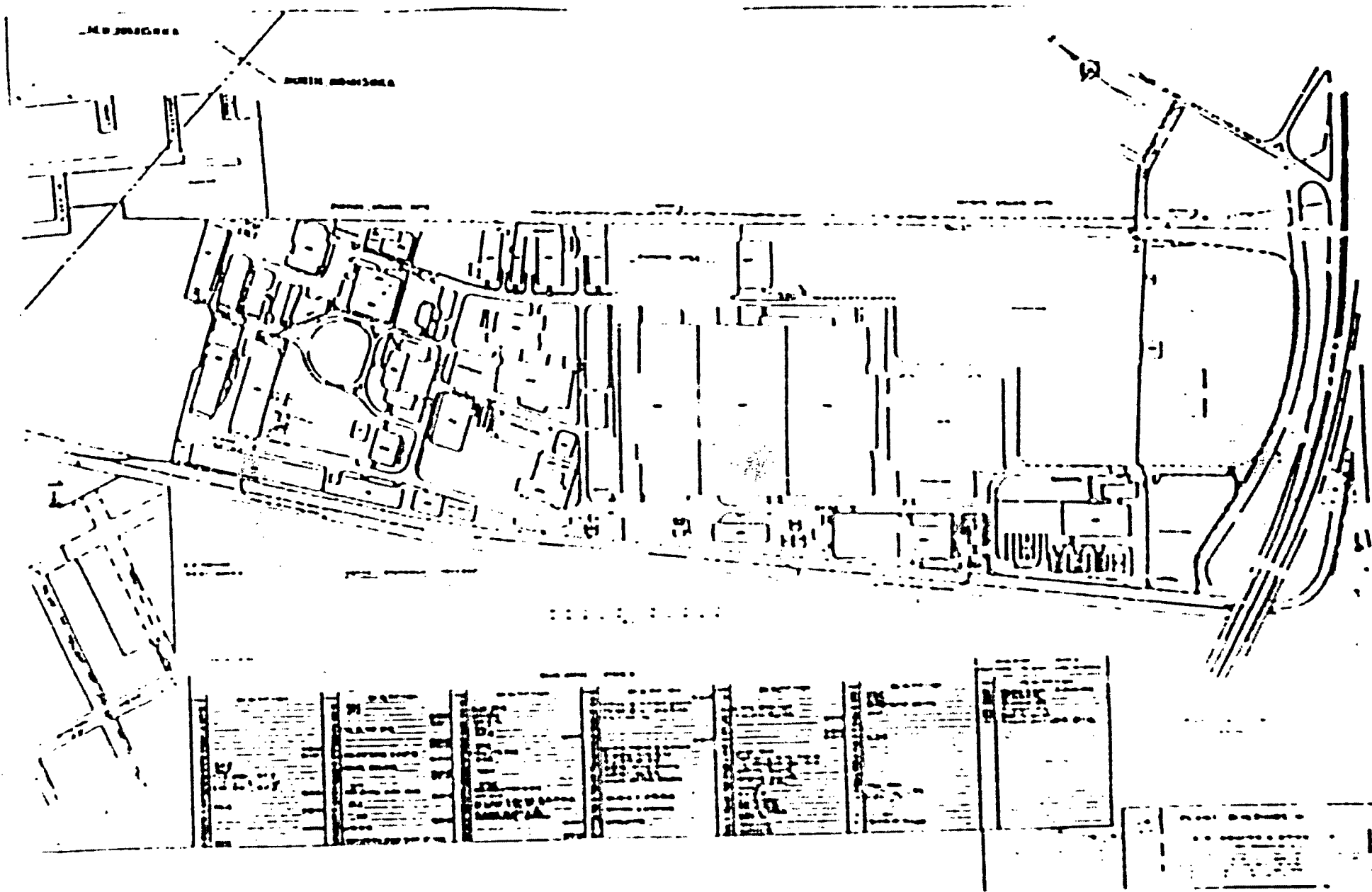


Portion of Middlesex County, New Jersey, showing
location of the S. B. Squibb & Co. Plant

Figure 1-A



Map of New Brunswick, New Jersey Area Indicating the Location of the Squibb Facility and Nearby Structures. 1.3



Portion of Middlesex County, New Jersey, showing
location of the E. R. Squibb & Sons facility

(10 mile Radius)



Description of Area Near the Site (Continued)

Primary routes used to service the Squibb New Brunswick, New Jersey site are US 1, Highway 130 and the New Jersey Turnpike. These routes, as well as secondary streets and roads are utilized and shown on the map labelled Figure 1-A.

The location of off-site emergency support organizations (Fire and Police stations and Robert Wood Johnson Hospital) are identified on the map labelled Figure 1. In addition, sites of potential emergency significance are also identified in Figure 1. A site plan and general area map which shows a portion of Middlesex County, New Jersey within a 10 mile radius of the E.R. Squibb & Sons, Inc. facility are included. The site plan is identified as Figure 2 while the general area map is labelled Figure 3.

Resident population within a five mile radius from the Squibb New Brunswick plant site is estimated to be 300,000 individuals, based on 1990-1992 census data. Approximately 200,000 individuals are employed within a five mile radius with 100,000 daily commuters passing the site.

1.3 Description of Facility and Site - Building 124

The radiopharmaceutical manufacturing facility is a two-story brick structure located on the southwest end of the site. All manufacturing and processing of radiopharmaceuticals are conducted in the rear of the plant (building 124) on the ground floor making access and egress for evacuation of personnel an easy task. Unrestricted administrative offices are located on the first and second floor in front of the plant away from the normal manufacturing operations. There are no elevators and the only stairways are those located in the unrestricted office areas and those leading to the second floor machine room.

All buildings within the site are provided with portable fire extinguishers distributed and maintained in accordance with NFPA 10, as required under the provisions of the OSHA 1910 subpart L and NJAC 5-18.

Although the license authorizes the possession and use of various nuclides in significant quantities, typical production operations are limited to the use of approximately five isotopes with maximum inventories ranging from 5 to 150 Curies. Specific isotopes and possession quantities normally possessed and processed are as follows:

Isotope	Maximum Inventory	Form
^{131}I	150 Curies	Sodium Iodide
^{90}Sr	15 Curies	Strontium Chloride
^{90}Sr	75 Curies	Strontium Chloride
^{51}Cr	5 Curies	Sodium Chromate
^{57}Co	0.05 Curies	Cobalt Chloride

Description of Facility and Site - Building 124 (Continued)

All processes within the site are protected by a looped fire protection water distribution system supplied by independent water sources. The site maintains three 1,500 gpm fire pumps, two of which are supplied by a 300,000 gallon above ground water tank.

Radiological facilities are provided with class 2 hose stations supplied by the building sprinkler system in accordance with NFPA 14 and maintained as specified under subpart L of OSHA 1910 and NJAC 5:18.

Every work area where radioactive materials are stored, processed or tested is equipped with automatic sprinklers. Hot cells, which are constructed of steel, concrete and lead, serve as primary containment in the event of an explosion. The building and its charcoal filtration systems are considered secondary containments.

1.3.1 Shielding

Leaded glove boxes and hoods are used to manufacture and fill radiopharmaceuticals of different concentrations. The shielding used varies from one to two inches of lead depending on the radionuclide and activity. The lead is encased in stainless steel which is expected to maintain its effectiveness under the most severe postulated accident conditions. In many cases, additional shielding is provided in the glove boxes and fume hoods to shield the bulk radioactive material to maintain radiation levels on the outside of the enclosure as low as practicable.

The hot cells are constructed of steel and concrete equivalent to form four to eight inches of lead. The steel and concrete used in the walls, flooring and ceiling of the hot cells range from 14 inches to more than three feet in thickness.

It is unlikely that a fire or explosion would occur within these hot cells. Therefore, it is highly improbable that an accident would occur which would reduce the effectiveness of the shielding.

1.3.2 Process Systems

A. Building 124

The manufacturing areas are served by a non-recirculating air conditioned supply system utilizing all outside air introduced through a prefilter and a high efficiency particulate filter. A general system exhausts the various spaces through filtration equal to that of the supply system. Fume hoods, wherein particulate matter is the expected contaminant, are exhausted through an F-85 and a High Efficiency Particulate Air (HEPA) filter followed by a 1" high efficiency carbon filter to arrest any possible gaseous contaminant. The Room 181 cave is exhausted through an F-85 and a HEPA filter and three 1" charcoal filters. Certain manufacturing glove boxes are also exhausted through an F-85, a HEPA and two or three one-inch high efficiency carbon filters.

Each of the eleven fume hood system filter banks service from one to five fume hoods or other ancillary equipment. Each fume hood system has a manual air bypass to be used during filter changes.

Building 124 (Continued)

Each glove box filter bank services up to five glove box units or similar equipment. Each glove box system has access to an auxiliary system offering identical filtration. There are no bypasses to allow passage of unfiltered extl air. There are twelve glove box systems and six auxiliary systems available for use during filter changes or maintenance.

Filtration for three hot cells is accomplished by employing two identical exhaust systems. One is in continuous operation, while the other exhaust system serves as an auxiliary system when the primary is shut down for decay prior to filter changes or maintenance. Each system is filtered by three roughing, three HEPA and nine one-inch equivalent activated charcoal filters. There are no bypasses to allow passage of unfiltered cave system air.

Each filter bank is equipped with before and after continuous sample tubes used to check charcoal filter efficiencies. They are changed and assayed on a routine basis. The sample tubes are counted and an evaluation is made as to which bank should be changed, if applicable. There is no definite filter change criterion. Each system is examined individually to provide the most effective reduction in effluent.

The combination of particulate and gaseous filters described serves to reduce the effluent of radionuclides such as ^{131}I , etc. to the lowest practicable level.

All exhaust systems are discharged to the effluent exhaust stack. The system used for sampling extl air from the stack is comprised of six one-inch lines within the extl duct. Each of these lines hold six pitot tubes facing upstream. The one-inch lines connect to two two-inch lines that pass through the main exhaust duct, then combine into a six-inch line. The system is drawn by a fan that exhausts to another extl duct prior to entry back to the main duct exhaust. The effluent air sample drawn from the six-inch line post fan, runs continuously at approximately 1.85 cubic feet per minute and is changed each work day.

The radioactivity collected in the sampler is constantly measured by the stack alarm detector which will sound an alarm in the Health Physics operations area should the integrated activity representing the 24 hour effluent limit for I-131 as specified in Appendix B, Table II, Column I of 10CFR20 be exceeded. The sample is a TEDA 2.25 in. diameter cartridge #TC-45 with 40-50 mesh impregnated carbon or equivalent. The sampling system has been designed to ensure isokinetic sampling.

B. Building 81

Building 81 engineering safeguards include a fire protection system, key card access control, and explosion proof electrical fixtures in the mixed hazardous waste storage area, which is isolated from the main storage area by fire walls.

This facility also contains two separate ventilation systems. One partially recirculating air system services the dry storage and office areas. The second ventilation system, services the mixed hazardous waste storage area and the waste processing area. The ventilation system in Building 81 is a once-through system without recirculation. Both ventilation systems have HEPA filters and charcoal filters, with effluent from both systems continuously monitored by an integrating filter that is collected and analyzed for efficiency on a routine basis.

1.3.3 Alarm Systems and Release Prevention Capability

An "Indicating and Alarm" panel in the Health Physics office provides the following

- Alarm and indicating lights for supply systems,
- Filter bank fire alarms,
- "Air failure" indication for gaseous air sampling, and
- Indicating lights showing status of critical filtration systems (i.e., lights will indicate which filter banks are in use and those that are on "standby.")

1.3.4 Support Systems

Fire protection is provided at each branch connection to glove boxes and fume hoods, etc. by means of "photoelectric" type smoke detectors. Carbon filters are also monitored by means of "photoelectric" type smoke detectors in the duct work. Generally, detectors will isolate a filter fire from the air stream by closing metal-sealed shutoff valves and transfer the effluent to the standby filters, or stop the fan, depending on the type system involved. Should the air system which supplies automatic controls fail, all filter intake and exhaust valves are designed to fail safe (in the regular operating position).

