NRC FORM 374
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 83

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, 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	
1. E. R. Squibb and Sons, Inc. One Squibb Drive 2. P. O. Box 191 New Brunswick, New Jersey 08903-0191	In accordance with letter dated February 28, 1989, 3. License number 29-00139-02 is amended in its entirety to read as follows: 4. Expiration date April 30, 1997 5. Docket or Reference No 030-05222

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with Atomic Nos. 1 through 83 inclusive, except Strontium 90	A. Any	A. Not to exceed 5 curies per radionuclide and 1000 curies total
B. Iodine 131	B. Any	B. 150 curies
C. Molybdenum 99/ Technetium 99m	C. Any	C. 500 curies
D. Any byproduct material with Atomic Nos. 1 through 83 inclusive, except Strontium 90	D. Any	D. Not to exceed 200 millicuries per radionuclide and 5 curies total
E. Hydrogen 3	E. Any	E. 2 curies
F. Carbon 14	F. Any	F. 4 curies
G. Sulfur 35	G. Any	G. 2 curies
H. Any byproduct with Atomic Nos. 1 through 83 inclusive, except Strontium 90	H. Any	H. Not to exceed 10 millicuries per radionuclide and 1 curie total
I. Hydrogen 3	I. Any	I. 40 millicuries
J. Carbon 14	J. Any	J. 40 millicuries
K. Phosphorus 32	K. Any	K. 100 millicuries
L. Sulfur 35	L. Any	L. 300 millicuries
M. Iodine 125	M. Any	M. 20 millicuries
N. Nickel 63	N. Plated sources in detector cells	N. Not to exceed 15 millicuries per source and 750 millicuries total

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 29-00139-02

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Amendment No. 83

9. Authorized use:

A., B., and C. (1) Research and development as defined in Section 30.4 of 10 CFR 30.
(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.

D. through N. Research and development as defined in 10 CFR 30.4.

CONDITIONS

10. A. Licensed material in Items 6.A., B., C. and N. may only be used at licensee's facilities at One Squibb Drive, New Brunswick, New Jersey.

B. Licensed material in Items 6.D., E., F., G. and N. may only be used at licensee's facilities at Route 206 and Provinceline Road, Lawrenceville, New Jersey.

C. Licensed material in Items 6.H. and N. may only be used at licensee's facilities, Princeton House, 905 Herrontown Road, Princeton, New Jersey.

D. Licensed material in Item 6.K., L., M. and N. may be used only at the licensee's facilities at 675 College Road East, Princeton Forrestal Center, Plainsboro, 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.

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

14. Experimental animals administered licensed materials or their products shall not be used for human consumption.

15. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.

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(15. continued) CONDITIONS

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 3 months.

C. In the absence of a certificate from a transferor indicating that a 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 gas; or

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

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

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

F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. 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 shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 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 involved, the test results, and corrective action taken.

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

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(Continued) CONDITIONS

16. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 10 CFR 20.203(a)(1), the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols.

17. Detector cells containing a titanium tritide foil or a scandium tritride 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 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory.

19. The licensee shall not acquire licensed material 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. The licensee may transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."

21. The licensee shall maintain and execute the response measure of his Radiological Emergency Contingency Plan submitted to the Commission on March 28, 1990. 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 period of two years from the date of the changes and shall furnish the Chief, Nuclear Materials Safety Branch, Division of Radiation Safety and Safeguards, 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.

22. The licensee is authoirzed to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

    A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

    B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

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(22. continued) CONDITIONS

C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

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

A. Application dated February 28, 1989
B. Letter dated June 16, 1989
C. Letter dated October 4, 1989
D. Radiological Contingency Plan dated March 28, 1990
E. Letter dated May 17, 1990
F. Letter dated May 24, 1990
G. Letter dated July 24, 1990
H. Letter dated April 15, 1991
I. Letter dated November 25, 1991

UNITED STATES NUCLEAR REGULATORY COMMISSION

For the U.S. Nuclear Regulatory Commission

Date APR 17 1992

By Original Signed By:
Elizabeth Ullrich

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

APR 17 1992

License No. 29-00139-02
Docket No. 030-05222
Control No. 110363

E. R. Squibb & Sons, Incorporated
ATTN: Daniel K. Balkunow
Squibb Institute for Medical Research
One Squibb Drive
P. O. Box 191
New Brunswick, New Jersey 08903-0191

Dear Mr. Balkunow:

Please find enclosed the renewal of your NRC Material 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 Region I Material Licensing Section, (215) 337-5093, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

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We wish you success in operating a safe and effective licensed program.

Sincerely,

Original Signed By:
Elizabeth Ullrich

Elizabeth Ullrich
Senior Health Physicist
Nuclear Materials Safety Branch
Division of Radiation Safety
and Safeguards

Enclosures:
1. Amendment No. 83
2. Requirements for Materials Licensees
3. NRC Forms 3 and 313
4. 10 CFR Parts 2, 19, 20, and 170
5. Agreement State List

DRSS/NMS
Ullrich
04/13/92

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03/28/92

PO Box 4000
Princeton, NJ 08543-4000

030-05222

Squibb
Technical Operations

May 24, 1990

Mr. Francis M. Costello
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

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License No. 29-00139-02
Docket No. 030-05222
Control No. 110363

Mr. Costello:

Enclosed are responses to the questions proposed in your February 23, 1990 letter regarding the license renewal application of E. R. Squibb & Sons, Inc.

1. Documents previously submitted and to be included as part of the license application are as follows:

   a) the original application dated February 28, 1989
   b) the June 16, 1989 letter describing the responsibilities of the Radiation Safety Committee
   c) the October 4, 1989 letter requesting a change in frequency of instrument calibration for radiation detection equipment. The NRC has already approved Items 1 b & c.

2. The revised Radiological Contingency Plans (RCP) was submitted to you on March 30, 1990.

3. Every reasonable effort to maintain personnel radiation doses ALARA is made by the licensee's Radiation Safety staff. Among some of the practices utilized by the staff to identify and correct, if applicable, personnel dose related problems are:

   a) Health Physics management reviews all dosimetry data received from our film badge and TLD processor.

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b) Any dose greater than 100 mRem to a worker's whole body and/or 1000 mRem to one's extremities must be reported to the Health Physics department immediately by the film badge and TLD processor.

c) Health Physics personnel will perform an investigation should an individual receive a dose as described in 3b. This investigation shall include but is not limited to recommending procedural changes, additional shielding, rotating employees' assignments, if applicable, and other corrective actions deemed appropriate to keep exposures ALARA.

d) Periodic audits of radiation areas are performed by Health Physics management to supplement the survey program. Recommendations are made on the spot to correct any problems noted.

e) Routine bioassay thyroid monitoring is required for personnel handling greater than a millicurie of I-131 and I-125. Action limits are 50 nCi for I-125 and 70 nCi for I-131.

4. Contamination and exposure rate surveys of areas where radioactive material is used or stored are performed by the Health Physics staff. These surveys are taken at intervals specified in NRC Reg. Guide 8:21 Table I. Action levels for cleansing are approximately 1E-05 uci/cm^2. Exposure rates shall be maintained ALARA.

   Survey records will be maintained by radiation safety personnel.

5. The flow rate of our room air samplers is 10 lpm. The collection efficiency is approximately 98%.

6. No "portal" monitors are used for personnel contamination checks when leaving a controlled area. However, hand-held "pancake" probe geiger counters, hand and shoe counters (which consist of an array of pancake probes), and NaI detectors in I-125 areas are used for personnel monitoring prior to exiting a controlled area. The sensitivity of such instruments is approximately 1E-04 uCi/cm^2.

   The sensitivity was determined by taking a known quantity of I-131 (NIST traceable) then assaying it in NaI detection system to determine a count rate. Knowing the efficiency (uCi/cpm) of the NaI Detection System, a corresponding activity was determined for the detection

system using the above information. The count rate of a geiger counter with a pancake probe was then established from the known activity.

Background levels are generally less than 200 cpm at contamination check stations.

7. The high radiation area near the filter banks observed during a recent inspection of the New Brunswick facility has been surrounded by a chain link fence. Exposure rates outside of this area are less than 100 mRem/hr.

8. The licensee possesses the following NRC regulated material in the form of sealed sources.

	[mCi]	
Ni-63	8	Variac Electron Capture Detector Model #6000 S#2653
Cs-137	34	Beckman Model LS-7500 Serial #7776057
Cs-137	93	ICN Model #375 Serial #978
Cs-137	5.5	Baird Atomic Check Source #SD10-S811
Ni-63	15	Hewlitt Packard Electron Capture Detector Model #19312 S#2050A02219 Series #5880
Ba-133	.019	Packard Model #1900CA S#102859
Ba-133	.019	Packard Model #2500TR S#103362
Ni-63	12	Perkin Elmer Electron Capture Detector Model #900
Cs-137	207	Ohm Density Gauge Model RTR-N S#1010
Ba-133	.006	Technical Associates Model L.S. #006891
Ni-63	15	Hewlitt Packard Electron Capture Detector Model #19312 Serial #10771 Series 5880
Ni-63	15	Hewlitt Packard Electron Capture Detector Model #19312 Serial #10124 Series 5880
Cs-137	91	ICN Check Source
Ni-63	15	Hewlitt Packard Electron Capture Detector Model #19233 Serial #2843A20315 Series 5890
Ba-133	.020	Hewlitt Packard L.S.C. Model #A2000 Serial #36789
Cs-137	250	Ohm Density Gauge Serial #0636 Series 3400
Ni-63	8	Variac Electron Capture Detector Model 6000 S#2651
Ni-63	15	Hewlitt Packard Electron Capture Detector Model #A2020 S#L2237
Ba-133	.020	Packard LSC Serial #86510 Model A2020
Cs-137	.030	Beckman Model LS 3801 S#7014572
Cs-137	.037	Beckman Model LS 7800 S#7280235
Cs-137	.030	Beckman Model LS 3801 S#7014887
Ba-133	.020	Packard Model #1419 Tri-Carb 2000CA
Cs-137	.030	Beckman Model #5801 LSC S#7014983
Ba-133	.019	Packard Model #B1500 LSC S#100441
Ba-133	.020	Packard Model #A2250 LSC S#101337

	[mCi]	
Ba-133	.019	Packard Model #B1500 LSC S#109824
Ba-133	.018	Packard Model #2200 LSC S#B292
Ni-63	15	Hewlitt Packard Model #19233 Series 5890
Ba-133	.019	Packard Model #A2200 S#102404
Ba-133	.019	Packard Model #A1600 S#101815
Ba-133	.019	Packard Model #A2200 S#102030
Ba-133	.040	Beckman LS500TD S#7040854
Ba-133	.019	Packard 1600CA Model #A1600 S#101636
Ba-133	.019	Packard 1600CA Model #A1600 S#102472
Ba-133	.019	Packard 1600CA Model #A1600 S#102492
Cs-137	.010	Dosimeter Corp. Check Source 3060 S#4489RD
Ba-133	.019	Packard Model #A2500 TR S#103168
Ba-133	.019	Packard Model #1900CA S#102860
Ba-133	.019	Packard Model #A2550 S#103006
Ba-133	.020	Packard Model #2050CA S#36562

9. The procedure for examining incoming packages is as follows:

I. **Receipt Requirements**

A. All packages containing radioactive materials shall be delivered to any of the following locations:

1. R & D Receiving - Lawrenceville
2. Wing 2 of the Clinical Pharmacology Unit - Princeton House
3. Receiving Dock - 675 College Road, Forrestal Greens
4. Building 124 - New Brunswick
5. Designated areas at future licensed sites approved by the NRC

B. When a radioactive package is received it must be checked for any obvious leakage or damage by receiving personnel. It then must be placed in a controlled isotope receipt area.