The plant is also equipped with an auxiliary generator which will automatically engage in the event of an electrical power failure. The generator is capable of maintaining the air systems, emergency lighting and radioactive air sampling system for the plant.

1.3.5 Control Operations

Air velocity measurements in ventilated enclosures are conducted at least quarterly to ensure regulatory guidelines are satisfied.

In addition, plant engineers routinely monitor the plant's control systems located in the machine room area to ensure they are functioning properly.

1.3.6 Location of Communication and Assessment Centers

Two areas within the site have been designated to control and coordinate on-site radiological emergency activities.

1.3.7 Health Physics Command Center

The Health Physics Command Center is located immediately outside the restricted area of the Radiodiagnostic Manufacturing facility. This area contains radiological emergency supplies, equipment, instrumentation and a communication system for all rooms and areas within the Radiopharmaceutical Production plant. Small scale radiological activities occurring within Building 122 and 124 as well as all other emergency activities of a radiological nature would be coordinated or directed from this location.

1.3.8 Alternate Emergency Command Center

The Building 109 Command Center is the Emergency Command Center. The Health Physics office in Building 80/84, Room 316 is equipped with emergency supplies, instruments and equipment to perform evaluations of radiological incidents that might occur within the licensed site. Telephones and portable walkie talkie radios are available for emergency communication.

Any radiological incident that requires temporary evacuation of the production plant or within a site research facility would be coordinated and controlled from either of these two locations. In addition, an emergency vehicle equipped with radiological and environmental monitoring supplies and communication equipment is available on site 24 hours a day.

1.3.9 Communications Equipment

The on-site communication systems consist of telephones, a site paging network and walkie-talkies. Security, Environmental Health & Safety and emergency response personnel are equipped with paging units activated by the site paging system. A fire evacuation system and/or the Building 124 intercom system is utilized to notify personnel of emergencies within the manufacturing areas. In addition, UHF radios are used to transmit vital information and instruction in the event of an emergency.

1.3.10 Facility for Assessment Teams

The facility designated for use by staff performing post-accident and recovery assessment and protective action functions is the Health Physics command center and/or conference room in bldg 124. If not accessible the Building 109 Command Center will be used.

1.3.11 Location of Assembly & Relocation Areas

In the event of a radiological incident in Building 122 or 124, all radiopharmaceutical operational personnel are required to evacuate the plant and assemble in the east parking lot (located between 115 and 124). Upon assembling, contamination surveys and accountability of personnel will be performed. Instructions to relocate or further direction will come from the Emergency Director.

1.3.12 Identification of Process & Storage Areas for Radioactive Materials

All manufacturing, packaging and testing laboratories within the diagnostic plant are located on the first floor. These areas occupy approximately 40,000 square feet. Entrances to as well as the perimeters around the facility are labelled with "Caution Radiation Area" signs

The radioactive waste processing and storage location (Building 122) is located in the secure radiation area behind the manufacturing plant.

The interim waste storage area is located in Building 81, adjacent to the drum yard on the corner of Avenue E and Elm Street.

The radiosynthesis suite is located on the 2nd floor of Building 107. Building 107 is located between Avenue A and Avenue E, and connected at the north side to Building 105 and to the south side by Building 109 and Building 115

SECTION 2

ENGINEERED PROVISIONS FOR ABNORMAL OPERATIONS

2.0 Description of Postulated Incidents

Described below are postulated incidents which may result in exposure to off-site personnel, but have a low probability of occurrence. These are included to provide examples of possible incidents, and how they are detected and investigated. Also refer to Section 5, Figure 5, "Radiological Assessment/Corrective Action Guidelines".

A. Condition I

The incident outlined below describes equipment malfunction and human error in a manufacturing procedure that could result in the release of significant amounts of Iodine I-131 within the plant as well as beyond the site boundaries.

During the transfer of 8 Curies of Sodium Iodine (I-131) from the bulk allocation hot cell room 174 to the Iodotope Therapeutic capsule manufacturing area (room 172), the operator trips over the cord to the buffing machine and causes the following to take place:

1. The transfer cart turns over and the 8 Curies of iodine are released into the hallway upon impact.
2. The buffing machine is pulled into the cart and wall and becomes activated causing its motor to strike a sharp object on a fork truck.
3. An electrical fire results near the spill causing the iodine to volatilize. Because of the nature and location of the incident, a significant amount of free iodine is vented through the air handling system. Some of the remaining material has a potential to escape to the environment through the cave hallway area and outside door. This event could possibly affect on-site and off-site personnel.

B. Condition II

A short circuit occurs in an equipment charging station or emergency lighting unit. Either of these situations would generate sparks and create an enormous amount of smoke. The electrical breaker servicing either unit would automatically trip to the off position to prevent an electrical fire within the plant.

2.1 Detection of Emergency Conditions

A. Condition I

Since the manufacturing plant is equipped with overhead sprinkler units located throughout the facility, any discharge of water from the building sprinkler system would activate the fire pump station located in building 123 which sends a signal to the main guard house. The security officer on duty would notify the company's fire brigade, the zone utility engineer and sound the evacuation alarm to alert all building 122 and building 124 personnel.

Condition I (Continued)

Remote monitoring detectors located in manufacturing locations would inform Health Physics operational personnel of areas with radiation levels of 50 mR/hr. These detectors are calibrated at least semiannually to produce a blue warning light and an audible alarm in the work area and in the Health Physics operations area should background levels reach 50 mR/hr. If the level of radiation is measured at 100 mR/hr or greater, a red light and alarm will be activated on the Health Physics control panels. In the event a situation similar to the above occurs, emergency response personnel will be notified and the contingency plan activated.

B. Condition II

This type of emergency would be detected by operational personnel during production hours. Should an incident of this nature occur during nonproduction hours, the plant security force is likely to detect such abnormal occurrences during periodic building checks. In the event an incident of this nature were to escalate, the overhead sprinkler units located throughout the facility would activate.

SECTION 3

CLASSES OF RADIOLOGICAL CONTINGENCIES

Classification and Notification of Incidents

This section describes the classes of incidents according to the severity and the potential impact of the radiological incident. An incident is defined as an event or a series of events, either deliberate or accidental, leading to the release, or potential release, into the environment of radioactive materials in sufficient quantity to warrant consideration of protective actions. The purpose of the classification system is to assist the Emergency Director in assigning a severity level to particular situations while in their initial stages so that off-site assistance organizations can be promptly notified, if necessary. It also provides for the ability to escalate or downgrade any emergency class when appropriate as the incident continues to unfold. The two classification systems are Alert and Site Area Emergency. Examples of incidents for each class are as follows:

Alert	Site Area Emergency
Electrical power failure for \approx 1 hour which results, or is projected to result in off-site TEDEs greater than 100 mRem but less than 1,000 mRem*	Electrical power failure for \geq 8 hours which does not or would not be projected to result in off-site TEDEs exceeding 1,000 mRem*
Fire in production area requiring on-site or assistance from local authorities. Could result in off-site TEDEs greater than 100 mRem but less than 1,000 mRem*	Explosion of propane tank at nearby facility or LPG line near site which does not or would not be projected to result in off-site TEDEs exceeding 1,000 mRem* except near the site boundary
Fire/major incident involving vehicle carrying 1 Ci of radioactive materials within the site. Could result in off-site TEDEs greater than 100 mRem but less than 1,000 mRem*	Fire causing the burning of carbon filters which does not or would not be projected to result in off-site TEDEs exceeding 1,000 mRem* except near the site boundary
Two or more contaminated injured personnel requiring off-site hospital assistance could result in off-site TEDEs greater than 100 mRem but less than 1,000 mRem*	Multiple Cunes of volatile iodine spill in hallway off-site. TEDEs not expected to exceed 1,000 mRem* except near the site boundary
Dose rate at perimeter \geq 2 mR in any one hour period	Dose rate at perimeter \geq 20 mR in any one hour period
24 hour avg stack release \geq 50% limit as specified in Appendix B, Table 2, Column 1 of 10 CFR 20	24 hour avg stack releases \geq 5,000% limits as specified in Appendix B, Table 2, Column 1 of 10 CFR 20

*Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, Table 2-1 PAGs for the Early Phase of a Nuclear Incident, May 1992.

3.2 Notification and Coordination of Radiological Incidents for all Classes of Emergencies

Any event that requires the implementation of the Radiological Contingency Plan (RCP) [Appendix G of Crisis Management Plan] will involve the Crisis Management Plan. The Crisis Management Plan supersedes the Radiological Contingency Plan for Level 2, 3 and 4 radiological contingencies, as defined in the Crisis Management Plan (See Section #3, Page CMP-5 of Crisis Management Plan)

A. Levels of Response - New Brunswick Crisis Management Plan

Levels of response for the New Brunswick Crisis Management Plan (CMP)

- Level 1:** An emergency event within the capabilities and training of the operating department
- Level 2:** An emergency event not within the capabilities or training of the operating department, but within the resources of the site. This may be considered an RCP "Alert" if site emergency response personnel are required
- Level 3:** An emergency event handled by on-site response groups but requiring additional resources for the purposes of technical support, clean up, or hazardous waste removal. This is equivalent to an RCP "Alert"
- Level 4:** An emergency event requiring emergency action by off site response groups or the incident has extended beyond the limits of the site. A Level 4 incident requires the complete activation of the Crisis Management Team. This is equivalent to an RCP "Site Area Emergency"

The Radiation Safety Officer or his designee has the authority and will be responsible for the following actions regarding Level 1 CMP incidents of a radiological nature

1. Decision to declare radiological emergency of any classification
2. Activation of on-site emergency response organizations
3. Ensuring notification is made to federal, state, and local regulatory agencies
4. The initiation of on-site protective actions

5. Escalating or downgrading the event to the next emergency classification if appropriate.

6. Terminating the emergency or entering a Recovery Mode

The above actions will be accomplished primarily through the assessment of environmental data, plant conditions and severity levels of incidents that are obtained from assistance groups.

3.3 Information to be Communicated

This section describes the type of information to be communicated when requesting off-site emergency assistance or when reporting a radiological incident

The information being conveyed shall not include technical terms and jargons or provide an under or over evaluation of the seriousness of an incident. Information to be communicated shall include the following

1. Name & Title of person requesting assistance or reporting an incident
2. Company name
3. Type & location of incident
4. Services requested
5. Call back telephone number
6. Plant status
 - a. Releases of radioactive material
 - b. Injuries
 - c. Recommendations for off-site protective action

If the condition of reporting is for the purpose of a drill, the statement "THIS IS A DRILL" will be repeated before and after the message

SECTION 4

ORGANIZATION FOR CONTROL OF RADIOLOGICAL CONTINGENCIES

4.0 Organization for Control of Radiological Contingencies

This section describes the organization of emergency assistance groups or personnel who would be notified in the event of an on-site radiological incident. Their authorities and responsibilities are outlined as well as the communication chain identified for the notification, alerting and mobilizing these individuals.

4.1 Normal Plant Organization

The Emergency Director (ED) or any member of his supervisory staff has the authority and responsibility to declare a radiological emergency and initiate the appropriate response personnel (see organizational chart - Figure 4).

4.2 On-site Emergency Response Organization

Any Level 1 or Level 2 CMP event of a radiological nature occurring at the New Brunswick facility would be controlled by the Radiation Safety Officer or Health Physics supervisory personnel. During normal production hours, at least one of those individuals are generally present at this site.

On-site emergency response personnel may be notified and provide assistance during production and non-production periods.

4.2.1 Direction & Coordination

In order to activate the Radiological Contingency Plan without delay, various functional groups have been identified and are responsible for performing specific tasks during emergency situations. These response groups are outlined in Figure 4.

4.2.2 Plant Staff Emergency Assignments

The responsibility and authority of on-site emergency plant staff are described as follows:

A. Emergency Director

The Emergency Director for a Level 1 and Level 2 CMP event is the plant's Radiation Safety Officer who is experienced in the area of emergency response and has a thorough understanding of the Radiological Contingency Plan. This individual has the knowledge and ability to assess the radiological impact of an incident based upon environmental data obtained from the Emergency Monitor Team, and existing production procedures and processes. He has been designated to act on behalf of the company during any emergency situation involving radioactive materials or radiation. The ED has the overall authority to initiate, control and close out response operations.

Emergency Director (Continued)

for radiological events occurring within the license site. He also has the authority to allow re-entry into buildings where radioactive substances are processed. His authority may be delegated to a Health Physics supervisor or a manager assigned to the Radiopharmaceutical Production Plant. His authority may also be delegated to the site Incident Commander (IC) in cases of fire, injury or release requiring non-radiological emergency response groups. Upon this delegation to the IC, the Radiation Safety Officer or alternate assumes the role of radiological safety officer for the site response (see figure 4A).

Levels 3 and 4 events will involve the CMP as previously described in Section 3.2.

B. Emergency Monitoring Team

The Emergency Monitoring Team (EMT) is responsible for assessing radiological incidents and their immediate radiological impact. This group consists of individuals with training and experience in the area of radiation safety. Group leaders (Health Physics Supervisors) are responsible for assuring these individuals obtain exposure rates, determine contamination levels, sample and calculate air concentrations, restrict access to controlled areas, collect environmental data, decontaminate equipment and assist the Emergency Director in determining the level of severity of an incident. Assistance and guidance are also provided to First Aid and Fire fighting personnel as well as other local emergency response individuals or groups.

C. Fire Protection & Prevention

The Manager Fire/Loss Prevention, Environmental Health & Safety Department [Incident Commander (IC)], is experienced in the field of emergency response and is familiar with the workings of the Radiological Contingency Plan. This individual is supported by members of Plant Safety, Human Resources, Public Affairs and other Plant Operational groups. He has overall authority for the management, control and close out of on-site fire and first aid emergencies. In his absence, the captains of the plant's First Aid Squad and Fire Brigades are responsible for directing the actions of these groups. Only the Manager, Fire Loss/Prevention, Associate Director of the EHS Department, Emergency Director or their designee can authorize re-entry into the site after an emergency of a non-radiation hazard.

D. Crisis Management Liaison

The Crisis Management Liaison is an Environmental Health and Safety professional who is experienced in the area of emergency response and is knowledgeable of radiological emergency measures. This individual is a technical advisor to on-site and off-site emergency responding groups, provides initial notification and maintains contact with local and state authorities regarding conditions at the license site, and also handles environmental related issues.

PLANT EMERGENCY RESPONSE GROUP

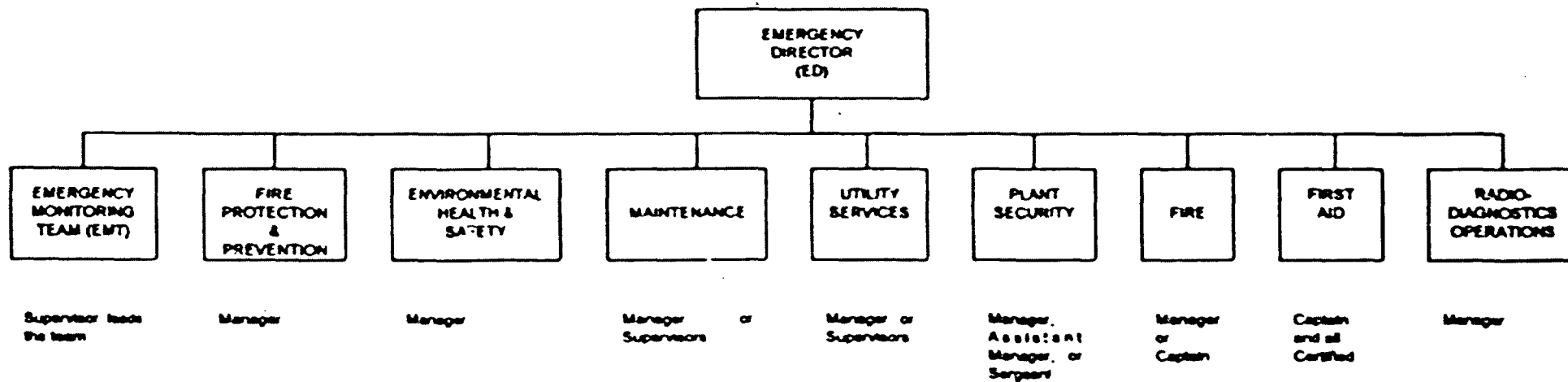
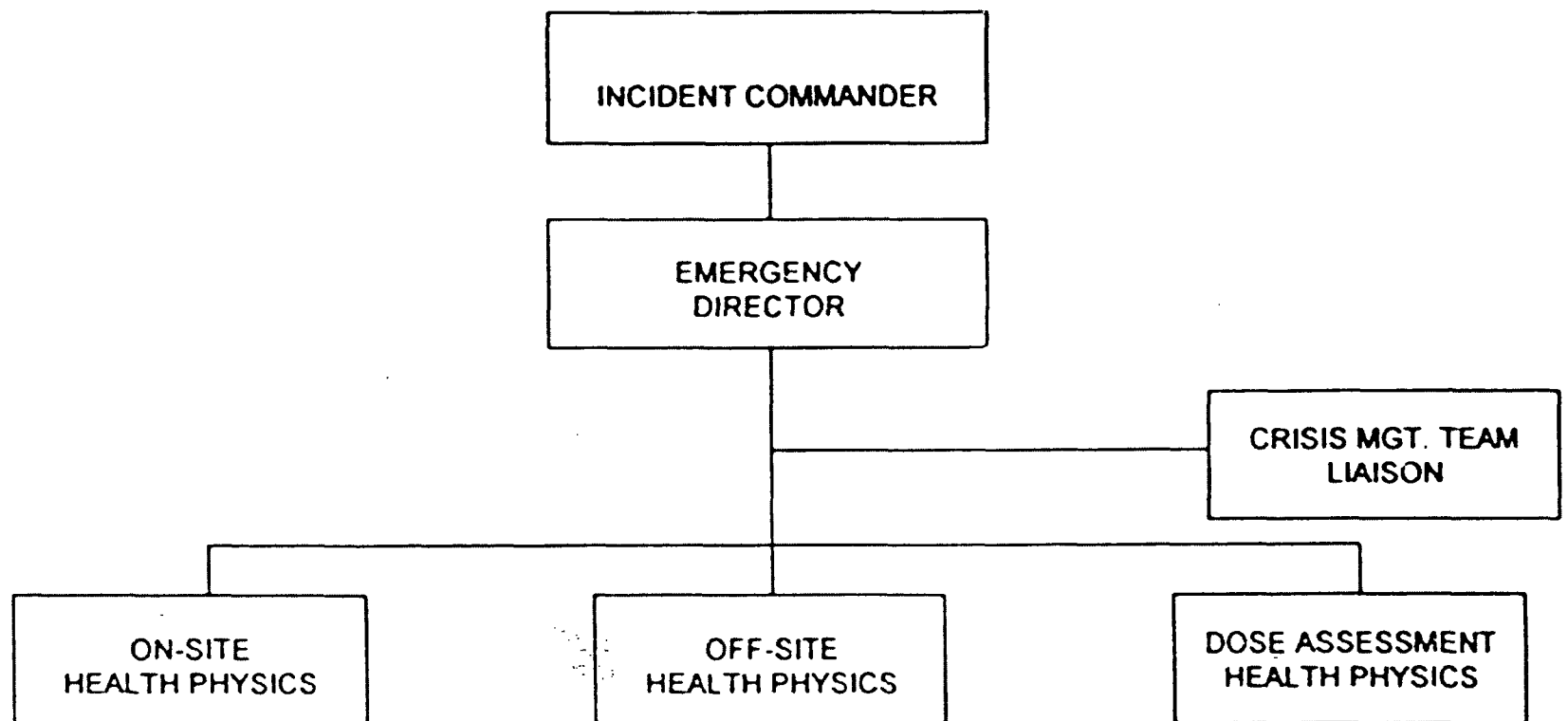


Figure 4



- 1 Search and rescue
- 2 Bldg 124 surveys
- 3 On-site surveys
- 4 Film badge issue to off-site responders
- 5 Bldg. 124 recovery

- 1 Perimeter/fenceline surveys
- 2 Off-site environmental surveys and sampling
- 3 Changing of environmental TLDs
- 4 Off-site contamination checks
- 5 Post accident environmental sampling

- 1 Obtain meteorological data
- 2 Airborne radioiodine determination
- 3 Determine magnitude of release and exposure rate
- 4 Estimate population dose
- 5 Recommend protective actions

Decon Team

- 1 Personnel and equipment contamination checks and decon
- 2 Vehicle contamination checks and decon

E. Maintenance

The manager or supervisor of maintenance personnel assigned to Building 122 and 124 will be notified immediately of equipment failure or other unusual occurrences within the Radiopharmaceutical Plant. Any of these individuals has the authority to assign electricians and general maintenance personnel to the Radiopharmaceutical Plant to service electrical systems and perform general maintenance. They are also responsible for maintaining electrical and mechanical plant systems operations, and assisting in repair, damage control and post-event assessments. All maintenance personnel and supervisors within this group are familiar with plant operational equipment. Each receives an initial radiation safety orientation and annual retraining.

F. Utility Services

Operational support of HVAC and miscellaneous utility systems are performed by personnel assigned to Zone Utility Services. Employees assigned to this group check utility systems servicing the Radiopharmaceutical Plant at intervals of approximately four hours on a 24-hour basis. These employees are constantly monitored for radiation exposure and receive an initial radiation safety orientation as well as annual training on good radiation safety practices and procedures. All group personnel are familiar with plant operational equipments and systems.

In the event an incident occurs when Building 124 is in a non-production phase, the utility service supervisor will be contacted by Plant Security personnel. The utility supervisor is responsible for overseeing the service of plant system operations, assisting in repair and damage control, and post assessment operations.

The Radiation Safety Officer or Health Physics supervisors are responsible for notifying the manager or supervisors of the Utility Service group if an incident involving emergency operations and/or utilities equipment occur within the Diagnostic Manufacturing Plant.

G. Plant Security

The role of the Plant Security Department in the event of a radiological emergency would include notification of on-site and off-site response personnel, assisting in evacuation of plant personnel, establishing and maintaining communication with support groups, and directing traffic flow and barricading restricted areas. This group is directed by a Security Manager and Assistant Security Managers who are experienced in emergency response and are familiar with the Radiological Contingency Plan.

Plant Security (Continued)

The licensed site is manned by full-time uniformed security personnel on a 24-hour basis. Tours of non-restricted areas of the Production Plant are performed by security personnel during non-production times.

H. Manufacturing and Production

The responsibility of the Radiodiagnostics Operations Manager or his alternate is to inform the Emergency Director and Plant Emergency Personnel of the activities and procedures being conducted within the plant during an emergency. This individual is extremely knowledgeable of all facets of the radiopharmaceutical manufacturing, filling and packaging operations. He is familiar with emergency response procedures and the Radiological Contingency Plan.

I. Plant Fire Brigade

The plant maintains an organized Fire Brigade currently consisting of approximately two full-time and seven volunteer fire protection personnel. This group is capable of providing and responsible for full fire prevention, fire suppression and hazardous materials response to locations within the licensed New Brunswick site. Brigade members are equipped with personal protective equipment conforming to OSHA 1910 Subpart L. They receive annual training from various recognized training schools.