C. Immediately upon receipt, a Health Physics representative must be notified. This individual shall remove the packing list from the exterior of the package and review to determine if the external package surfaces require monitoring.

D. If the package contains radionuclides in quantities and chemical forms as those specified in Section II B, no external package monitoring is required. The Health Physics representative shall complete a "Radioisotope Receipt

Notification Card" and notify the investigator.

E. If the package contains radionuclides in quantities and chemical forms greater than those described in Section II B, the following must be performed:

1. A leak test of the exterior of the package is performed. This is accomplished by firmly drawing a piece of absorbent material over the exterior surfaces of the package and counting this material for the presence of radioactivity on a properly calibrated detection instrument. Removable contamination in excess of 0.01 uci per 100 cm^2 must be reported immediately to Health Physics management.

2. Measure radiation levels at the outer surfaces of a package. Report dose rates in excess of 200 mRem/hr at the package surface and 10 mRem/hr at one meter from the package surface immediately to Health Physics management.

3. Record all results of E1 & 2 on the "Radioisotope Receipt Notification Card".

II. Monitoring Requirements

A. Paragraph 20.205 of "10CFR Part 20" requires recipients of certain packages containing radioactive materials to be monitored for leakage and radiation levels within a specified time after receipt. The Health Physics department is responsible for ensuring that these requirements are met.

The majority of packages containing radioactive materials received at facilities of E. R. Squibb & Sons do not require the monitoring specified by regulations, however there are procedures which should be followed when such packages arrive. These procedures are described in Section I "Receipt Requirements".

B. "Monitoring Exempt" packages are those which do not require leak testing or radiation surveys after receipt. They are described as follows:

1. Packages containing no more than 10 mCi of radioactive materials consisting solely of tritium, carbon 14, sulfur 35 or Iodine 125.

2. Packages containing only radioisotopes with half lives less than 30 days and a total quantity of 100 mCi or less.

3. Packages containing only radioactive materials as gases or in "special form"
   * NOTE: Special form refers to radioactive material which is solid or encapsulated and so designed that the radioactivity is not released under a series or rigorous tests which are described in 10CFR Part 71.

4. Table of "monitored exempt" package quantities for radioisotopes in liquid form most commonly received for use in our research facilities are:

RADIOISOTOPES	MONITORING EXEMPT QUANTITIES (mCi)
14 C	10 mCi
45 Ca	1 mCi
141 Ce	1 mCi
51 Cr	100 mCi
153 Gd	1 mCi
3 H	10 mCi
125 I	10 mCi
22 Na	1 mCi
32 P	100 mCi
86 Rb	1 mCi
35 S	10 mCi
46 Sc	1 mCi
85 Sr	1 mCi
99 Tc	1 mCi
201 Tl	100 mCi

C. All incoming packages which do not meet the requirements for "monitoring exempt" shall be monitored for leakage and surveyed for radiation by Health Physics personnel. Procedures for

monitoring these packages are outlined in Section I E. The period of time in which the package must be monitored after receipt is within 3 hours during normal business hours and within 18 hours of receipt if the package arrives after normal business hours.

III. General Procedures for Opening Packages

A. Report all damaged or leaking packages promptly to the Health Physics office. Appropriate regulatory agencies will be notified only by Health Physics management.

B. Receiving personnel and researchers should not be enticed by vendors or carriers into accepting or returning a damaged or incorrect shipment of radioactive materials.

C. The opening of packages containing radioactive materials must only be performed by adequately trained personnel. Gloves must be worn during the procedure.

D. All radioactive packages shall be opened on flat surfaces preferably within a well ventilated area, and full use should be made of protective clothing and protective equipment such as shields, tongs, etc.

E. As a package is opened, carefully monitor all packaging material for the presence of contamination with a properly calibrated detection instrument.

F. Remove and deface all radiation labels and discard to rubbish along with contamination free packing material.

G. Behind appropriate shielding, leak test the inner container for the presences of gross contamination, making certain to check for broken seals, breakage, loss of contents or change in color of absorbent material around the container. Report any unusual events to Health Physics immediately.

IV. After Hours Receipt

The delivery of radioactive materials to facilities of E. R. Squibb & Sons should only be made Monday through Friday between the hours of 8:00 AM and 4:00 PM. Holiday and weekend deliveries must be pre-arranged.

10. The likelihood of an individual to receive an intake of 40 MPC hours at our license facility is minimal. The licensee continuously monitors all rooms with a potential for elevated airborne radioactive materials. Assays of all radiopharmaceutical manufacturing areas are performed daily. Should an area exceed 25% MPC, additional posting is required and occupancy is restricted. Bioassay thyroid uptake measurements are taken at least weekly. Minimum detectable activity (MDA) for a 2-minute assay for I-131 is 10 nCi. This is well below the Annual Limit of Intake (ALI) of 30 uCi to the thyroid as outlined in proposed 10CFR 20 dated January 9, 1986. Action limits for no iodine work is 50 nCi for I-131 to the thyroid. Should a person receive 70 nCi to the thyroid, he or she is removed from a radiation area. Investigations and reports accompany these actions.

11. The procedure of leak testing sealed sources:

    A. A 100 cm^2 wipe is taken every 6 months around the casing of the sealed source.

    B. Wipes of gamma emitting sources are read on a fixed geometry and shielded open ended G-M tube and scaler. This apparatus can detect 1E-04 uCi/cm^2 on a smear for the gamma emitting isotopes in our sealed sources.

    C. Ni-63 is the only pure beta emitter of our sealed sources. Contamination wipes will be counted on a liquid scintillation counter or equivalent. A Ni-63 source is on order to verify minimum detectable activity for this isotope.

12. Workers who use greater than one millicurie of I-131 or I-125 in research and development are required to assay their thyroid for potential uptake.

13. All maintenance personnel and any supervisory employee assigned to radiation controlled areas are required to notify Health Physics when scheduling the services of outside contractors in radiation areas. The Health Physics department shall provide the following:

A. Specific instructions on radiation safety procedures and precautionary measures to be followed while in and prior to exiting radiation laboratories.
B. Issue dosimetry (if deemed appropriate).
C. Evaluate work areas for exposure rates and contamination levels.
D. Recommend appropriate protective clothing (i.e. lab coat and booties) if applicable.
E. Instructions on emergency procedures.
F. Exposure reports to workers upon request.

14. The majority of ancillary personnel who frequent restricted areas regularly are members of the Site Maintenance department. These employees are instructed by the Health Physics staff as described in 10CFR19.12. Refresher training is provided annually if appropriate. In addition, every reasonable effort is made to provide specific instructions similar to those outlined in item #13 to all ancillary personnel who on occasion frequent or work in restricted areas.

15. All new employees, ancillary employees, and contractors are required to be instructed by Health Physics prior to frequenting radiation areas or before authorization is granted to work with radioactive materials. Retraining is provided as needed, or annually if appropriate.

16. Calibration of the instruments used to determine bioassays of the thyroid is accomplished with the use of a neck phantom.

17. Laboratory procedures for work with radioactive materials are as follows:

    1) The Health Physics Department will determine what personal monitoring equipment must be worn while in a controlled area.

    2) Film badges (and TLD's if required) must be worn by all individuals working in a radiation controlled area.

    3) Protective work clothing and safety shoes must be worn while working with radioactive material.

    4) No eating, storage of food, smoking or application of cosmetics is permitted within a controlled area.

    5) Pipetting by mouth is not permitted.

6) Handling radioactive materials with an open sore or cut below the wrist is not permitted. The cut must be covered by the Squibb Medical Department before the employee may handle radioactive materials.

7) Thyroid uptake measurements are required for personnel handling millicurie quantities of iodine or as requested by Health Physics.

8) It is the responsibility of each female radiation occupational worker to identify when she becomes pregnant and immediately notify the company through the Medical department. If required, urine samples for pregnancy testing of female occupational workers must be submitted to the Medical department.

9) Work areas should be surveyed by the workers for radiation and contamination before commencing, during the processing and after the completion of assignment. All radioactive contaminated areas must be cleaned and rechecked.

10) Gloves must be worn while handling radioactive materials and removed before handling non-radioactive materials.

11) Carts should be used to transport radioactive material when appropriate.

12) All work with open vessels of radioactive material must be done in a properly ventilated area or as directed by the Health Physics Department.

13) All radioactive materials must bear a radiation warning label specifying isotope, date, and approximate amount of activity in microcuries or millicuries.

14) Radioactive waste must be discarded in accordance with "The Radioactive Waste Disposal Procedures".

15) Radioactive waste or cartons bearing the marking "Radioactive" must not be discarded into non-radioactive waste containers.

16) No radioactive liquid waste shall be placed in sanitary sewer system unless authorized by Health Physics.

17) Hands, shoes and clothing must be monitored before leaving a controlled area.

18) All purchases of radioactive material must be approved by the Health Physics Department.

19) Health Physics must be notified before instituting procedures that involve new isotopes, or added risk of contamination, volatilization, or exposure.

20) All spills involving radioactive material must be reported to the Health Physics Department.

21) Refrigerators shall not be used jointly for foods and radioactive materials.

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

23) All injuries shall be reported to a supervisor immediately.

24) Film badges and TLD's should be promptly returned to Health Physics as required, e.g. weekly or monthly.

25) The operating department must notify Health Physics when any occupational worker is hired, transferred or terminated.

18. The Radiation Safety Committee approves users and uses of licensed material by reviewing Health Physics's evaluation of the following:

    1. Isotopes and quantities of use.
    2. Storage and use locations.
    3. Procedure for use.
    4. Equipment for this procedure.
    5. Other hazards.
    6. Potential for volatilization.
    7. Ventilation.
    8. Radiation monitoring equipment.
    9. Disposition of radioactive material.
    10. Previous experience.
    11. In-house training.

19. Licensed material users approved by the Radiation Safety Officer will be reported to the Radiation Safety Committee at the next Committee meeting.

20. An amendment to the license is also being requested to include the following:

    a) Increase the possession limit at the Forrestal Greens facility (location D on our February 27, 1989 license renewal application) for Sulphur 35 from 100 millicuries to 300 millicuries.

    b) A request to perform iodinations using quantities up to 20 millicuries of I-131 in our I-125 iodination facility located in building 80-84 at the New Brunswick site.

    c) Changes in Radiation Safety Committee membership. Biographical profiles of current members are attached.

        Mr. D. K. Balkunow, Radiation Safety Officer, Department Head of Health Physics
        Dr. P. Fernandes, Director of Microbial Genetics and Biochemistry
        Mr. D. Fritzsche, Manager of Personnel Planning and Selection
        Dr. C. Leopold, Associate Director of Medical
        Dr. E. Nickoloff, RSC Chairperson, Director of Science & Technology Administrative Resources
        Dr. P. Roets, Director of Worldwide Occupational/ Environmental Safety
        Mr. G. Thompson, Director of Radiodiagnostic Operations
        Dr. A. Tobia, Counsel - Squibb Institute
        Ms. S. Voigt, Associate Director of Environmental Health & Safety

I trust that this information is adequate and clear. If you have any questions, please feel free to contact me. My telephone number is 201-519-1721.

A check for $120.00 is enclosed.

Very truly yours,

Larry Gaines
Technical Supervisor
E. R. Squibb & Sons, Inc.

LG:pcp
cc: Mr. J. Gresh RSC
    Ms. D. Silva RSC Alternates

Daniel K. Balkunow

(b)(6)

Work Experience:

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

March 1990 to Present: 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"

(b)(6)

Rider College, Lawrenceville, NJ
B. S. Commerce
Majored in Accounting with a minor in Finance. Earned degree while employed full time with present employer.

(b)(6)

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

Prabhavathi B. Fernandes
(b)(6)

Tel: (609) 683-6078 (work)
Tel: (b)(6) (home)

Date of Birth: (b)(6)

EDUCATION

Doctor of Philosophy	Thomas Jefferson University Philadelphia (b)(6)
Master of Science	Madras University India (b)(6)
Bachelor of Science	Bangalore University India (b)(6)

POSITIONS HELD

Director,
(August 1988-Present)

Microbial Genetics and Biochemistry
The Squibb Institute for Medical Research
P.O. Box 4000
Princeton, NJ 08543-4000

Senior Project Leader:
(October 1985-
August 1988)

General Microbiology
Pharmaceutical Products Division
Abbott Laboratories
Abbott Park,, IL 60064

Project Leader:
(1983-September 1985)

General Microbiology
Pharmaceutical Products Division
Abbott Laboratories
Abbott Park,, IL 60064

Senior Research Microbiologist
(1980-1982)

In Vivo Microbiology
The Squibb Institute for Medical Research
E. R. Squibb and Sons
P.O. Box 4000
Princeton, NJ 08543-4000

Research Assistant Professor of Microbiology and
Post-doctoral Fellow in Clinical Microbiology:
(1978-1980)

Department of Microbiology and Immunology
Temple University School of Medicine
Philadelphia, PA

Post-Doctoral Fellow:
(1976-1978)

Molecular Membrane Biology
The Institute for Cancer Research
Philadelphia, PA

Post-doctoral Fellow: (1975-1976)	Cell Membrane Lipids and L-forms Thomas Jefferson University Philadelphia, PA
Medical Technologist: (1972-1974, part-time)	Clinical Laboratory Thomas Jefferson Hospital Philadelphia, PA
Research Associate: (1971-1972)	Immunochemistry Laboratory University of Ghent Belgium
Medical Technologist: (1968-1971, part-time)	Christian Medical College Hospital Vellore, India

MEMBERSHIP IN SCIENTIFIC SOCIETIES

American Society for Microbiology
Society for General Microbiology
New York Academy of Sciences
American Association for the Advancement of Science
Pseudomonas Club
Eastern Branch of the ASM
Industrial Society for Microbiology
American Chemical Society

Observer, National Committee for Clinical Laboratory Standards

PATENTS

1. Naphthyridine antianaerobe compounds.
2. Erythromycin A Derivatives.

RESPONSIBILITIES AT SQUIBB

I am the Director of the Microbial Genetics group, Microbial Biochemistry group, and the Screening and Fermentation groups.

Since my formal training in bacterial genetics was deficient, I attended the ADVANCED BACTERIAL GENETICS course offered at COLD SPRING HARBOUR LABORATORIES, in May-June, 1989. I also completed a course on RECOMBINANT DNA TECHNIQUES at Rutgers University in January, 1989.

The genetics group is responsible for heterologous expression in yeast and bacteria and also for developing screens using novel targets for therapeutic agents in the area of antibacterials, antivirals, biosynthesis of cholesterol, oncogenes and cardiovascular areas.

The biochemistry group is responsible for identifying novel targets for therapeutic agents and determining the selectivity of novel compounds for these targets.

The natural products group is responsible for identifying new chemical entities for use in the therapeutic areas outlined above.

ACCOMPLISHMENTS AT ABBOTT

I ESTABLISHED A NEW MICROBIOLOGY DEPARTMENT WITH STATE OF THE ART TECHNOLOGY. I DIRECTED THE MICROBIOLOGY DEPARTMENT IN THE ANTI-INFECTIVE DIVISION WHICH IS RESPONSIBLE FOR ANTI-BACTERIAL, ANTI-VIRAL AND ANTI-TUMOR TESTS.

As a senior project leader at Abbott Laboratories, I was a manager of nineteen technical staff with four having Ph.Ds, and others having a Masters degrees of Bachelors degrees. My overall responsibilities included advising on the direction of research in the antiinfective discovery division and directing the in vitro and in vivo evaluation of all antibacterial agents at Abbott.

My Project Team was divided into three sections:

1) In vitro microbiology
2) In vivo microbiology
3) Bioassay Laboratories

In the in vitro laboratories, the bioactivity of all new antibacterial agents discovered at Abbott was determined. The tests conducted by this group included minimum inhibitory concentrations, minimum bactericidal concentrations, killing kinetics, effect of serum and urine on the activity of compounds, synergy tests, establishing antibacterial agent concentration in susceptibility disks, tissue culture for *Chlamydia*, and mode of action of new antibacterial agents. The frequency of resistance development to new antibacterial agents was also determined by this group. Two of the staff were involved with screening bacteria isolated from soil samples for new antibiotics.

In the in vivo group, mouse protection tests and various models of human diseases such as pyelonephritis, meningitis, pneumonia, and infections in immunosuppressed mice were used to evaluate the relative potency of new antibacterial agents. The effect of antibacterial agents on the normal intestinal microflora was evaluated in this section of the microbiology team. Also, a hamster colitis model which I developed at Squibb had been set up to determine the activity of novel compounds against *Clostridium difficile* colitis.

I established new methods for accurately and efficiently determining the concentration of antibacterial agent in serum, urine and tissue samples in the bioassay laboratory. Serum and urine samples from Phase I and II clinical studies on new agents or on new formulations of older antibiotics were also assayed for antibiotic content in the bioassay laboratory.

New methods were set up in the microbiology team. These include tests to determine the antibacterial activity of monoclonal antibodies and immunomodulatory agents. A *Candida* pyelonephritis model was established to determine the activity of anticandidal agents. An influenza model was established in mice to determine the activity of antiviral agents against this important viral pathogen. Anti-HIV and anti-Herpes tests were performed under contract at a University center. We established in vitro and in vivo methods for evaluating anti-tumor compounds. In addition to identifying antibacterial agents made at Abbott to have novel properties which would

warrant clinical studies, it was also my responsibility to evaluate compounds developed at other companies for purposes of in-licensing.

Once a compound was identified to take into clinical studies, my team performd all microbiology studies required for filing of IND and NDA applications. I was responsible for writing these reports. I was also involved in setting up pre-clinical microbiology and Phase I pharmacokinetic studies of these antibacterial agents and support the clinical development of these antibacterial agents.

I am experienced in presenting regression analysis and interpretive criteria for new antibacterial agents to the National Committee for Clinical Laboratory Standards. This was necessary for clinical laboratories to be able to test the new antibacterial agent after their approval. I presented the susceptibility criteria for clarithromycin, difloxacin and temafloxacin to the NCCLS. The criteria I presented had been accepted for Phase II clinical trials.

During the last four years at Abbott, I identified four quinolones, as potential drug candidates. These compounds are undergoing clinical evaluation. My department completed the microbiology work required for the IND filing and I wrote the microbiology section of their IND application. Of these compounds, temafloxacin and tosufloxacin are in Phae III clinical trials. Both these compounds have been licensed to companies in Japan (Fugisawa and Toyama). I also evaluated a new macrolide, clarithromycin (A-56268) from Taisho pharmaceuticals. My department completed the microbiology work for its IND. I wrote the microbiology section of its IND application and this compound is in Phase III clinical trials. During the phase I studies of this compound I identified, with the help of Dr. Les Frieberg, the 14-hydroxy metabolite of clarithromycin and we hold the patent on this compound. In addition to supporting the anti-infective discovery area, I worked with the drug delivery venture team in the diagnostics division at Abbott to find new, improved erythromycin formulations. I also supported the Chemical and Agricultural Products Division and the Hospital Products Division to identify and solve microbiology related problems.

In summary, the Microbiology team in the anti-infective division is now recognized in the United States and Internationally for its work in antibacterial agents and clinical microbiology and during my five year tenure, I was directly involved with the 4 quinolones, 1 macrolide and 1 anti-viral agent which reached clinical trials.

In recognition of my achievements at Abbott I was elected to the Volweiler Society (an academic society at Abbott whose members have outstanding scientific ability) and was awarded the Abbott Presidential Award in February, 1988.

ACCOMPLISHMENTS AT SQUIBB

TWO YEARS OF SUPERVISING AND CONDUCTING IN VIVO MICROBIOLOGY STUDIES

As the supervisor of the in vivo microbiology section at Squibb, I studied the in vivo potency of aztreonam, the first monobactam antibacterial agent. In order to differentiate between the beta-lactam antibiotics, I developed animal models which were used to demonstrate the advantages of Squibb's new antibacterial agent. My accomplishments at Squibb are described below:

1) Intestinal microflora studies to demonstrate that aztreonam does not alter the normal, beneficial microflora in the intestinal tract.
2) Developed models for infections in immunosuppressed mice.
3) Developed animal models for pneumonia.
4) Developed animal models for pyelonephritis.
5) Developed methods for continuous administration of antibiotics to rodents.
6) Developed a working knowledge of the large penicillin and cephalosporin field.
7) Presented papers at national meetings on the in vivo activity of aztreonam.

FIVE YEARS OF RESEARCH AT THREE UNIVERSITIES IN PHILADELPHIA

My accomplishments during my faculty position and post-doctoral fellowships are described below:

1) As a faculty member at Temple University, I was successful in obtaining a grant for developing a MEMBRANE PROTEIN VACCINE against *Pseudomonas aeruginosa*.
2) Developed a novel, electrophoretic method for the identification of bacteria on the basis of their proteins.
3) Studied the mechanism of secretion of cholera toxin.
4) Studied the pathogenesis of L-forms of streptococci.
5) Studied the structure of gram negative cell membranes.
6) Supervised the isolation and characterization of the first bacteriocin isolated from *Bacteroides fragilis*, an anaerobic bacterium.
7) During graduate school and post-doctoral years, I became familiar with ANAEROBIC MICROBIOLOGY, ELECTRON MICROSCOPY, and TISSUE CULTURE.

TEACHING EXPERIENCE

I have been involved with teaching medical students and infectious disease fellows for twelve years.

EXPERIENCE IN CLINICAL MICROBIOLOGY

Since 1968, I have been closely associated with clinical microbiology. This has helped me immensely in determining the areas where there is the greatest need for new drugs.

1) Three years of experience at Christian Medical College Hospital. This hospital is one of the largest and most advanced hospitals in Asia.
2) Three years of experience in the clinical microbiology laboratory at Thomas Jefferson University Hospital, Philadelphia.
3) Two years as a FELLOW IN CLINICAL AND PUBLIC HEALTH MICROBIOLOGY at Temple University, Philadelphia. This made me eligible for the American Board of Clinical Microbiology.
4) While at Abbott, I maintained a close relationship with the microbiologists at Evanston Hospital in order to remain knowledgeable about current developments in infectious diseases. In order to remain familiar with current practices in infectious diseases, I

regularly attended infectious disease rounds at Evanston General Hospital, Evanston, Illinois.