In the event of a fire, explosion or other emergency incident that could require the assistance of the fire brigade, the Fire Alarm System would automatically notify Security and simultaneously notify building personnel to evacuate the area. Security would notify the plant fire brigade to respond.

Plant fire brigade members respond to the Firehouse and confirm location of alarm from guard via radio to Gate House. They would respond with the engine and squad vehicle to alarm locations. The senior fire officer on duty assumes immediate command of all fire fighting activities. Should he be notified that a site emergency exists, he immediately initiates the Bristol-Myers Squibb New Brunswick Crisis Management Plan. The Crisis Management Plan is written to include all emergencies within the New Brunswick facility.

The officer in charge will keep management informed of all activities in the field. Where assistance is needed for fire fighting or during off-shift periods, the plant guard will alert the North Brunswick Fire Department. If additional help is needed beyond local mutual aid capacity, Middlesex County Fire Coordinator will be alerted by the North Brunswick Fire Department.

Plant Fire Brigade (Continued)

When an incident exists, all production personnel will begin shut-down and evacuation procedures as directed by Plant Management. Areas remote from the incident area may continue or discontinue operations as directed by Plant Management.

J. Plant First Aid Squad

The Bristol-Myers Squibb First Aid Squad consists of approximately ten (10) full-time company employees who are all volunteer members. The squad is responsible for responding to medical emergencies including life threatening situations within the site and for transporting injured personnel to outside medical facilities. This assistance is provided during production hours (7:00 a.m. - 4:00 p.m.). Personnel are alerted by the paging system that is initiated through the main security post, where all medical emergencies are reported by designated personnel. Coverage for off-shift and weekends is provided by the local community First Aid Squad.

First Aid personnel generally respond to calls with the squad's fully equipped ambulance. The site is divided into four zones with First Aid personnel assigned within those zones responding directly to the scene of medical emergencies within their zone. First Aid kits and certain other equipment are located throughout the plant site. Squad members receive training monthly during regular two-hour drill sessions.

4.3 Local Off-site Assistance to Facility

A. Medical Treatment Facility

A letter of agreement to treat Bristol-Myers Squibb personnel in the event of a radiological emergency outside the scope of our on-site Medical department capabilities was obtained from St. Peter's Medical Center (SPMC). Joint radiological contingency plan training drills, and exercises are conducted routinely to ensure program readiness with SPMC emergency response personnel.

B. First Aid Personnel and Ambulance Service

The licensee has no formal agreement with outside first aid personnel and ambulance services. Members of the local township first aid and ambulance service groups have participated in emergency exercises at the licensee facility.

C. Fire Fighting

The North Brunswick Fire Department is responsible for responding to site fire emergencies. Additional fire fighting resources are available through a mutual aid support system. Letters of agreement are on file

D. Law Enforcement

Both the New Brunswick and North Brunswick Police Departments have agreed to assist the licensee's plant security staff in directing traffic during emergencies. Each unit is located approximately two miles from the facility. Every two years, all groups providing emergency assistance will be invited to participate in exercises. Agreements will be reviewed annually and renewed every four years

4.4 Coordination with Participating Government Agencies

The principal local, county, state and federal organizations or agencies having responsibilities for radiological emergencies in the vicinity of the licensed facility are as follows:

1. North Brunswick Township Office of Emergency Management
2. Middlesex County Office of Emergency Management
3. N J State Police Office of Emergency Management
4. Environmental Protective Agency Region II
5. U S NRC

The Office of Emergency Management for the Township of North Brunswick is located approximately one mile south of the licensee's facility. This group has authority for the coordination efforts of other assistance groups and for providing emergency planning for its township.

In the event of an emergency, the Incident Commander (Crisis Management Plan) is responsible for evaluating plants for containment and the potential spread of hazardous material as well as instituting local evacuation procedures for individuals outside the facility.

The Middlesex County Hazardous Material Emergency Response Unit (HAZMAT) has the authority to respond and investigate all incidents of a radiological or chemical nature within the county of Middlesex. Their responsibilities include investigation, containment, over packing and response to basic hazardous material incidents. They interface with local, state and federal authorities during emergency situations.

The county HAZMAT unit has a facility located within 15 miles of the licensee's site.

Coordination with Participating Government Agencies (Continued)

The New Jersey State Police Office of Emergency Management (NJ SPOEM) works in conjunction with the State of New Jersey Department of Environmental Protection. Its role is one of operational control. This group is responsible for the coordination of assistance from county, local, state and federal agencies.

Its response capabilities include the ability to perform alpha, beta, gamma and neutron monitoring, air sampling and decontamination procedures.

The NJ SPOEM has two facilities located within 15 miles of the license site. One is located approximately six miles north of the site while the other one is located approximately 15 miles south of the site.

Region II of the Environmental Protection Agency is responsible for providing monitoring assistance along with the DOE during the initial phase of a radiological incident. If an incident should continue for several days, the EPA would then take the lead role for off-site monitoring in support of state agencies.

Specific authorities and responsibilities of this group are defined in the Federal Emergency Radiological Plan. Region II of the EPA is located approximately 40 miles north of the license site.

SECTION 5

RADIOLOGICAL CONTINGENCY MEASURES

5.0 Emergency Response Measures

Described in this section are actions to be taken for the activation of response organization, and assessment and correction actions to be taken for each emergency class (see Figure 5)

5.0.1 Use of Protective Equipment and Supplies

All individuals assisting in a radiological emergency shall

1. Wear protective apparel (e.g. head covers, uniforms, shoe covers and gloves)
2. Wear individual respirators as deemed appropriate by the Radiation Safety Officer or designee.
3. Be provided with personnel monitoring equipment (e.g. film badges, ring TLDs, pocket dosimeters and/or portable monitoring equipment)

All items are located in an emergency cabinet located at the Building 124 Emergency Control Center. Additional items are located in Building 80/84 and the Health Physics emergency van.

5.0.2 Contamination Control Measures

Contaminated areas and locations where background radiation measures more than 100 mR/hr will be barricaded and their access limited as directed by the Plant Radiation Safety Officer or designee.

Areas immediately outside the affected sections will serve as monitoring areas for on-site emergency personnel and volunteers

The Radiation Safety Officer or designee must review all available radiation surveillance data for a view of emergency actions required to bring the emergency under control and to determine any items requiring follow-up. The Radiation Safety Officer or designee must insure that:

- All re-entry and recovery teams have dosimeter and dose measuring instruments
- Respiratory protection devices are worn by all personnel within areas where air concentrations exceed occupational levels specified in Appendix B, Table 1 of 10CFR20
- In the recovery phase, all actions are carefully planned and reviewed

- Comprehensive radiation surveys of site facilities will be conducted and all radiological problem areas defined.
- Radiation exposures of personnel who participate in recovery operations will be reviewed and additional personnel will be used, if necessary

RADIOLOGICAL ASSESSMENT/CORRECTIVE ACTION GUIDELINES

Problem	Assessment Action	Corrective Action
1. Loss of electrical power to fans (also diesel generator backup does not work).	<ul style="list-style-type: none"> • Evacuate the building, communicate with maintenance, assay personnel for contamination. If not corrected within one half hour, assay room concentrations - LEVEL 1 CMP. • If room air concentrations elevated greater than 20% - ALERT • Site emergency only if elevated air concentrations outside the building (or building evacuated for greater than 48 hours) • Recovery to normal mode after contamination and air concentrations surveys throughout the building 	<ul style="list-style-type: none"> • Assure personnel accountability. • If not corrected within one half hour, close all hoods, special enclosures, containers, and room doors with potential volatile iodine • Same as above, but use SCBA • If malfunction not expected to be repaired within a few hours, arrange additional electricity
2. Fire	<ul style="list-style-type: none"> • Evacuate building - call security to initiate fire response ALERT. • Survey personnel for contamination in 124 parking lot • If no radioactive material involved in fire - ALERT due to fire. • If radioactive material involved in fire (e.g., truck with 1 Ci of I¹³¹, glove box or fume hood filters) - ALERT. • If fire needs outside assistance - SITE AREA EMERGENCY • If fire involves multi Cunes of I¹³¹ and is out of the "cave" air system - SITE AREA EMERGENCY. • Explosion of propane tank or LPG line near site - SITE AREA EMERGENCY. 	<ul style="list-style-type: none"> • Assure personnel accountability. • Move personnel to alternative site as directed by Emergency Director (wind direction of a possible release) and fire chief (fire and explosion considerations). • Issue dosimetry to fire personnel and accompany them to scene with suitable equipment • Same as above, doses to emergency personnel may be 25 Rem to stop an environmental release or control a fire, and greater than 25 Rem to save life

RADIOLOGICAL ASSESSMENT/CORRECTIVE ACTION GUIDELINES - continued

Problem	Assessment Action	Corrective Action
3. Radioactive material spill > 1 mCi	<ul style="list-style-type: none"> • Evacuate immediate area; Emergency Director to be notified - LEVEL 1 CMP. If volatile by means of mix with corrosives or fire - ALERT. 	<ul style="list-style-type: none"> • Assess and decontaminate personnel and equipment/ shield material as appropriate.
4. Radioactive material spill > 1 mCi with contaminated personnel	<ul style="list-style-type: none"> • Same as above and notify first aid through security. • Two or more contaminated persons needing off-site hospital assistance - ALERT 	<ul style="list-style-type: none"> • Same as above • Health Physics staff member or alternate to accompany contaminated victims to hospital to monitor for contamination with appropriate equipment
5. Flood in or near controlled area.	<ul style="list-style-type: none"> • Assess threat to radioactive material - LEVEL 1 CMP • Notify maintenance for corrective measures 	<ul style="list-style-type: none"> • Maintenance with sump pump • Move radioactive materials away from potentially flooded areas as practical
6. Elevated air effluent emissions	<ul style="list-style-type: none"> • > 2μ avg. limit over 24 hour period as specified in Appendix B, Table 2, Column 1 of 10 CFR 20 - LEVEL 1 CMP • > 50μ avg. limit over 24 hour period or > 2 mR as specified in Appendix B, Table 2, Column 1 of 10 CFR 20 - ALERT. • > 5,000μ avg. limit over 24 hour period or > 20 mR as specified in Appendix B, Table 2, Column 1 of 10 CFR 20 - SITE AREA EMERGENCY 	<ul style="list-style-type: none"> • Check filter efficiencies and change filters as appropriate. Localize source of emission, contain material in solution • Same as above, plus check on inventory for filters - assume exposure to be from plume from stack. Suspend all work with volatile materials • Same as above

6.1 Exposure Control In Radiological Contingencies

6.1.1 Radiation Protection Program

The on-site radiation protection program outlines the procedures and equipment to be employed to maintain radiation guidelines. It provides for personnel monitoring equipment, full face respirators and protective apparel to be used exclusively during radiation emergency conditions. The Emergency Director and/or alternate will ensure that all emergency personnel stay below the exposure guidelines by continuously monitoring pocket dosimeters. In addition, all emergency personnel will be surveyed for external and internal contamination upon leaving the restricted areas or as instructed by the Emergency Director or his alternate.

The Emergency Director or alternate shall have the authority to allow greater doses to volunteers carrying out lifesaving and other emergency activities. These exposures, however, shall not exceed the guidelines recommended in EPA 400-R-92-001.

6.1.2 Exposure Guidelines

A. Emergency Workers

The exposure guidelines for on-site emergency response teams, fire fighters, first aiders, medical doctors, nurses and rescue teams shall be limited to 5 Rem TEDE except under planned or unplanned emergency life saving situations.

In less stressful situations where emergency life saving measures are not required, but entry into the radiological area is necessary to protect property, to stop the release of radioactive materials or to control a fire, dose limits should not exceed 25 Rem TEDE.