PUBLICATIONS

1. Smith, H.L. and P. Bhat-Fernandes. A modified decarboxylase-dihydrolase medium. Appl Microbiol 26:620-621, 1973.

2. Fernandes, P.B. and C. Panos. Persistence, pathogenesis and morphology of an L-form of *Stretococcus pyogenes* adapted to physiological conditions when in immunosuppressed mice. Infect Immun 14: 1228-1240, 1976.

3. Fernandes, P.B. and H.L. Smith. The effect of anaerobiosis and bile salts on the growth and toxin production of *Vibrio cholerae*. J Gen Microbiol 98: 77-86, 1977.

4. Fernandes, P.B., J.M. Clark and H.L. Smith. Morphology of *Vibrio cholerae* during enterotoxin production under anaerobic conditions. J Ultrastruct Res 58: 232-240, 1977.

5. Fernandes, P.B. and C. Panos. A wall-less microbial isolate from a human renal biopsy. J Clin Microbiol 5: 106-107, 1977.

6. Fernandes, P.B. and M.E. Bayer. Membrane-bound enterotoxin of *Vibrio cholerae*. J Gen Microbiol 103: 381-387, 1979.

7. Fernandes, P.B., R.V. Nardi and S.F. Franklin. The resolution of membrane proteins on the basis of charge, size, and hydrophobicity. Anal Biochem 91: 101-114, 1978.

8. Fernandes, P.B., K.M. Welsh and M.E. Bayer. Characterization of membrane-bound NAD glycohydrolase activity in *Vibrio cholerae*. J Biol Chem 254: 9254-9261, 1979.

9. Fernandes, P.B. and K.R. Cundy. Demonstration of cell envelope bound exotoxin A in *Pseudomonas aeruginosa*. Infect Immun 28: 411-416, 1980.

10. Fernandes, P.B., C. Kim, K.R. Cundy and N.H. Haung. Antibodies to cell envelope proteins of Pseudomonas aeruginosa in cystic fibrosis patients. Infect Immun 33: 527-532, 1981.

11. Hayes, T.J., K.R. Cundy, P.B. Fernandes and J.K. Hoober. Purification and characterization of a bacteriocin from from *Bacteroides fragilis*. J Bacteriol 55: 1171-1177, 1983.

12. Fernandes, P.B., C.M. Vojtko, R.R. Bower and J. Weisz. Spenolimycin, a new spectinomycin-type antibiotic. III: Biologic properties. J Antibiot 37: 1525-1527, 1984.

13. Stamm, J.M., C.W. Hanson, D.T.W. Chu, R. Bailer, C. Vojtko and P.B. Fernandes. In vitro evaluation of A-56619 and A-56620, new aryl-fluoroquinolones. Antimicrob Agents Chemother 29:193-200, 1986.

14. Fernandes, P.B., D.T.W. Chu, R.R. Bower, K. Jarvis, N. Ramer and N.L. Shipkowitz. In vivo evaluation of A-56619 and A-56620, new aryl-fluoroquinolones. Antimicrob Agents Chemother 29:201-208, 1986.

15. Chu, D.T.W., G.R. Grannemann and P.B. Fernandes. Abbott-56619. Drugs of the Future 10: 543-545, 1985.

16. Chu, D.T.W., G.R. Grannemann and P.B. Fernandes. Abbott-56620. Drugs of the Future 10: 546-547, 1985.

17. Chu, D.T.W., P.B. Fernandes, A.K. Claiborne, E. Pihuleac, C.W. Nordeen, R.E. Maleczka and A.G. Pernet. Synthesis and structure-activity relationships of novel aryl-fluoroquinolone antibacterial agents. J Med Chem 28: 1558-1564, 1985.

18. Chu, D.T.W., P.B. Fernandes, A. Claiborne, E.H. Gracey and A.G. Pernet. Synthesis and structure-activity relationships of new arylfluoronaphthyridine antibacterial agents. J Med Chem 29: 2363-2369, 1986.

19. Chu, D.T.W., P.B. Fernandes and A. Pernet. Synthesis and biological activity of benzothiazolo[3,2-a] quinolone antibacterial agents. J Med Chem 29: 1531-1534, 1986.

20. P.B. Fernandes, C.W. Hanson, J.M. Stamm, C. Vojtko, N.L. Shipkowitz, and E. St. Martin. The frequency of in vitro resistance development to quinolones and the use of a murine pyelonephritis model to demonstrate selection of resistance in vivo. J Antimicrob Chemother 19: 449-466, 1987.

21. Fernandes, P.B., N. Shipkowitz, R.R. Bower, K.P. Jarvis, J. Weisz and D.T.W. Chu. In-vitro and in-vivo potency of five fluoroquinolones against anaerobic bacteria. J Antimicrob Chemother 18: 693-702 1986.

22. D.T.W. Chu, P.B. Fernandes, R.E. Maleczka, J C.W. Nordeen and A.G. Pernet. Synthesis and structure- activity relationships of 1-aryl-6,8-difluoroquinolone antibacterial agents. J Med Chem 30: 504-509, 1987.

23. Fernandes, P.B., R. Bailer, R. Swanson, C.W. Hanson, E. McDonald, N. Ramer, D. Hardy, N. Shipkowitz, R.R. Bower and E. Gade. In vitro and in vivo evaluation of A-56268 (TE-031): A new macrolide. Antimicrob Agents Chemother 30: 865-873, 1986.

24. Weinberg, D.S., P.B. Fernandes, C.-C. Kao, J.M. Clark, D.P. Bonner and R.B. Sykes. Evaluation of aztreonam, cefoperazone, latamoxef and ceftazadime in the hamster colitis model. J Antimicrob Chemother 18: 729-746, 1986.

25. Hanson, C.W., R. Bailer, E. Gade, R.A. Rode and P.B. Fernandes. Regression analysis, proposed interpretive zone size standards, and quality control guidelines for a new macrolide antimicrobial agent (TE-031). J Clin Microbiol 25: 1079-1082, 1986.

26. Fernandes, P.B., D. Hardy, R. Bailer, E. McDonald, J. Pintar, N. Ramer, R. Swanson and E. Gade. Susceptibility testing of macrolide antibiotics against *Haemophilus influenzae* - correlation of in vitro results with in vivo efficacy in a mouse septicaemia model. Antimicrob Agents Chemother, 31: 1243-1250, 1987.

27. Hardy, D.J., R.N. Swanson, D.M. Hensey, N.R. Ramer, R.R. Bower, C.W. Hanson, D.T.W. Chu and P.B. Fernandes. Comparative antibacterial activities of A-62254 and two reference fluoroquinolones. Antimicrob Agents Chemother 31: 1768-1774, 1987.

28. Fernandes, P.B., R. Swanson, and D.T.W. Chu. Relative in vivo potency of new fluoroquinolones against two intracellular pathogens, *Salmonella typhimurium* and *Legionella pneumophila*. Rev of Infect Dis 10: S1 1988.

29. Fernandes, P.B. and D. Garmaise. Resistance to erythromycin. J Antimicrob Chemother 20:449-450, 1987.

30. Fernandes, P.B., D.T.W. Chu, R.N. Swanson, N.R. Ramer, C.W. Hanson, R.R. Bower, J.M. Stamm and D.J. Hardy. A-61827 (A-60969) A new fluoronaphthyridine with activity against both aerobic and anaerobic bacteria. Antimicrob Agents Chemother 32: 27-32, 1988.

31. Swanson, R.N., J. McAlpine, G. Brill, N.L. Shipkowitz, R.R. Bower, K. Jarvis, M. Mitten and P.B. Fernandes. Enhanced resistance to bacterial infections in mice treated with A-63122, a rhamnolipid. Submitted to J. Antibiot.

32. Jackson, M., J.P. Karwowski, R.J. Theriault, P.B. Fernandes, R.C. Semon and W.L. Kohl. Coloradocin, a new antibiotic from *Actinoplanes*. I. Taxonomy, fermentation and biological properties. J Antibiot 40: 1375-1382, 1987.

33. Fernandes, P.B., N. Ramer, R. Rode and L. Freiberg. Bioassay for A-56268 (TE-031) and Identification of its major metabolite, 14-hydroxy 6-O-methyl erythromycin. Eur J Clin Microbiol Infect Dis 7: 73-76, 1988.

34. Fernandes, P.B. Mode of action, and in vitro and in vivo activities of the fluoroquinolones. J Clin Pharmacology. 28: 156-168, 1988.

35. Rosen, T., D.T.W. Chu, I.M. Lico, P.B. Fernandes, L. Shen, S. Borodkin and A.G. Pernet. Asymetric synthesis and properties of the enatiomers of 7-(3-aminopyrrolidin-yl)-1-(o,p-difluorophenyl)-1,4-dihydro-6-fluoro-4-oxo-1,8-naphthyridine-3-carboxylic acid hydrochloride (a-60969). J Med Chem 31:1586-1590, 1988

36. Fernandes, P.B., D.J. Hardy, D. McDaniel, C.W. Hanson and R.R. Swanson. The in-vitro and in-vivo activity of clarithromycin against *Mycobacterium avium*. Antimicrob Agents Chemother 33:1531-1534, 1989.

37. Hardy, D.J., D.M. Hensey, J.M. Beyer, C. Vojtko, E.J. McDonald and P.B. Fernandes. Comparative in vitro and in vivo activities of new 14-, 15- and 16-membered macrolides. Antimicrob Agents Chemother 32:1710-1719, 1988.

38. Barry, A.L., P.B. Fernandes, J.H. Jorgensen, C. Thornsberry, D.J. Hardy and R.N. Jones. Variability of clarithromycin and erythromycin susceptibility tests with *Haemophilus influenzae* in four different broth media and correlation with the standard disk diffusion test. J Clin Microbiol 26:2415- 2420, 1988.

39. Fernandes, P.B., W.R. Baker, L.A. Freiberg, D.J. Hardy and E.J. McDonald. New macrolides active against *Streptococcus pyogenes* with inducible and constitutive

type of macrolide-lincosamide-streptogramin B resistance. Antimicrob Agents Chemother. 33:78-81, 1989.

40. Swanson, R.N., D.J. Hardy, N.L. Shipkowitz, C.W. Hanson, N.R. Ramer, L.J. Coen and P.B. Fernandes. Phenelfamycins, a novel complex of elfamycin-type antibiotics. III. Activity in vitro and in a hamster colitis model. J. Antibiot 52:94-1-1, 1989.

41. Hardy, D.J., C.W. Hanson, D.M. Hensey, J.M. Beyer and P.B. Fernandes. Susceptibility of *Campylobacter pylori* to macrolides and fluoroquinolones. J Antimicrob Chemother 22:631-636, 1988.

42. Chu, D.T.W., P.B. Fernandes, A.K. Claiborne, L.Shen, A.G. Pernet. Structure-Activity relationships in quinolone antibacterials: design, synthesis and biological activities of novel isothiazoloquinolones. Drugs Exptl Clin Res 24:379-383, 1988.

43. Klein, L.L., C.M. Yeung, P. Kurath, J.C. Mao, P.B. Fernandes, P.A. Lartey and A.G. Pernet. Synthesis and activity of nonhydrolyzable pseudomonic acid analogues. J Med Chem 32:151-160, 1989.

44. Fernandes, P.B., R.N. Swanson, D.J. Hardy, C.W. Hanson, L. Coen, R.R. Rasmussen and R.H. Chen. Pacidamycins, a novel series of antibiotics with anti-*Pseudonomas aeruginosa* activity. III. Microbiologic profile. J Antibiot 42:521-526, 1989.

45. Rosen, T., P.B. Fernandes, M.A. Marovich, L. Shen, J. Mao and A.G. Pernet. Aromatic dienoyl tetramic acids. Novel antibacterial agents with activity against anaerobes and staphylococci. J Med Chem 32:1062-1069, 1989.

46. Fernandes, P.B., R.N. Swanson, D.J. Hardy, E.J. McDonald, N. Ramer. Effect of dosing intervals on efficacy of clarithromycin and erythromycin in mouse infection models. Drugs Exptl Clin Res 14:441-444, 1988.

47. Fernandes, P.B., and D.J. Hardy. Comparative in vitro potencies of nine new macrolides. Drugs Exptl Clin Res 14:445-451, 1988.

48. Fernandes, P.B. and R.N. Swanson. Correlation of in vitro activities of the fluoroquinolones to their in vivo efficacies. Drugs Exptl Clin Res 14:375-378, 1988.

49. Fernandes, P.B., R.N. Swanson, D.J. Hardy, C.W. Hanson, D.McDaniel, J. Beyer & R.H. Chen. Coumamidines, new broad spectrum antibiotics of the cinodine type. III. Microbiologic activity of coumamidine γ1. J Antibiot 42:538-541, 1989.

EDITORIAL BOARD

1. Drugs Under Experimental and Clinical Research, Bioscience Ediprint.

2. Diagnostic Microbiology and Infectious Diseases, Elsevier Science Publishing Company

3. Drug News and Perspectives, Prous Science Publishers.

REQUESTED REVIEWS AND PRESENTATIONS

1. Fernandes, P.B., R.R. Bower and N.L. Shipkowitz. Murine models for experimental pyelonephritis. In Proceedings of the Symposium on Urogenital Tract Infections, Philadelphia, November, 1984. Editors: A. Bondei, D. Stieritz, J.M. Campos and L.A. Miller, Plenum Publishing Corporation, 1988.

2. Fernandes, P.B., D.P. Bonner and R.B. Sykes. Aztreonam: A new concept in beta-lactam antibiotics. Comprehensive Therapy 9: 21-26, 1983.

3. Fernandes, P.B. In vivo evaluation of immunomodulators using animal models for human disease. Presented at the Fall Meeting of The Immunotoxicology Group, Chicago, November, 1985.

4. Fernandes, P.B. Mode of action, in vitro and in vivo activity of quinolones. Presented at conference on New Antibacterial Agents held by the American College of Clinical Pharmacology, May 1986.

5. Fernandes, P.B. In vitro and in vivo activity of fluoroquinolone antibacterial agents. Presented at the International Symposium on the Chemistry and Biology of Quinolone Anti-infective Agents. Chicago, September, 1986.

6. Fernandes, P.B. and D.T.W. Chu. Quinolones. Chapter 12, Section V, In Annual Reports in Medicinal Chemistry, 22:117- 126, 1987.

7. Fernandes, P.B. The Macrolide Revival. T he Antimicrobic Newsletter 4: 25-34, 1987.

8. Fernandes, P.B. and L.L. Shen. Quinolones: Mode of action and mechanisms of resistance. In Clinical Implications of Antimicrobial Resistance: Mechanisms, Testing Problems and Epidemiology. Plenum Publishing Company, New York, 1987.

9. Fernandes, P.B. New antibiotics - discovery and development. Presented at the summer meeting of the Illinois Society for Microbiology, Chicago, June 1987.

10. Fernandes, P.B. Editor, Telesymposium on Fluoroquinolones. Prous Publishers, 1989.

11. Fernandes, P.B. and D.T.W. Chu. Quinolone Antibacterial Agents. Chapter 14, In Annual Reports in Medicinal Chemistry, 23:113-140, 1988.

12. Fernandes, P.B. and D.T.W. Chu. Design and mode of action of anti-infective quinolones. Advances in Drug Research. Volume 22, 1990 (In Preparation).

13. Chu, D.T.W. and P.B. Fernandes. Mini-Review on The Fluoroquinolones: Structure-Activity Relationships. Antimicrob Agents Chemother 33:131-135, 1989

14. Fernandes, P.B. and D.T.W. Chu. Quinolone Antibacterial Agents. Chapter 14, In Annual Reports in Medicinal Chemistry 23:113-140, 1988.

PRESENTATIONS AT NATIONAL AND INTERNATIONAL MEETINGS:

1. Fernandes, P.B., J.M. Clark and H.L. Smith. The effect of anaerobiosis on the growth, toxin production, and morphology of Vibrio cholerae. Presented at the 75th Annual meeting of the American Society for Microbiology, New York, 1975.

2. Fernandes, P.B. and C. Panos. Survival of an L-form of *Streptococcus pyogenes* in immunosuppressed mice. Presented at the 76th Annual Meeting of the American Society for Microbiology, May, 1976.

3. Fernandes, P.B. and M.E. Bayer. Characterization of membrane proteins of a human enterotoxigenic *Escherichia coli*. Presented at the 77th Annual Meeting of the American Society for Microbiology, 1977.

4. Fernandes, P.B. and M.E. Bayer. Identification of membrane bound subunits of *Vibrio cholerae* enterotoxin by immunoprecipitation and NADase assay. Presented at the 78th Annual Meeting of the American Society for Microbiology, 1978.

5. Fernandes, P.B., R.V. Nardi and S.F. Franklin. The resolution of bacterial membrane proteins on the basis of their size, charge and hydrophobicity on Triton-urea-acetic acid gels. Presented at the American Society for Microbiology Conference on Microbial Membranes, 1978.

6. Fernandes, P.B. and K.R. Cundy. Release of membrane bound exotoxin A of *Pseudomonas aeruginosa*. Presented at the 79th Annual Meeting of the American Society for Microbiology, 1979.

7. Feldman, A., C.C. Dietz and P.B. Fernandes. Identification of non-fermentative gram-negative bacilli by resolution of proteins using polyacrylamide gel electrophoresis. Presented at the 79th Annual Meeting of the American Society for Microbiolgy, 1979.

8. Fernandes, P.B. and K.R. Cundy. Exotoxin A of *Pseudomonas aeruginosa*: Studies on the secretion and isolation of membrane-bound toxin. Presented at the 80th Annual Meeting of the American Society for Microbiology, 1980.

9. Fernandes, P.B., D.P. Bonner, R.P. Whitney, B.H. Miller, C.O. Baughn and R.B. Sykes. SQ 26776: Efficacy in experimental infections. Presented at the 21st Interscience Conference on Antimicrobial Agents and Chemotherapy, 1981.

10. Fernandes, P.B., D.L. Santoro, C.C. Kao, D.P. Bonner and R.B. Sykes. Antibiotic-associated colitis-A side effect not produced with aztreonam in the hamster model.

Presented at the 22nd Interscience Conference on Antimicrobial Agents and Chemotherapy, 1982.

11. Bonner, D.P., P.B. Fernandes and R.B. Sykes. Aztreonam in combination with other antibiotics as therapy for single and mixed bacterial infections in mice. Presented at the 13th International Congress of Chemotherapy, 1983.

12. Chu, D.T.W., H.E. Gracey, P.B. Fernandes and A. Pernet. The synthesis and antibacterial activities of novel 1-phenyl- naphthyridines and 1-phenyl-6,7-methylene deoxy-quinolones. Presented at the 24th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1984.

13. Chu, D.T.W., P.B. Fernandes, A.K. Claiborne, T.J. O'Donnell, E. Pihuleac, C. Nordeen and A. Pernet. A-56619 and A-56620: Synthesis and antibacterial activities of the novel aryl-fluoroquinolones and their analogues. Presented at the 24th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1984.

14. Hanson, C., E. Gade, P.B. Fernandes and A. Pernet. Disk susceptibility correlation to agar dilution susceptibilities and two new aryl-fluoroquinolones: A-56619 and A-56620. Presented at the 24th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1984.

15. St. Martin, E., J. Stamm, E. McDonald, C. Vojtko and P.B. Fernandes. A-56619 and A-56620: Effects of pH, isoelectric point, divalent cations, and combination with other agents on in vitro activity. Presented at the 24th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1984.

16. Hanson, C., R. Bailer, E. Gade, D. Chu, P.B. Fernandes and A. Pernet. In vitro evaluation of aryl-fluoroquinolones: A-56619 and A-56620. Presented at the 24th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1984.

17. Stamm, J., C. Hanson, N. Ramer, E. St. Martin and P.B. Fernandes. A-56619 and A-56620: Comparative in vitro bactericidal activity, inoculum size effect, killing kinetics, and development of resistance. Presented at the 24th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1984.

18. Fernandes, P.B., J. Weisz, R. Bower, N. Shipkowitz, K. Jarvis and A. Pernet. A-56619 and A-56620: In vitro potency against anaerobic bacteria and in vivo efficacy in a subcutaneous abscess model. Presented at the 24th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1984.

19. Fernandes, P.B., D.Chu, R. Bower, N. Shipkowitz, K. Jarvis, N. Ramer and A. Pernet. A-56619 and A-56620: Efficacy in experimental infections. Presented at the 24th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1984.

20. Fernandes, P.B., N. Shipkowitz, D. Chu, L. Coen, N. Ramer and G.R. Grannemann. Pharmacokinetic studies with A-56619 and A-56620 in mice and dogs. Presented at the 24th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1984.

21. Karwowski, J.P., M. Jackson, P.B. Fernandes and R.J. Theriault. Discovery of spenolimycin, a new spectinomycin-type antibiotic. I. Taxonomy, fermentation,

and biological activity. Presented at the 24th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1984.

22. Marcotte, P., L. Freiberg, P.B. Fernandes, D. Brodie and A. Petersen. Enzymatically activated pro-drugs of erythromycin. Presented at the 24th Interscience Conference of Antimicrobial Agents and Chemotherapy, 1984.

23. Chu, D., P.B. Fernandes, N.L. Shipkowitz, C. Vojtko and A. Pernet. Comparative in vitro and in vivo potencies of A-56620, ofloxacin, and ciprofloxacin. Presented at the 14th International Congress of Chemotherapy, 1985.

24. Fernandes, P.B., C. Vojtko, R.R. Bower, D. Chu and A. Pernet. Comparative in vitro and in vivo potencies of A-56619, ofloxacin, and ciprofloxacin. Presented at the 14th International Congress of Chemotherapy, 1985.

25. Cooper, C.S., D.T.W. Chu, P.B. Fernandes, E. Pihuleac and A. Pernet. The synthesis and antibacterial activities of novel substituted 7-amino-1-aryl-6-fluoro-quinolones. Presented at the 25th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1985.

26. Chu, D.T.W., P.B. Fernandes, A.K. Claiborne, H.E. Gracey and A. Pernet. A-60969: Synthesis and antibacterial activity of the novel aryl-fluoro-naphthyridine and its analogs. Presented at the 25th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1985.

27. Stamm, J., C. Vojtko, J. Weisz, C. Hanson, D.T.W. Chu and P.B. Fernandes. A-60969: In vitro potency of a new aryl-difluoronaphthyridine. Presented at the 25th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1985.

28. Fernandes, P.B., R.R. Bower, K. Jarvis, R. Swanson and D.T.W. Chu. A-60969: Efficacy of a new aryl-fluoro naphthyridine in experimental animal infections. Presented at the 25th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1985.

29. Fernandes, P.B., D. Hardy, R. Swanson, E. McDonald, R. Bower, N. Shipkowitz and D.T.W. Chu. Antibacterial activity of A-62254 a new quinolone. Presented at the 26th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1986.