Life saving activities - no specific upper limit is given for thyroid exposure since in extreme cases complete thyroid loss might be an acceptable penalty for a life saved. However, every effort will be made to use respiratory equipment to maintain the dose to the thyroid as low as reasonable achievable. Situations may also occur in which a dose in excess of 25 Rem for an emergency worker would be unavoidable to carry out a life saving operation, or to avoid extensive exposure of a large population. This situation is highly unlikely and remote at best.

B. General Public

Protective action guidelines for members of the general public (e.g., sheltering, evacuation) shall be based on projected off-site dose calculations and will be recommended to County and State officials in an ex-post-facto effort to minimize the risk of exposure from an event that has already occurred. Recommendation for protective action for members of the general public will be in accordance with the following EPA guidelines:

General Public Dose Limits	
TEDE	1 Rem
Thyroid	5 Rem

5.1.3 Monitoring

All emergency personnel and volunteers involved in any radiation emergency shall submit to follow-up urinalysis testing and/or thyroid uptake measurements if deemed necessary by the Radiation Safety Officer or his alternate. These tests will be performed as specified by the Radiation Safety Officer or his alternate to determine if individuals have internally ingested isotopes as a result of the incident.

If internally deposited radioisotopes are detected, the total activity to the organ and whole body shall be determined. Individuals will be removed from the restricted areas if it is determined that he or she might receive additional exposure which could cause him or her to exceed limits specified in 10 CFR Part 20.

Self reading dosimeters and/or permanent record dosimeters will be issued to emergency workers during radiological incidents. Records of exposure to emergency workers will be maintained by the Health Physics department.

5.2. Decontamination of Personnel

Decontamination equipment and supplies are available for use by emergency personnel. Every effort will be made to decontaminate individuals to background levels. The primary concern will be to provide treatment and care to individuals in the event of life threatening situations while at the same time minimizing the spread of contamination.

SECTION 6

EQUIPMENT AND FACILITIES

6.0 Communication Equipment

6.0.1 On-site Communications

The primary systems for on-site communication, from the time a plant emergency commences until the all clear signal is given, will be by telephone. In-plant short wave radios, police car radios and also couriers will be used as alternate methods of in-plant communication. In-plant short wave radios and the plant paging systems are checked routinely.

6.0.2 Off-site Communications

Off-site communication consists primarily of the use of telephones to notify appropriate authorities and agencies in order to request assistance, with the short wave radio system utilized as a backup.

Communications will be facilitated upon the arrival of the North Brunswick Township Emergency Management and State Police Civil Defense Truck with their three-way radio. These vehicles, with their operators, will be stationed near the Crisis Command Center or the Incident Command Post. The direct line phone between the Building 111 Gate House, Control Center and the North Brunswick Police Headquarters will also be used.

6.1 Emergency Monitoring Equipment

Various monitoring equipment is available for use by members of the radiological emergency teams. The designated equipment includes but is not limited to geiger counters, ion chambers, self reading dosimeters and weather stations. Effluent monitoring is described in section 1.3 of the plan.

Additional monitoring equipment is available on site for use in determining effluent concentrations and other essential tests that may be required.

SECTION 7

MAINTENANCE OF RADIOLOGICAL CONTINGENCY PREPAREDNESS CAPABILITY

7.0 Maintenance of Emergency Preparedness Capability

7.0.1 Written Emergency Plan Implementing Procedures

The following describes the means for assuring that written emergency implementing procedures will be prepared and clearly state the duties, responsibilities, action levels and actions to be taken by each group or individual responding to an emergency condition

- Each manager of on-site response group (Fire, First Aid, Security and Health Physics) shall be responsible for preparing and distributing emergency implementing procedures relating to their specific function
- The Radiation Safety Officer or his designee shall schedule annual meetings with all emergency response personnel to review function and provide radiation safety instructions

7.0.2 Training

The most important part of maintaining emergency preparedness is providing adequate training to all personnel. New employees whose assignments entail working with radioactive materials are given initial training regarding the safe handling of radioactive materials. Personnel assigned to the manufacturing facility will receive annual training on emergency procedures and the Radiological Contingency Plan. This practice is essential since many of the manufacturing personnel have responsible roles in the activation and implementation of the Radiological Contingency Plan.

The Plant Emergency Response Group and any individual responsible for preparing, maintaining and implementing the emergency plan will participate in training drills annually. Material that will generally be covered will include but not be limited to the following:

- Portable radio use and proper protocol
- Classification of incidents
- Planning sessions and drills
- Review of Radiological Contingency Plan organization and responsibilities
- Off-site organization communication drills, table-top exercises
- Full scale emergency exercise, including off-site response personnel

Training (Continued)

Emergency Monitoring Team will receive routine training. Various members of the Emergency response group will cover specific areas of hazardous material response. Material to be covered includes but is not limited to the following areas:

- Site control.
- Response procedures.
- Review of the Radiological Contingency Plan
- Responsibilities of Emergency Monitoring Team
- Restricted area control.
- Persons' protective equipment
- Measurement and control of contamination
- Evacuation - control and accountability.
- Radiation safety.
- Instrumentation workshop
- Use of portable radios and protocols
- Assembly of emergency response equipment
- Workshop with First Aid, Fire and Security personnel
- On-site emergency exercise.
- Full scale emergency exercise, including off-site response personnel, annually
- Respirator training

Records of all radiological training will be maintained by the Radiation Safety Officer.

7.0.3 Exercises

The Plant Emergency Response Group will plan and coordinate radiological emergency exercises at least every two years. This group will be responsible for inviting off-site organizations to participate in these exercises, and for the testing of procedures and equipment for notification and communication with local state and federal agencies. Exercise scenarios will be developed by the Plant Emergency Response Group and not be revealed to participants.

7.0.4 Exercise Critique

The Plant Emergency Response Group will be responsible for the selection of one or more individuals from the manufacturing plant to prepare an exercise critique. They will act as nonparticipation observers who will evaluate the appropriateness of the emergency plan, its procedures, facilities, equipment, and personnel training.

Exercise Critique (Continued)

Records and reports from exercises and exercise critiques will be maintained until the license is terminated. Any deficiencies identified from exercise critiques or scenarios will be reviewed and corrected as soon as practical by the Radiation Safety Officer.

7.0.5 Review and Updating of the Plan and Procedures

A team of emergency response personnel who are members of the Plant Emergency Response Group will meet after each exercise to review the emergency preparedness program of the corporation, including the Radiological Contingency Plan, and their implementing procedures to ensure that they are workable and meet local state and federal requirements. This team of employees will include participants from the following disciplines: Security, Site Safety and Industrial Hygiene, Fire, First Aid, Maintenance, and Utility Services. These individuals will review off-site letters of agreement annually and assure they are renewed at least every four years.

Any deficiencies noted in the emergency programs will be the responsibility of these individuals to correct prior to approval of the Radiological Contingency Plan by members of the Radiation Safety Committee.

7.0.6 Maintenance and Inventory of Emergency Equipment, Instrumentation and Supplies

A physical inventory by the Health Physics department will be conducted quarterly to ensure that all equipment and instrumentation are in working order and calibrated as required. Quarterly inventories will also be performed on emergency supplies, respirators, self-contained breathing apparatuses, fire fighting equipment, supplemental lighting, and all communication equipment. Any defective equipment shall be repaired or replaced as soon as practical. Deficiencies in emergency supplies shall be replaced as needed.

7.0.7 Verification of Emergency Telephone Numbers

All emergency telephone numbers included in the Radiological Contingency Plan will be verified at least quarterly. The activities of the telephone conversation (i.e. time and date call was placed, person answering the call, and the number dialed) will be recorded on the Emergency Telephone Number Verification log.

SECTION 8

RECORDS AND REPORTS

8.0 Records of Reports and Incidents

The Emergency Director is responsible for reporting and recording incidents of abnormal operation, equipment failure, and other deficiencies that lead to a plant emergency or activation of the Radiological Contingency Plan

The recording and reporting of incidents of abnormal operation are logged on an incident investigation report. This documents the cause of the incident, personnel and/or equipment involved, the extent of injury and/or damage (on-site and off-site) resulting from the incident and the necessary corrective or preventive actions.

All of the Emergency Director's activities during an incident are logged on the Emergency Director's Information Report. On this form, the Emergency Director documents the time and source of initial incident notification, description of the incident, classification, request for on-site and off-site assistance, notification and time of upgrade, downgrade and close out. All records shall be maintained until the license is terminated.

8.1 Records of Preparedness Assurance

The following records shall be maintained to confirm the preparedness to respond to radiological incidents:

- Training records
- Records of quarterly communication checks with off-site support groups
- Records of maintenance inventory of equipment, instruments and supplies
- Drills and exercise
- Off-site agreements
- Radiation Safety Committee updates and distribution
- Records of written reports to federal, state and local agencies

SECTION 9

RECOVERY

9.0 Recovery

9.0.1 Assessing Damage to the Facility

Environmental monitoring personnel and maintenance and utility service personnel are responsible for assessing the damage to and the status of the facility's capabilities to confine radioactivity. Specifically, these groups will check and restore to normal operations all safety related equipment involved in the incident and make recommendations to the Emergency Director as to how to prevent further degradations, releases or recurrences of the incident

Among the items and areas to be checked or evaluated include

- Vacuum system.
- Air filtration fans.
- Emergency generator.
- Air filter.
- Radiation detection equipment and instrumentation
- Estimate of damage to plant and equipment resulting from incident
- Fire suppression equipment
- Effluent controls and monitoring instruments and equipment

This information is evaluated by the Emergency Director and is used to aid him in his actions in restoring the plant to normal operation

9.0.2 Re-entry

The following criteria shall be used to determine when re-entry into the plant may be considered

Decontamination has been completed or contained

- Radiation levels are reduced to normal working levels
- All equipment used to control the spread of contamination is operable
- All shielded equipment and enclosures are functional
- Airborne radioactivity is below the maximum limit specified in 10CFR20, Table I of Appendix B.

This data is collected by personnel assigned to the Emergency Monitoring Team and forwarded to the Emergency Director for use before allowing re-entry to commence.

9.0.3 Recovery and Return

The Emergency Director must review all emergency monitoring logs to determine if the actions taken to bring the emergency situation under control have been completed. Specific responsibilities entail insuring the following

- Personnel and equipment leaving radiation controlled areas are not contaminated.
- Vehicles used to transport injured personnel are free of contamination
- Any radiological conditions are properly defined, barricaded and posted with appropriate signs.
- Contaminated floor areas that must be walked on in the vicinity of the emergency are covered or decontaminated
- Appropriate actions have been taken to return the plant to a normal operating condition, consistent with recognized Health Physics procedures and practices