30. Chu, D.T.W., P.B. Fernandes, A.K. Claiborne, R.E. Maleczka, E. Pihuleac, L. Shen and A.G. Pernet. Recent developments in the quinolone antibacterial agents. Synthesis and antibacterial activity of aryl-fluoro- quinolones. Presented at the Gordon Research Conferences in Medicinal Chemistry, August 1986.

31. Rosen, T., P. Fernandes, D.T.W. Chu, C. Cooper, V.J. Grief, S.W. Fesik, L.L. Shen and A.G. Pernet. Asymmetric synthesis and biological activity of substituted 7-pyrolidinyl-1-aryl-6-fluoroquinolones. Presented at the American Chemical Society Spring meeting, 1987.

32. Fernandes, P.B., and L.A. Freiberg. Antibacterial activity of N-demethyl and 14-hydroxy metabolites of A-56268 (TE-031). Presented at the 26th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1986.

33. Fernandes, P.B., R. Bailer, C.W. Hanson, E. Gade, C. Vojtko, E. McDonald and D. Hardy. In vitro evaluation of A-56268 (TE-031): A new macrolide. Presented at the 26th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1986.

34. Fernandes, P.B., R. Bailer, C.W. Hanson, E. Gade, C. Vojtko, E. McDonald and D. Hardy. In vitro evaluation of A-56268 (TE-031); a new macrolide. Presented at the 26th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1986.

35. Hanson, C., R. Bailer, E. Gade and P.B. Fernandes. Disk susceptibility correlation to agar dilution susceptibilties with a new macrolide: Abbott-56268 (TE-031). Presented at the 26th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1986.

36. Cooper, C.S., D.T.W. Chu, P.B. Fernandes, L. Shen, E. Pihuleac and A. Pernet. The synthesis and antibacterial activity of aromatic imine containing quinolones. Presented at the 26th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1986.

37. Rosen, T., D.T.W. Chu, C.S. Cooper, P.B. Fernandes, R.E. Maleczka and A. Pernet. The synthesis and antibacterial activity of enantiomerically homogeneous substituted 7-(4-aminopyrrolidinyl)-1-aryl-6-fluoroquinolones. Presented at the 26th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1986.

38. Chu, D.T.W., P.B. Fernandes, A.K. Claiborne, R.E. Maleczka, P. Klock, L. Shen, J. Patel and A. Pernet. A-62254: Synthesis and antibacterial activity of 1-difluorophenyl-6-fluoro-quinolone and its analogs. Presented at the 26th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1986.

39. Eisenstein, T.K., J.J. Meisler Jr., R. Swanson and P.B. Fernandes. A new macrolide, A-56268 (TE-031), provides superior therapy against aerosol and IP *Legionella* infection in guinea pigs. Presented at the 87th Meeting of the American Society of Microbiology, 1987.

40. Baker, W.R., P.B. Fernandes, B. Bopp, K. Marsh, H. Nellans, J. Clark, T. Herrin and S. Hannick. Synthesis and biological activity of erythromycin A 11,12 cyclic carbamates. Presented at the 27th Interscience Conference on Antimicrobial Agents Chemotherapy, 1987.

41. McAlpine, J.B., R.J. Theriault, K.D. Grebner, D.J. Hardy and P.B. Fernandes. Minor products from the microbial transformation of 6-O-methyl erythromycin A by Mucor circinelloides. Presented at the 27th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1987.

42. Waites, K.B., K.C. Canupp, P.B. Fernandes and G.H. Cassell. In vitro susceptibility of mycoplasmas and ureaplasmas to new macrolides and aryl-fluoroquinolones. Presented at the 27th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1987.

43. Freiberg, L.A., L. Klein, S. Hannick, H.N. Nellans, P.B. Fernandes and A.G. Pernet. A-63075, A potent 14-membered macrolide with minimal gastrointestinal side-effects. Presented at the 27th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1987.

44. Hardy, D.J., D.M. Hensey, E.J. McDonald, C. Vojtko and P.B. Fernandes. Comparative in vitro potencies of six macrolides. Presented at the 27th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1987.

45. Chu, D.T.W., P.B. Fernandes, A.K. Claiborne, L. Shen and A. Pernet. New structure-activity relationship of quinolone antibacterials: The nature of the 3-carboxylic acid groups. Presented at the 27th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1987.

46. Rosen, T., D.T.W. Chu, I. Lico, P.B. Fernandes, L. Shen and A.G. Pernet. The design, synthesis and properties of A-65485 and related quinolone antibacterial agents. Presented at the 27th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1987.

47. Karwowski, J.P., M. Jackson, R.J. Theriault, P.B. Fernandes, P.E. Humphrey and L. Coen. Tirandalydigin, a novel tetramic acid of the tirandamycin-streptolydigin type. I. Taxonomy of the producing culture, fermentation and biological activity. Presented at the 27th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1987.

48. Lartey, P., R. Goldman, W. Kohlbrenner, D. Norbeck, N. Wideburg, W. Rosenbrook, D. Riley, R. Hallas, C. Maring, D. Gramponik, S. Fesik and P.B. Fernandes. CMP-KDO synthetase as a target for antibacterial drug design. Presented at the 27th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1987.

49. Lartey, P., D. Norbeck, W. Rosenbrook, R. Hallas, D. Grampovnik, R. Goldman, C. Doran, J. Capobianco, P.B. Fernandes and A. Pernet. Design and in-vitro evaluation of anti-bacterial CMP-KDO synthetase inhibitors. Presented at the 27th Interscience Conference on Anti-microbial Agents and Chemotherapy, 19[illegible]7.

50. Jackson, M., J.P. Karwowski, R.J. Theriault, P.B. Fernandes, M.L. Maus and W.L. Kohl. Phenelfamycins, a novel complex of elfamycin-type antibiotics. I. Taxonomy of the producing organism, fermentation and biological properties. Presented at the 27th Interscience Conference on Antimicrobial Agents an Chemotherapy, 1987.

51. Rosen, T., P.B. Fernandes, L.Shen, M.A. Marovich, J. Mao and A. Pernet. Aromatic dienoyl tetramic acids. Novel antibacterial agents with activity against anaerobes and staphylococci. Presented at the 27th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1987.

52. Girolomi, R.L., M. Jackson, J.P. Karwowski, R.J. Theriault, P.B. Fernandes and W. Kohl. A. 65636, a novel anthramycin type antibiotic with potent antianaerobe activity. I Taxonomy of the producing organism, fermentation and biological properties. Presented at the 27th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1987.

53. Fernandes, P.B., R.N. Swanson, D.J. Hardy, E.J. McDonald and N. Ramer. Effect of dosing intervals on efficacy of clarithromycin and erythromycin in mouse infection models. Presented at the 8th International Symposium on Future Trends in Chemotherapy, 1988.

54. Fernandes, P.B. and D.J. Hardy. Comparative in vitro potencies of nine new macrolides. Presented at the 8th International Symposium on Future Trends in Chemotherapy, 1988.

55. Fernandes, P.B. and R.N. Swanson. Correlation of in vitro activities of the fluoroquinolones to their in vivo efficacies. Presented at the 8th International Symposium on Future Trends in Chemotherapy, 1988.

56. Chu, D.T.W., P.B. Fernandes, A.K. Claiborne, L. Shen and A.G. Pernet. New structure-activity relationship of quinolone antibacterials: design, synthesis and biological activities of novel isothiazolo-quinolones. Presented at the 8th International Symposium on Future Trends in Chemotherapy, 1988.

57. Fernandes, P.B., R. Swanson, D.J. Hardy, C.W. Hanson, C. Vojtko, D. McDaniel, J. Beyer, J.B. McAlpine, and R.H. Chen. Coumamidines, new broad spectrum antibiotics. II. Structural determination and microbiologic activity. Presented at the 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1988.

58. R.N. Swanson, D.J. Hardy, C.W. Hanson, L. Coen, D. Hensey, R.H. Chen, J.B. McAlpine, and P.B. Fernandes. Pacidamycin, A novel series of antibiotics with *Pseudomonas aeruginosa* activity II. Structural determination and microbiologic profile. Presented at the 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1988.

59. Fernandes, P.B., W.R. Baker, L.A. Freiberg, E. McDonald, and D.J. Hardy. New macrolides which have activity against bacteria with inducible and constitutive-type of MLS-resistance. Presented at the 28th Interscience Conference of Antimicrobial Agents and Chemotherapy, 1988.

60. Swanson, R.N., D.J. Hardy, N.L. Shipkowitz, C.W. Hanson, N.R. Ramer, J.E. Hochlowski and P.B. Fernandes. Treatment of *Clostridium difficile* colitis with tiacumicins B and C in hamsters. Presented at the 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1988.

61. Swanson, R.N., J.B. McAlpine, G.M. Brill, N.L. Shipkowitz, R.A. Rode and P.B. Fernandes. Enhanced resistance to bacterial infections in mice treated with A-63122, a Rhamnolipid. Presented at the 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1988.

62. Swanson, R.N., D.J. Hardy, N.L. Shipkowitz, C.W. Hanson, N.R. Ramer and P.B. Fernandes. The activity of phenelfamycins in vitro and in a hamster model of *Clostridium difficile* colitis. Presented at the 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1988.

63. Fernandes, P.B and C.W. Hanson. Partial bacterial cross-resistance between DNA gyrase and eukaryotic topoisomerase II inhibitors. Presented at the 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1988.

64. Cooper, C.S., D.T.W. Chu, P.L. Klock, P.B. Fernandes, L.L. Shen and E. Pihuleac. The synthesis and antibacterial activity 1-aryl-6-fluoroquinolones containing 3-methyl-3-aminopyrrolidine or 4-methyl-4-aminopiperidine substituents at the 7-position. Presented at the 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1988.

65. Fernandes, P.B., D.J. Hardy, R.N. Swanson, D. McDaniel and C.S. Cooper. Comparative in vitro and in vivo activity of fluoroquinolones which differ in a single fluorine group. Presented at the 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, 1988.

66. Freiberg, L.A., C.J. Maring, P.A. Lartey, C.M. Edwards, D. Grampovnik, D. hardy and P. Fernandes. Synthesis and antimicrobial activities of 9-N,N-dialkylamino-9-deoxo-10,11,12,13-tetrahydroniddamycins. Presented at the 29th Interscience Conference Antimicribial Agents and Chemotherapy, 1989.

David A. Fritzsche
(b)(6)

PROFESSIONAL EXPERIENCE

BRISTOL-MYERS SQUIBB COMPANY
Princeton, New Jersey 08543

September 1983 to Present

6/89-Present — Director Human Resources Administration and Services
The Squibb Institute for Medical Research
Provide a full range of Human Resources services to assigned client groups within the Research Institute. Coordinate Human Resources services across the department and maintain liaison with Corporate and group level HR departments on related areas including HR policy, Relocation, Recruitment advertising and coordination and other company sponsored employee programs.

6/85-6/89 — Manager Personnel Planning and Selection
Squibb Corporation
Directed Recruitment and Employee Relations activities for the Corporate Staff and other assigned groups within the company. Coordinated company-wide recruitment programs, monitored and reported on recruitment activities to senior management. Participated in the development of the HR portion of the Company strategic plan including chairing the committee that researched and wrote the recruitment goals. Chaired the HR policy committee, researched and rewrote company HR policy manual. Designed and implemented Substance abuse testing and education program and flexible work schedule program. Directed the company's employee relocation program and employee relations programs such as United Way, Service Awards, Tuition Aid, etc.

9/83-5/85 — Senior Personnel Planning and Selection Associate
Squibb Corporation
Recruited for management level and above positions in R&D, Corporate staff, Worldwide Business Development and Engineering. Provided career counseling to employees.

E. J. BETTINGER COMPANY / GUERIN, BALDWIN & COMPANY
Philadelphia, PA

6/80-9-83 — Personnel Consultant
Recruited a broad range of candidates for entry-level sales to general management. Assignments included Engineering, Systems, Finance, Chemical, Human Resources, Product Development, Legal and Manufacturing Management

6/71-5/80 — **ETHICON, INC.**
Sommerville, NJ

VALLEYLAB, INC.
Boulder CO

PROFESSIONAL ORTHOPEDICS,INC.
West Berlin, NJ

Progressively increasing roles in sales and sales management in the medical device industry. Product focus was on operating room requiring presence during surgery to instruct surgeons and nurses in technical aspects of devices. District sales grew at least 50% per year for 8 of 9 years.

EDUCATION

(b)(6)

RUTGERS UNIVERSITY GRADUATE SCHOOL
New Brunswick, NJ
Master of Science Industrial Relations and Human Resources Management

(b)(6)

URSINUS COLLEGE
Collegeville PA
Bachelor of Science Psychology

CURRICULUM VITAE — CLAYTON EDWARD [illegible], M.D.

Date of Birth:	(b)(6)
Citizenship	(b)(6)
High School:	Flushing High School, New York Graduated June, (b)(6) President, High School Honor Society
College:	Northwestern University: Evanston, Illinois Graduated June, (b)(6) B.A. Degree, Honors in Biology. Major: Biology
Medical School:	Georgetown University: Washington, D. C. Graduated May, (b)(6) M.D. Degree
Internship:	Straight Medical Internship. July, 1975 to June, 1976 Graduate Hospital of the University of Pennsylvania Philadelphia, Pa.
Residency:	Straight Medical Junior and Senior Residencies. July, 1976 to June, 1978 Graduate Hospital of the University of Pennsylvania Philadelphia, Pa.
Postgraduate Training:	Medical Oncology Fellowship Yale-New Haven Hospital, Department of Medical Oncology July, 1978 to June 1980. New Haven, Connecticut
Emergency Services Experience:	One full month daily as assigned medical intern, and approximately 40 full nights "moonlighting" as the sole ER physician in inner-city hospital (Graduate Hospital of the University of Pennsylvania, Philadelphia, Pa.). Several nights monthly in emergency rooms in Connecticut (Hospital of St. Raphael, New Haven; Meriden-Wallingford Hospital, Meriden; Danbury Hospital, Danbury), while an oncology fellow at Yale-New Haven Hospital. Employed 12-15 days/month as physician in Meriden-Wallingford Hospital ER,* Meriden, Conn., July, 1980 - May, 1981; and 6-8 days/month, in Danbury Hospital ER, ** Danbury, Conn., October, 1980-May, 1981. Attending, Emergency Department, Helene Fuld Medical Center,*** Trenton, N. J. Responsible for training medical students, Mobile I.C.U. Trenton paramedics, R.N.'s. Entails handling all Mobile I.C.U. ambulance telemetry and radio calls to field for all Trenton hospitals, as well as Trenton Poison Control Center. July, 1981 - May 1982.

* Daily census: 20 patients per physician per shift. Yearly ER census= 35,000 visits.

** Daily census: 30 patients per physician per shift. Yearly ER census= 60,000 visits.

*** Daily census: 45-50 patients per physician per shift. Yearly ER census= 35,000 visits.

Attending Emergency Department, The Medical Center at Princeton,* Princeton, N. J. Responsible for training Mobile I.C.U. paramedics, E.M.T.'s R.N.'s, and working with medical students and residents on emergency rotations. Entails handling mobile I.C.U. telemetry, and local poison control center. May, 1982 to present, continuously.

Director, Emergency Department, The Medical Center at Princeton, Princeton, N. J., January, 1985-January 1986.

Medical Licenses: New Jersey, #39201, active.
Connecticut, #20756, inactive.
Pennsylvania, #MD-019176-E, inactive.

Federal DEA License (b)(6) active.

New Jersey Controlled Dangerous Substances License:
D31858, active.

Certified in Basic and Advanced Cardiac Life Support (ACLS), Harvard Medical School and American Heart Association May, 1981.

Member, American College of Emergency Physicians.

Board Certified, American Board of Internal Medicine, 1980.

Board Eligible, American Board of Emergency Medicine, 1984.

ATLS Provider. Course taken 2/27/83, at University of Medicine & Dentistry of New Jersey

ACLS Provider: Course taken 2/27/83, at Harvard Medical School, May 14-May 16, 1981.

ACLS Instructor. Course taken at American Heart Association New Jersey Chapter, October, 1982.

Present Position: Associate Corporate Medical Director
E. R. Squibb & Sons, Inc.
One Squibb Drive, P.O. Box 191
New Brunswick, N. J. 08903
(201) 519-2845

Position involves directing an occupational medical clinic attending 2,700 Squibb employees, and supervising two other internists, five nurses, a lab technician, x-ray technician, optometrist, dentist and dental hygienist. Practice is 80% patient care.

Present Address: (b)(6)

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* *Yearly census: 30,000.*

CURRICULUM VITAE

EILEEN NICKOLOFF, Ph.D.

PROFESSIONAL EXPERIENCE:

9/85-Present **Director, Scientific Information Resources**
Squibb Institute for Medical Research
Princeton, N.J.
Responsible for R&D Computer Group (Scientic Information Systems) which handles all scientific computer functions for R&D. Named R&D Coordinator for new building to be built on Princeton site. Responsbile for Science Information at Squibb, which includes all library & literature searching functions.

9/84-9/85 **Administrative Director, Diagnostic R&D**
Squibb Institute for Medical Research
New Brunswick, N.J.
Responsible for all budgetary, personnel and scientific administrative functions including computer networking for a staff of 65 scientists.

1/80-9/85 **Director, Clinical Assay R&D**
Squibb Institute for Medical Research
New Brunswick, N.J.
Brought 13 immunoassays to market, including all research, development, validation, troubleshooting, antibody production, clinical studies and product coordination. Developed research assays for in-house use, including drugs, prostaglandins, bradykinin and complement factors.

1974-1980 **Director, In-Vitro Laboratory**
Director, Radiopharmacy
The Johns Hopkins Hospital
Baltimore, MD
Increased the number of in-vitro tests performed from 200 to 2500/month in four years. Supervised preparation and quality control testing for all clinical and research imaging agents.

1971-1974 **Clinical Chemist**
Harrisburg Hospital
Harrisburg, PA
Directed all clinical chemistry, dialysis, toxicology and urinalysis functions.

1970-1971 **Supervisor, Core Laboratory**
Thorndike Laboratory, Harvard Medical Unit
Boston City Hospital, Boston, MA
Directed Core Laboratory, setting up research assays. Validated assays for use in measuring blood changes during transcendental meditation.

BOARD CERTIFICATION:
American Board of Clinical Chemistry, 1976

PROFESSIONAL AFFILIATIONS:
American Association for Clinical Chemistry
President, New Jersey Chapter, 1983-4
Clinical Ligand Assay Society
President, National, 1979-80
General Chairman, National Meeting, 1979, 1982
Society of Nuclear Medicine
Co-Vice Chairman RIA, 1979 National Meeting

EDUCATION:
St. Joseph's College, Brooklyn, N.Y.
B.A., Chemistry (b)(6)

University of New Hampshire, Durham, N.H.
Ph.D., Organic Chemistry, (b)(6)

PUBLICATIONS:
10 Book Chapters
12 Journal articles
30 published abstracts

RESUME

PERSONAL DATA:

Philip Petrus Roets

(b)(6)

Date of Birth: (b)(6)
Height:
Marital Status:
Dependents:

EDUCATION:

University of Pittsburgh, Pennsylvania
D.Sc. (Hyg) in Industrial Hygiene - (b)(6)
M.Sc. (Hyg) in Industrial Hygiene -

University of Pretoria, Republic of South Africa
M.Sc. Majoring in Physiology, Anatomy and Biochemistry - (b)(6)
B.Sc. Majoring in Physiology, Anatomy and Biochemistry -

Membership to Scientific Associations and Governmental Committee:

National:
South African Institute of Public Health
*South African Clean Air Society
*South African Bureau of Standards, Advisory Committee of Acoustics
*Ad Hoc Committee on Occupational Health Education
*Ad Hoc Committee on Environmental Emissions Control in the South African Steel Industry
*South African Department of Mines Risk Committee on Occupational Diseases in Mines and Works
#Member of a four-man commission of inquiry appointed by Parliament to prepare a report for the South African President on research, training and legal aspects of occupational health

International:
British Occupational Hygiene Society
Permanent Commission and International Association on Occupational Health
American Industrial Hygiene Association
American Society for Testing and Materials - D-22
South African representative on the International Iron and Steel Institute's Committee on Environmental Emissions Control

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* Resigned active participation on moving to the U.S.A. November, 1975.

Final report submitted December 16, 1975, published by South African Government April, 1976

E.R. Squibb & Sons, Inc., New Brunswick, N.J.
1978-Present Manager, Industrial Hygiene & Safety

Quinnipiac College, Hamden, Connecticut
1975-1977 Associate Professor in Industrial Hygiene
1977-1978 Associate Dean, School of Allied Health and Natural Sciences

The South African Iron and Steel Industrial Corporation Ltd., (ISCOR)
1970-1975 Head of the Industrial Hygiene Department
1967-1970 Senior Industrial Hygienist
1964-1967 On study leave at the University of Pittsburgh
1962-1964 Assistant Industrial Hygienist

University of Pretoria, Republic of South Africa
1968-1975 Adjunct Professor in Industrial Physiology (part time)
1961-1962 Head of technical staff, Department of Anatomy
1960-1961 Microtechnician and histology demonstrator, Department of Anatomy
1958-1960 Technical Assistant, Department of Bacteriology

University of Pittsburgh, Pennsylvania
1965-1967 Assistant Professor in Occupational Health (part time)

COURSES TAUGHT:

Physiology I, University of Pretoria, 1968-1975
Industrial Physiology, University of Pretoria, 1968-1975
On the Job Training of Industrial Hygiene Personnel, ISCOR, 1968-1975
Introduction to Industrial Hygiene, Institute of Public Health, 1974
Industrial Hygiene for General Electric and St. Regis, Quinnipiac College, 1975-1976
Ch 437 Toxicity and Detoxication, Quinnipiac College, 1975-1976
IH 310 Introduction to Industrial Hygiene, Quinnipiac College, 1975-1976
IH 320 Industrial Hygiene I, Quinnipiac College, 1975-1976
Bi 211 Anatomy and Physiology, Quinnipiac College, 1976-1977
Bi 295 Applied Physiology, Quinnipiac College, 1976-1977
Bi 456 Environmental Health Practices I, Quinnipiac College, 1976-1977
IH 312 Particulates and Mists, Quinnipiac College, 1978-present
Bi/Ch 325 Principles of Toxicology, Quinnipiac College, 1978-present

PUBLICATIONS:

1. The Influence of Hypothermia on the Blood Glucose and Liver Glycogen of the White Rat. Roets, Philip P., M.Sc. Thesis, University of Pretoria, 1963.