9.0.4 Restoration of Operations

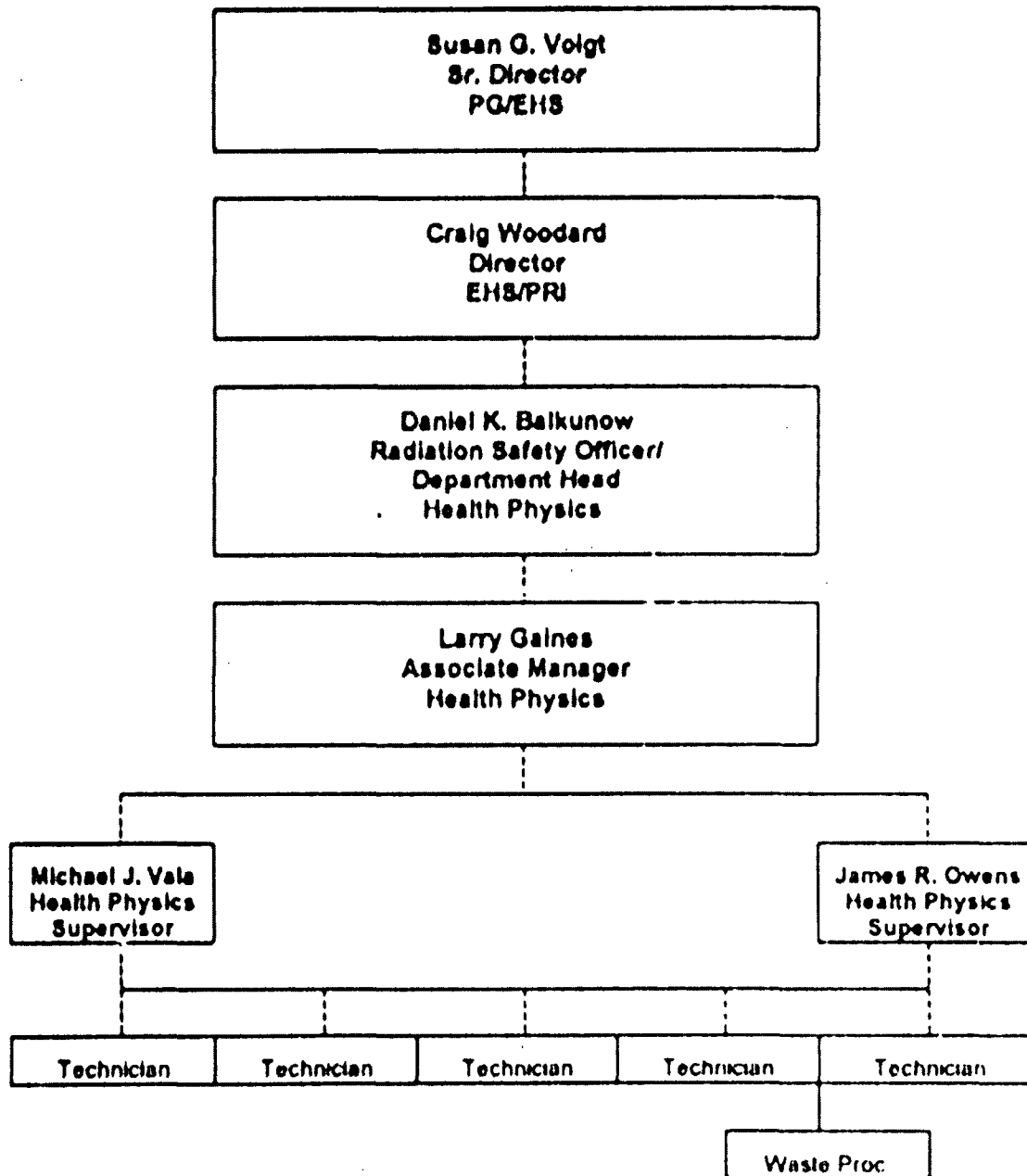
When satisfied that all conditions of the incident are under control and the plant can return to normal operating procedures, the Emergency Director will then

- Announce that the emergency has ended and authorize re-entry
- Summarize all actions and resulting conditions in the Emergency Log
- Revise radiological procedures to reflect minor changes resulting or observed during the incident.
- Direct that a readiness check be performed on all emergency equipment, instrumentation, supplies, etc
- Close out or recommend a reduction in emergency class by verbal summary to off-site authorities followed by written summary as required

ADDENDUM III

- A. **Organizational Chart**
 - B. **Radiation Safety Committee Membership**
 - C. **Radiation Safety Committee Résumés**
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A. Organizational Chart



B. Radiation Safety Committee Membership

Name	Title
D. Balkunow	RSO/Department Head, Health Physics
H. Bartlett	Director, Product & Systems Validation
J. Frankowski	Director, Radiodiagnostics Operations
D. Johnson	Counsel, BMSPG Technical Operations
K. Rinehart	Senior Research Investigator, Metabolism & Pharmacokinetics
C. Taday	Lab Planner, Pharmaceutical Research Institute
S. Voigt*	Sr. Director, PG/Environmental Health & Safety
C. Woodard	Director, Environmental Health & Safety/PRI
F. Yost	Scientific Advisor, Environmental Health & Safety

*RSC Chairman

C. Radiation Safety Committee Résumés

Daniel K. Balkunow

(b)(6)

Exemption 6
TJ

Work Experience:

BRISTOL-MYERS SQUIBB, NEW BRUNSWICK, NEW JERSEY. Pharmaceutical Manufacturer

May 1990 to Present: Radiation Safety Officer and Department Head, Health Physics Department

Manage the Health Physics Department and administer the company's radiation safety program

March 1990 - May 1990: Department Head, Biological Control

Managed and administered a Quality Control release laboratory involved with the testing and approval of ethical pharmaceuticals

October 1988 - March 1990: Department Head, Worldwide Environmental Control Validation/Quality Assurance Support

The function of this position was to administer and supervise Squibb's Worldwide Validation programs for controlled environments, water for injection systems, decontamination activities, and Worldwide Quality Assurance Support activities

February 1985 - October 1988: Radiation Safety Officer and Department Head, Health Physics Department

Managed the Health Physics Department and administered the company's radiation safety program

February 1975 - February 1985: Assistant Radiation Safety Officer and Section Head, Health Physics Department

Administered the functions of two technical supervisors and four bargaining unit employees to insure that all radiological operations were conducted in accordance with federal and state regulatory requirements. Functions included the development of standard operating procedures, training, the establishment of guidelines and work procedures for non-routine activities in the processing and handling of radioactive materials, and maintaining required records. Experienced in dealing with federal and state regulatory officials, license preparation, and assisting in all regulatory inspections. Interaction with all levels of management within Manufacturing, Sales, Quality Control, Research and Development, Engineering, Package Development, Transportation, and Purchasing, with regard to regulatory matters.

February 1974 - February 1975: Production Planner

Responsible for the scheduling and purchasing of raw materials and packaging components for the nuclear medicine product line

September 1965 - February 1974: Radioisotope Technician (Research)

Involved in process and product development of radioactive and non-radioactive drugs for future production and sales

Education

(b)(6)

University of Lowell
"Principles and Practices of Radiation Protection"

Rider College, Lawrenceville, NJ
B S Commerce

Major in Accounting with a minor in Finance Earned degree while
employed full time with present employer

Monmouth College, West Long Branch, NJ
Secondary Education Major - Science

Exemption 6
PII
TJ

HARRY J. BARTLETT

(b)(6)

Home

(b)(6)

Business 908-519-2106

EMPLOYMENT EXPERIENCE:

1989 - Present Bristol-Myers Squibb, New Brunswick, New Jersey

February 1993 - Present Director, Worldwide Environmental Control Operations

1989 - 1993 Director, Quality Control Operations

1988 - 1989 Director, Quality Assurance Operations

1981 - 1988 Department Head, Environmental Control

1979 - 1981 Section Head, Environmental Quality Assurance

1975 - 1979 Section Manager, Radiodiagnostic Quality Control

1972 - 1975 Technical Supervisor, Radiodiagnostic Quality Control

1971 - 1972 Product Release Coordinator, Radiopharmaceutical Quality Control

1970 - 1971 Complaint Chemist, Technical Services

1969 - 1970 Analytical Chemist, Quality Control

EDUCATION:

Muskingum College B.S. Chemistry (b)(6)
Fairleigh Dickinson University Advanced Courses in Pharmaceutical Chemical Studies Program

ADVANCED TRAINING COURSES:

Basic Principles and Applications of RIA - Albert Einstein Medical Center
Measurement of Radioactive Materials - National Bureau of Standards
Radiopharmaceutical Quality Control - N.Y.C. Medical Center
Control of Airborne Particulate Contamination - The Institute of Applied Pharmaceutical Sciences

COMMITTEE MEMBERSHIPS:

E.R. Squibb Radiation Safety Committee Member - 1984-1988
AIF-NBS Standards Committee - 1975 - 1979

MEMBERSHIPS:

Society of Nuclear Medicine
Health Physics Society
American Chemical Society
Institute of Environmental Sciences
Air Pollution Association
International Society of Pharmaceutical Engineers

Mr. John Frankowski

Director, Radiodiagnostics Operations

Bachelor of Science in Chemical Engineering; Credits towards Master of Business Administration.

Employed by Bristol-Myers Squibb in 1972 as a Supervisor, Radiodiagnostics Manufacturing; Section Head, Radiodiagnostics Manufacturing in 1974; Section Head, Parenteral Manufacturing in 1978; Manager, Radiodiagnostics Quality Control in 1986 and Manager, Radiodiagnostics Distribution in 1989, until his present appointment in 1994.

DEANE A. JOHNSON

BRISTOL-MYERS SQUIBB COMPANY
P. O. Box 4000
Princeton, New Jersey 08543-4000
(609) 282-6602

EXPERIENCE

Counsel Pharmaceutical Group Technical Operations and Human Resources	1992 - Present
Counsel U.S. Pharmaceutical Group and Mead Johnson Nutritional Group	April, 1990 - 1992
Senior Division Counsel U.S. Pharmaceutical Group and Mead Johnson Nutritional Group	January, 1990
Senior Associate Division Counsel U.S. Pharmaceutical Group and Mead Johnson Nutritional Group	1988 - 1989
Associate Division Counsel U.S. Pharmaceutical Group and Mead Johnson Nutritional Group	1986 - 1987
Senior Staff Attorney Mead Johnson Company	1980 - 1985
Staff Attorney Mead Johnson Company	1975 - 1980

EDUCATION

J.D. Indiana University School of Law
B. A. Emory University

(b)(6)

ADVANCED TRAINING COURSES IN RADIATION SAFETY:

Health Effects of Ionizing Radiation - Eastern Regional Radon Training Center, Rutgers University - 1998
Radioactive Waste Management - Eastern Regional Radon Training Center, Rutgers University - 1998
Radiation Protection Program Mgmt - Eastern Regional Radon Training Center, Rutgers University - 1998
Basic Radiolotope Theory - Eastern Regional Radon Training Center, Rutgers University - 1998

PROFESSIONAL AFFILIATIONS

Member	American Bar Association
Member	Customs & International Trade Bar Association
Member	Indiana State Bar Association
Member	Supreme Court of Indiana
Member	U.S. Court of International Trade

October 21, 1998

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JAY KENT RINEHART

(b)(6)

*Exemption 6
TJ*

SENIOR RESEARCH INVESTIGATOR I

Tel: (b)(6)

Soc. Sec. No.

(b)(6)

EDUCATION

Ph.D., University of Minnesota - Organic Chemistry
B.Sc., University of Cincinnati - Chemistry

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*Exemption 6
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EMPLOYMENT HISTORY

1990 to present - Senior Research Investigator, Bristol-Myers Squibb, Princeton, NJ

Supervise laboratory involved in the preparation of isotopically labelled compounds for use in drug discovery studies.

1988 to 1990 - Senior Research Scientist, Health & Environment Group, Battelle Memorial Institute, Columbus, Ohio

Group Leader, Synthesis. Supervised 4-6 chemists and was responsible for design of synthesis routes and preparation of isotopically labelled compounds. Managed programs for environmental fate and product chemistry studies conducted under FIFRA guidelines and supervised Study Directors. Responsible for proposal preparation and marketing of synthesis and product chemistry studies.

1988 - Research Associate, Discovery Research, PPG Industries, Inc., Barberton Technical Center, Barberton, Ohio

Designed new synthesis routes to protected amino acids and improved processes for amino acid protection. Designed and synthesized new monomers for optical polymers.

1984 to 1988 - Research Associate, Biochemicals, Radiochemist, PPG Industries, Inc., Barberton Technical Center, Barberton, Ohio

Designed synthesis routes and prepared isotopically labelled herbicides and metabolites. Supervised radiochemical preparations by outside contractors. Group Leader - supervised two chemists in preparation and purification of analytical standards. Designed synthesis routes for preparation of metabolite and process standards. MDL and MedChem system supervisor (VAX 11/750).

August, 1993

1969 to 1984 - Senior Research Chemist, Biochemicals Synthesis, PPG Industries, Inc., Barberton Technical Center, Barberton, Ohio

Designed and synthesized novel compounds for screening as herbicides, insecticides, fungicides and PGRs. Proposed and completed a program for synthesis of herbicide safeners which resulted in the successful commercialization of a new patented thiocarbamate safener. Conducted early process development work for potential herbicides. Work in a wide variety of synthesis areas resulted in several classes of herbicides, fungicides and miticides unique to PPG.

1967 to 1969 - Senior Research Chemist, Organic Exploratory Synthesis, PPG Industries, Inc., Barberton Technical Center, Barberton, Ohio

Proposed and carried out work in dichloroketene chemistry resulting in the publication of a new preparation of 4,5-benzotropolone. Worked extensively in ethylene oxide chemistry, including the use of high pressure equipment.

PROFESSIONAL SOCIETIES

ACS, Division of Organic Chemistry
ACS, Princeton Local Section

TRAINING

Tritium Labelling and Analysis Workshop, National Tritium Labelling Facility, Lawrence Berkeley Labs, Berkeley, CA, June, 1993

Planning, Managing and Appraising Performance, Squibb College, December, 1990

PUBLICATIONS AND PATENTS

Parham, W. E.; Rinehart, J. K. "1,3-Bridged Aromatic Systems. II. A New Synthesis of Metacyclophanes"; *J. Am. Chem. Soc.* 1967, 89, 5668-5673.

Rinehart, J. K. "Substituted Indenes as Precursors to Metacyclophanes"; *Diss. Abstr. B* 1968, 28, 3656-3657.

Stevens, H. C.; Reich, D. A.; Rinehart, J. K.; Lavanish, J. M. "The Reaction of Dichloroketene with Aldehydes"; Abstracts of Papers, First Central Regional Meeting of the American Chemical Society, Akron, OH; Akron Section of the American Chemical Society; Akron, OH, 1968; Abstract 85.

Parham, W. E.; Johnson, D. R.; Hughes, C. T.; Meilahn, M. K.; Rinehart, J. K. "1,3-Bridged Aromatic Systems. V. Strained Aromatic Systems"; *J. Org. Chem.* 1970, 35, 1048-1053.

Parham, W. E.; Davenport, R. W.; Rinehart, J. K. "1,3-Bridged Aromatic Systems. VI. 12, 13-Benzo-16-Bromo[10]metacyclophane"; *J. Org. Chem.* 1970, 35, 2662-2666.

Stevens, H. C.; Rinehart, J. K.; Lavanish, J. M.; Trenta, G. M. "The Hydrolysis of 7,7-Dichlorobicyclo[3.2.0]hept-2-en-6-one"; *J. Org. Chem.* 1971, 36, 2780-2784.

Hardies, D. E.; Rinehart, J. K. U.S. Patent 3 742 010, 1973.

Hardies, D. E.; Rinehart, J. K. U.S. Patent 3 852 464, 1974.

Hardies, D. E.; Rinehart, J. K. U.S. Patent 4 022 609, 1977.

Rinehart, J. K. U.S. Patent 4 055 656, 1977.

Rinehart, J. K. U.S. Patent 4 055 657, 1977.

Rinehart, J. K. U.S. Patent 4 056 549, 1977.

Rinehart, J. K. U.S. Patent 4 059 609, 1977.

Rinehart, J. K. U.S. Patent 4 066 440, 1978.

Rinehart, J. K. U.S. Patent 4 075 006, 1978.

Hardies, D. E.; Rinehart, J. K. U.S. Patent 4 113 878, 1978.

Rinehart, J. K. U.S. Patent 4 117 155, 1978.

Rinehart, J. K. U.S. Patent 4 120 886, 1978.

Rinehart, J. K. U.S. Patent 4 213 915, 1980.

Rinehart, J. K. U.S. Patent 4 282 168, 1981.

Rinehart, J. K. U.S. Patent 4 294 764, 1981.

Rinehart, J. K. U.S. Patent 4 400 197, 1983.

Rinehart, J. K. U.S. Patent 4 443 628, 1984.

Rinehart, J. K. U.S. Patent 4 531 970, 1985.

Exemption 6
p11
TSS

Christine M. Tudas

(b)(6)

Work (609) 921-5107

Home (b)(6)

EDUCATION

(b)(6)

B.S. Biological Sciences
New York Institute of Technology
Old Westbury, NY
Cum Laude

EMPLOYMENT

- 1982 - Present Bristol-Myers Squibb Pharmaceutical Research Institute
Lawrenceville, NJ
Microbial Molecular Biology
- 1987 - Present Assistant Research Investigator
Primary Responsibilities
- Isolating of a wide variety of microorganisms from environmental products.
 - Supervising world wide sample collection.
 - Providing pure cultures to screening group.
 - Maintaining soil importation permits by reporting to U.S. Department of Agriculture.
 - Acting as departmental safety officer.
 - Member Bristol-Myers Squibb Corporate Radiation Safety Committee
- 1982 - 1987 Research Associate
Primary Responsibilities
- Screening microorganisms for targeted activities in anti-infective drug discovery program.
 - Optimizing fermentation conditions to enhance activity
 - Performing preliminary organic extractions and chromatographic characterization.
- 1987 - Acting as temporary Curator for the Squibb Culture Collection - Training new curator.
- 1980-1982 National Starch and Chemical Corporation
Bridgewater, NJ
Natural Products Division
- Technical Assistant
Primary Responsibility
- Chemical modification of various types of starch to optimize commercially useful properties.
 - Organic synthesis and characterization.
 - Trouble-shooting a compound used in the pilot plant

1979-1980

Children's Hospital Harvard Medical School
Boston, MA

Collaboration of Cell Biology - Endocrinology
Juvenile Diabetes Research Division

Research Assistant

Primary Responsibilities

- Radiolabelling, purifying and assaying of pancreatic and other hormones.
- Isolating and characterizing of human proinsulin and human antibodies to insulin.
- Trouble-shooting iodination procedures.
(attended Radioisotope handling course, Harvard School of Public Health)

1978-1979

Hempstead General Hospital
Hempstead, NY

Clinical Laboratory Intern

Primary Responsibilities

- Performing diagnostic assays in all areas: manual bench chemistry, special chemistry (radioimmunoassay) hematology, blood bank, serology, and microbiology.
Hired as part-time staff during rotation.
- Phlebotomy.

PROFESSIONAL SOCIETY

American Society for Microbiology

ACCOMPLISHMENTS

My microorganism isolation work has lead to the following Bristol-Myers Squibb anti-infective compounds for which patents are applied:

Scopularin
Culpin No. 4,914,245
Peptifluorin
Neopeptifluorin

SUSAN G. VOIGT

(b)(6)

(908) 519-2198 - Office

Exemption 6
TJH

EXPERIENCE

Bristol-Myers Squibb, New Brunswick, NJ (1986-Present)

Senior Director, Pharmaceutical Group Environmental Health & Safety. Provide comprehensive environmental, industrial hygiene, safety, risk management, toxicology, radiation and workers compensation services for the worldwide pharmaceutical group operations. Direct the AIIA accredited central Industrial Hygiene Analytical Laboratory

Environmental Health and Safety Director, Pharmaceutical Research and Manufacturing. Provide staff consulting services to domestic and international facilities. Provide comprehensive environmental and industrial hygiene services to the New Brunswick pharmaceutical manufacturing and research facility

Environmental/Occupational Health Department Head, Worldwide Occupational and Environmental Safety Division.

Exxon Chemical Americas, Baton Rouge, LA (1980-1986)

Plant Industrial Hygienist. Provide industrial hygiene services at petrochemical manufacturing site (1,500 employees). Served as the facility Radiation Safety Officer

Exxon Chemicals, U.S.A., Baton Rouge, LA (Summer, 1979)

Industrial Hygiene Intern. Participated in all aspects of comprehensive industrial program at the Baton Rouge Chemical Plant. Special emphasis on heat stress and laboratory ventilation systems

Weidinger Associates, Consulting Engineers, New York (Summer, 1978)

Computer Programmer. Projects included Economic Project Control

EDUCATION

Harvard School of Public Health, Boston, MA

Master of Science - Industrial Hygiene and Air Pollution

(b)(6)

Courses included: Noise Control, Toxicology, Radiation,

Ventilation, Epidemiology, Biostatistics, Air and Gas

Cleaning, Identification and Measurement of Air Contaminants,

Occupational Health Policy.

Exemption 6
TJH

Honors: Recipient of NIOSH Traineeship Grant

University of Pennsylvania, Philadelphia, PA

Bachelor of Arts - Biology (Genetics and Microbiology)

(b)(6)

Cum Laude

Courses included: Biochemistry, Organic and Inorganic Chemistry,

Microbiology, Molecular and Cellular Biology, Molecular Genetics

PROFESSIONAL CERTIFICATION AND AFFILIATIONS

American Board of Industrial Hygiene: CIIH
American Industrial Hygiene Association: Full Member
New Jersey Chapter - American Industrial Hygiene Association Member
International Commission on Occupational Health (ICOIH) Member

PUBLICATIONS

Prediction of Pneumoconiosis Risk by Bioassays of Particulate from Occupational Exposures with Smith, T. J., et al. Inhaled Particles. Vol 5, W H Walton, Ed Pergamon Press, 1981.

FREDERICK J. TUST JR.

(b)(6)

Exemptive 111
TJF

SUMMARY:

Research and development manager with broad experience in all aspects of research, development and marketing of isotopic and non-isotopic immunoassay products. Have expertise in Quality Control, GLP, scale-up and trouble shooting, transfer of products to manufacturing as well as interfacing chemistry and instrumentation. Directed exploratory research group for in-vitro diagnostics. Responsible for pharmacology and analytical chemistry for new in-vivo contrast agents for Magnetic Resonance Imaging. Currently responsible for monoclonal antibody production, organic synthesis for radioimmunoassay development and transfer of iodinated monoclonal antibodies to manufacturing.

EDUCATION

Ph.D Organic Chemistry/Biochemistry June (b)(6)
University of North Carolina, Chapel Hill
N.C.
NSF Fellow. (b)(6)

Exemptive 6
TJF

Bachelor of Arts, Chemistry, Hunter College.
1967

PUBLICATIONS

Seven abstracts
Fifteen papers
One patent

EXPERIENCE

1981 - Present

BRISTOL-MYERS SQUIBB

New Brunswick, New Jersey
Group Leader Research & Development and Group
Leader Operations.

Developed a predictive test for adverse reactions to X-ray contrast agents. Originated protocols which insured the transfer of in-vivo and in-vitro products from research to manufacturing, scaled-up, validated and transferred four new in-vitro products in six months. Responsible for research and scale-up of radiolabeled monoclonal antibodies for cancer therapy.

1971 - 1981

GENERAL DIAGNOSTICS DIVISION, WARNER-LAMBERT
MORRIS PLAINS, NEW JERSEY

Senior Scientist.

Project team leader, responsible for coordination of assay, instrument development and marketing of fluorescent immunoassays. Responsible for manufacturing a latex test which was marketed internationally. Developed small molecule latex assay for use in physicians' office. Developed fluorescent polarization assays for therapeutic drug

SEARLE DIAGNOSTICS INC.
Des Plaines, Illinois

Developed fluorescent labeled small molecule antigens. Searle Diagnostics was sold to Warner-Lambert, and I was transferred to New Jersey.

1972 - 1977

DEPARTMENT OF MEDICINE AND BIOCHEMISTRY
DUKE UNIVERSITY, DURHAM, NORTH CAROLINA

Research Fellow and Post Doctoral Fellow

Discovered a new form of superoxide dismutase.

PERSONAL

(b)(6)

Exempt to b
P 11
Tiff

ATTACHMENT #1

Figures

- Figure #1 - Buildings 124/122 Radiodiagnostic Manufacturing Facility**
- Figure #2 - Building 80/84, Room 207A Iodination Laboratory**
- Figure #3 - Building 107 Radiosynthesis Suite**
- Figure #4 - Building 81 Interim Waste Storage Facility**
- Figure #5 - Module H, Room 4613 Iodination Laboratory**
- Figure #6 - Module K, Room 3622 Iodination Laboratory**
- Figure #7 - Module K, Room 4319 Iodination Laboratory**

Building 80/84, Room 207A Isolation Suite

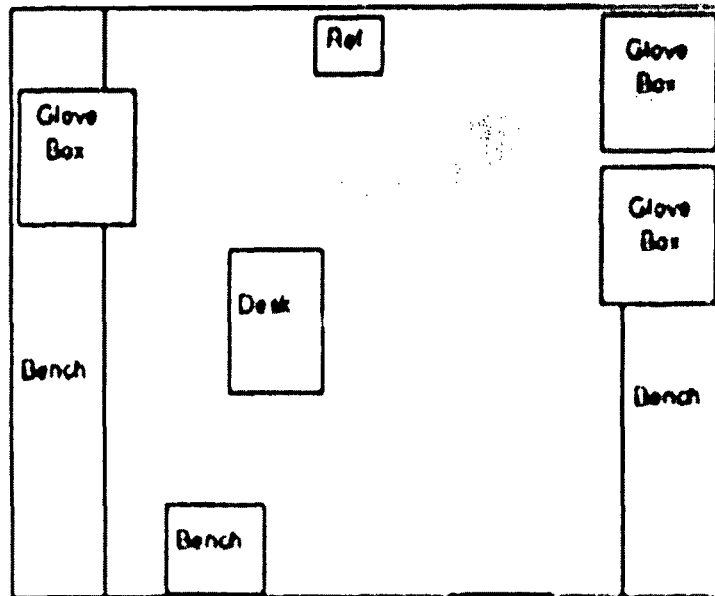


FIGURE 80 -
 BUILDING 80/84
 ROOM 207A ISOLATION SUITE

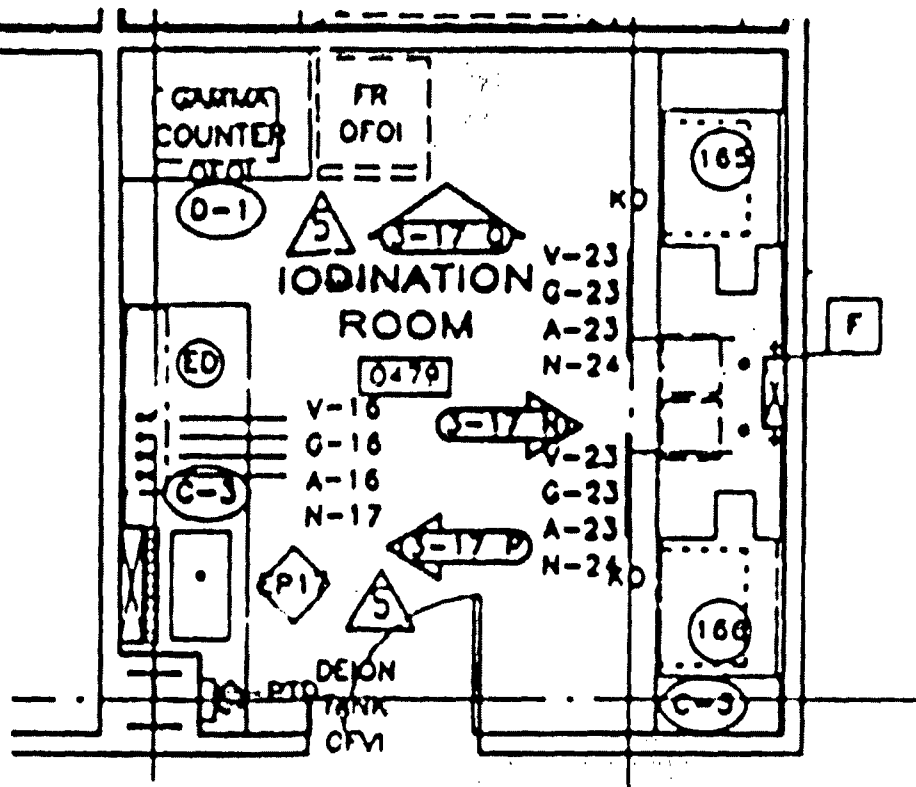
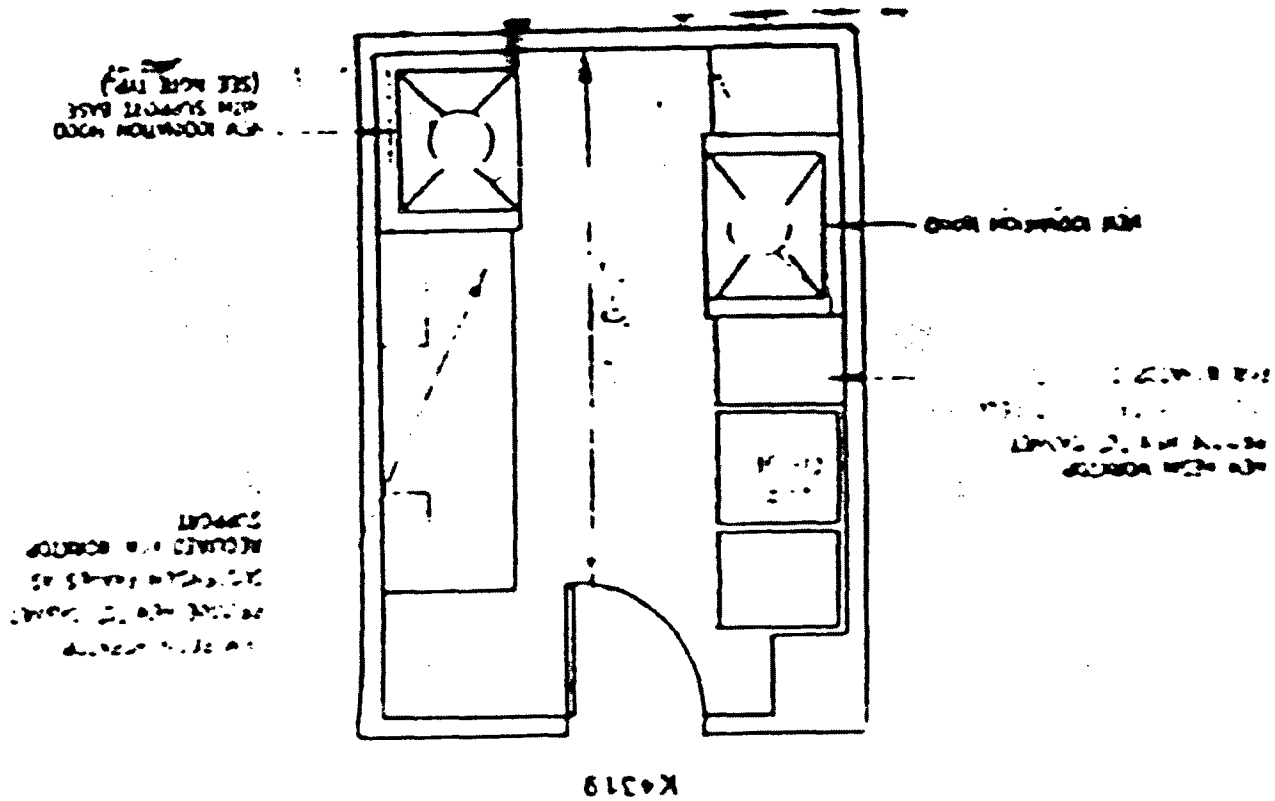


FIGURE 05
 AREA 1110004013
 CEPMATEP/ALB/MT/RY

FIGURE 17
MODULE & ROOM 4319
COMPUTATION LABORATORY



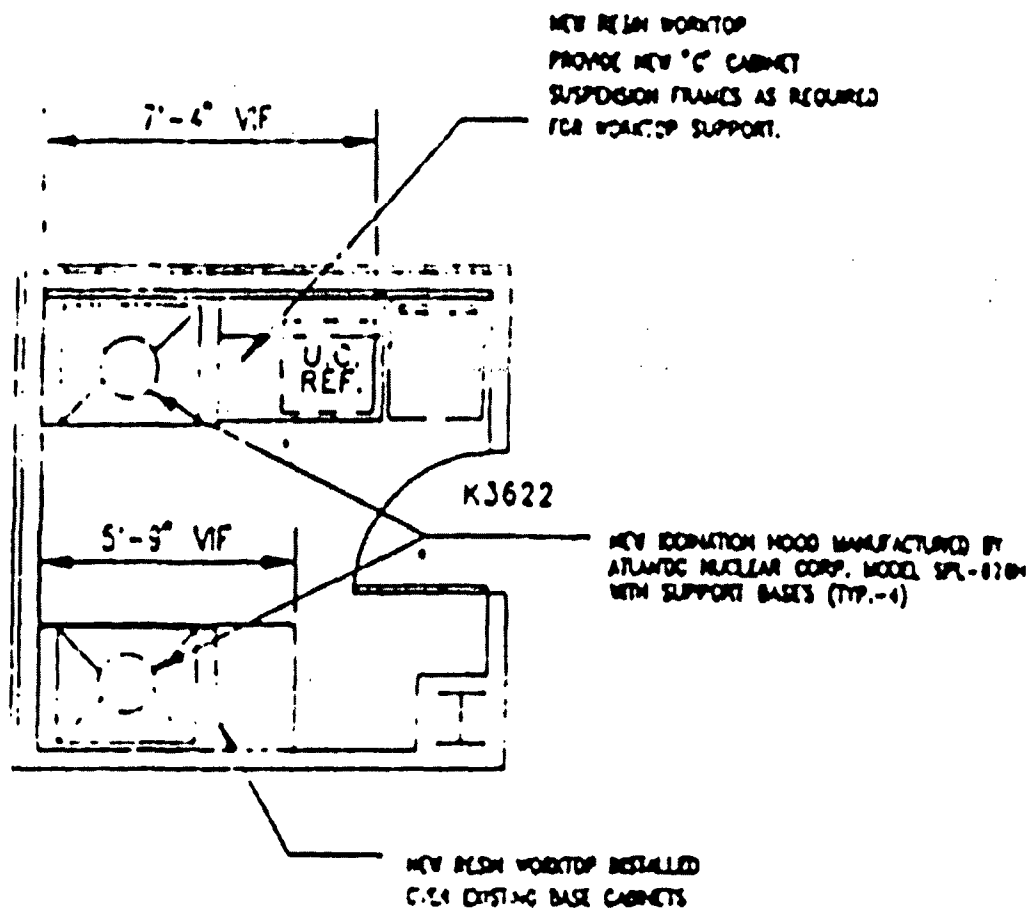


FIGURE 10
 MIXER K100000
 EXHAUST/EXHAUSTION

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

```

: PROGRAM CODE: 03211
: STATUS CODE: P
: REC CATEGORY: 14
: EXP. DATE: 19970430
: REC COMMENTS:
: RECON FIN ASSUP-RECON-FY

```

LICENSE FOR TRANSMITTAL

A. REGION *I*

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: F. B. FORTMAN & SONS, INC.
RECEIVED DATE: 970330
DOCKET NO: 3055722
CONTROL NO.: 124383
LICENSE NO.: 29-30110-02
ACTION TYPE: RENEWAL

2. REC ATTACHED

AMOUNT: 550.00
CHECK NO.: 1001512

3. COMMENTS

RECEIVED *Mr. A. Behne*
DATE *2/21/91*

B. LICENSE FOR MANAGEMENT GRANTOR (CHECK WHEN)

1. FEE CATEGORY AND AMOUNT: 501 100 1330

2. CORRECT FEE PAID. APPLICATION MAY BE FOR
AMENDMENT
RENEWAL
LICENSE

3. OTHER

SIGNED _____
DATE _____

Log 9/24/97
 Promised
 Check No. 00838592
 Amount ASD
 34
 Date 9/1/97
 AB