2. Reduction of Local Sweating by Cooling at the Same Site. P.P. Roets, FASEB Abstract, Atlantic City, 1966, 273.

3. Quantitative Aspects of the Local Response of Sweat Glands to Local Alteration of Skin Temperature. P.P. Roets, D.Sc. Thesis, University of Pittsburgh, U.S.A., 1967.

4. Environmental Hygiene in South African Iron and Steel Works, Second Air Pollution Conference Organized by the Department of Health. P.P. Roets, October 1970.

5. Industrial Hygiene at the South African Iron and Steel Industrial Corporation. P.P. Roets, 17th International Congress on Occupational Health, Buenos Aires, September, 1972.

6. Industrial Hygiene - A New Science in South Africa and at ISCOR. P.P. Roets, Biennial Health Congress organized by the Institute of Public Health, Port Elizabeth, November, 1972.

7. An Afrikaans translation of this paper was also published in: Bedryfshigiene 'n Nuwe Wetenskap in Suid-Afrika en by USKOR. Public Health Vol. 73(2), pp. 53-62, February, 1973. (above mentioned paper)

8. Some Meteorological Aspects of Planning of a New Plant Site at Saldanha Bay, South Africa. P.P. Roets and A.T. Holmes. Symposium on Environmental Control in the Steel Industry organized by the International Iron and Steel Institute, (IISI), Tokyo, Japan, February 18-21, 1974. Vol. 1, Sec. 7/E/101/0-Annex 16.

9. Continuous Measurement of Dust in Waste Gases. A.T. Holmes and P.P. Roets, Ibid IISI, Tokyo, Japan, 1974. Vol. 1, Sec. 2/E/108/0.

10. Aerological data in the first two hundred metres of air above the Saldanha Bay Development Region. H. Boegman, E.C. Halliday, W.S. Louw, P.P. Roets and J.J. Taljaard, CSIR Report APRG/75/10, May 1975.

11. Verslag van die Kommissie van Ondersoek, na Bedryfsgesondheid, December, 1975. (English translation published April, 1976).

ADMINISTRATIVE SKILLS - 1970-PRESENT

1. Managed and directed Industrial Hygiene program for ISCOR. Directly responsible for a staff of 14 scientists (see attached organization chart). With staff responsible for Industrial Hygiene function at 3 steel mills, 7 mines, 2 quarries, 60,000 employees.

2. Trained in management principles by ISCOR - Louis Allen "Management by Objectives" program. Several courses and seminars.

3. Organized and chaired an ad hoc committee on Occupational Health Education under auspices of the South African Institute of Public Health. Pressure from this committee led to a Government Commission of Inquiry into Occupational Health Legislation.

4. Appointed by South African President to above mentioned commission (see publication 11).

5. Organized and chaired an ad hoc committee on Environmental Emissions Control in the South African Steel Industry. Appointed the South African representative at the International Iron and Steel Institute's Committee on Environmental Emissions Control. (IISI/Env.)

6. Represented South Africa at IISI/Env. biannually at Brussels 1973-1975. Assisted in organizing a symposium in Tokyo. Developed 2 papers for the symposium (see publications 8 and 9). Delivered a paper at the symposium (8).

7. Instrumental in organizing a research program between the South African Department of Health, South African Weather Bureau, South African Council for Scientific and Industrial Research and ISCOR to investigate the feasibility of industrialization of the Saldanha Bay area (see publications 8 and 10). Result and recommendations of this research to the South African Department of Planning & Environment led to present plan of development for this area accepted by the South African Parliament in 1975. Largest export iron ore harbor on the African continent now in operation at this site.

8. As Associate Dean, share in the responsibility of managing and directing the School of Allied Health and Natural Sciences. A job description of this function is attached. The School of Allied Health and Natural Sciences has 70 faculty members, 1,044 students and offers 6 associate degrees, 16 baccalaureate degrees and 3 graduate degrees.

9. Manage and direct E.R. Squibb Industrial Hygiene program, domestic programs. Consultant to E.R. Squibb for Safety and Health Internationally.

Date	Subject	Centre
an.1974	Interim report on dust and SO_2 conditions in Dantu Hospital	Pretoria works
an.1974	Re-estimation of pneumoconiosis risk	Newcastle works
eb.1974	Report on overseas visit to Italy, USA and Japan	Headquarters
eb.1974	Ammonia vapours in plan production room	Headquarters
eb.1974	Risk classification of Steelworkers in dusty occupations	Pretoria works
ar.1974	Detailed dust survey	Pretoria works
ar.1974	Radiation Safety - Belt weighers	Pretoria works
pr.1974	Placing of loudspeakers in panoramic offices for equal sound distribution	Headquarters
pr.1974	Sound and vibration isolation between offices	Pretoria works
ay.1974	Noise survey	Pretoria works
ay.1974	Noise survey	Hooiplaas quarry
ay.1974	Dust survey	Hooiplaas quarry
une.1974	Detailed air pollution survey (SO_2, Smoke and settling dust 6-monthly report)	Newcastle works
une.1974	Use and misuse of Carbontetrachloride	Corporation wide
uly.1974	Lighting of workbenches - guideline and specification	Headquarters
ug.1974	Guideline in Legal consequences of being a controlled mine under occupational diseases Act	Uis Tin Mine
ept.1974	Air pollution at a possible site for a new works	Headquarters
ct.1974	Noise surveys at 3 of Iscor's subsidiary companies where the major work completed during this month	Headquarters

Iscor has a headquarters in Pretoria, 3 works; Pretoria, Newcastle and Vanderbijlpark, 2 iron ore mines; Thabazimbi and Sishen, one coal mine;

NAME

Phillip P. Roets — Associate Professor

(b)(6)

CITIZENSHIP (See instructions) — U.S. Citizen or U.S. National — (b)(6)

SEX — [X] Male [ ] Female

EDUCATION (Begin with baccalaureate and include postdoctoral training)

INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	PROFESSIONAL FIELD
University of Pretoria, South Africa	B.Sc.	(b)(6)	Physiology, Anatomy and Biochemistry
University of Pretoria, South Africa	M.Sc.		Physiology, Anatomy and Biochemistry
University of Pittsburgh, Pennsylvania	M.Sc. (Hyg)		Industrial Hygiene
University of Pittsburgh, Pennsylvania	D.Sc. (Hyg)		Industrial Hygiene

HONORS

MAJOR PROFESSIONAL INTEREST

ROLE IN PROPOSED PROGRAM

Faculty

TRAINING AND RELATED SUPPORT (See instructions)

PROFESSIONAL EXPERIENCE: (Starting with present position, list training and experience relevant to area of proposed program. List selectively publications that are most relevant to the training program)

GEORGE F. THOMPSON

Present Position: Director, Radiodiagnostic Operations and Productivity

Education:
Wilkes College - B. A. Biology, (b)(6)
U. S. Public Health Service
Course in Basic Radiological Health, 1968

Experience:
E. R. Squibb & Sons, Inc.
Chemical Technician - Quality Control, 1964 - 1966
Production Coordinator - Quality Control, 1966 - 1967
Supervisor - Radiopharmaceutical Q. C., 1967 - 1969
Bulk Supervisor - Radiopharmaceutical Mfg., 1969 - 1971
Section Head - Radiopharmaceutical Mfg., 1971 - 1980
Department Manager - Radiopharmaceutical Mfg., 1980 - 1988
Director - Radiodiagnostic Operations and Productivity, 1988 to Present

Societies:
Health Physics Society - Full Member
Society of Nuclear Medicine - Associate Member

RESUME

ANNETTE MUSTO TOBIA
(b)(6)

Date of Birth: (b)(6)

EDUCATION

J.D.	Rutgers Law School (Newark), June	(b)(6)
Ph.D.	New York University,	(b)(6) Department of Biology
M.S.	New York University,	(b)(6) Department of Biology
B.A.	Hunter College,	(b)(6) Biology (Major), Chemistry (Minor)

BAR ADMISSIONS

New Jersey

U.S. Patent & Trademark Office, Reg. Patent Attorney 30,115

EMPLOYMENT HISTORY--LEGAL

1989 to present	Counsel-Squibb Institute, Bristol-Myers Squibb Company, Princeton, New Jersey
1988 to 1989	Patent Counsel, Bristol-Myers Squibb Company, Princeton, New Jersey
1987 to 1988	Director-Shareholder, Stanger, Michaelson, Reynolds, Spivak & Tobia, Princeton, New Jersey
1986 to 1987	Vice president and general counsel, Hunterdon Pharmaceuticals, Inc., Lawrenceville, New Jersey
1982 to 1986	Attorney, legal and patent matters, private practice, Princeton, New Jersey
1979 to 1982	Patent attorney, Western Electric Company, Princeton, New Jersey

EMPLOYMENT HISTORY--TECHNICAL

June, 1977 to September, 1977	Consultant, Center for Environmental Studies, Princeton University
September, 1973 to June, 1974	Adjunct Assistant Professor, New York University, Graduate School of Arts and Sciences, Department of Biology
February, 1972 to September, 1973	Post Doctoral Fellow, Rockefeller University, Department of Chemical Biology.
September, 1969 to January, 1972	Graduate Research Technician, Einstein College of Medicine, Department of Cell Biology

LEGAL EXPERIENCE

- Provide advice and counsel to the Office of the President of the Squibb Institute for Medical Research and its support staff.
- Assist Division of BioMedical Evaluation and Investments in structuring equity investments in biotechnology companies.
- Negotiate and draft licensing, joint venture and research agreements for the Institute, including software and hardware acquisition.
- Serve as liaison on legal matters between the Institute and key corporate functions, such as business development, patents, licensing, diagnostics, and international legal.
- Serve as Counsel to the various committees responsible for complying with the New Jersey Worker and Community Right to Know Act, the Technology Transfer Act of 1986, the Animal Welfare Act, and the Radiation Safety Regulation.
- Patent prosecution, validity and infringement opinions, in the fields of molecular biology, genetics and chemistry, including recombinant DNA and gene transfer.

- Vice president and general counsel for a startup, public pharmaceutical company. Negotiated business contracts, partnership and confidentiality agreements, wrote licenses and sales agreements, and oversaw SEC matters.

TECHNICAL EXPERIENCE

- DNA, RNA and protein purification, analysis and manipulation including electrophoresis, column chromatography, DNA/RNA hybridization, radioactive labeling.

- Tissue culture of normal and tumor cells including cell synchronization, culture media, growth factors.

PROFESSIONAL ACTIVITIES

March, 1990	Attended the Pharmaceutical Manufacturers Association/National Institutes of Health Technology Transfer Conference, Georgetown University Conference Center, Washington, D.C.
December, 1989	Attended *in vivo* Thrombosis Models Symposium at the Merrill Lynch Conference Center, Plainsboro, New Jersey.
November, 1989	Attended the Frontiers Symposium on Thrombolysis at the National Institutes of Health, Bethesda, Maryland.
November, 1989	Attended the Art of Negotiating Seminar, New Jersey Law Center, New Brunswick, New Jersey.
November, 1989	Attended Joint Research & Development: Licensing New Technologies, The Food and Drug Law Institute, Washington, D.C.
June, 1989	Attended course on Molecular Biology of Neurobiology Disease, Cold Spring Harbor, New York.
April, 1988	Attended Biotechnology Patent Conference of the American Type Culture Collection, Washington, D.C.
November, 1987	Attended Labor and Employment Law Section of the New Jersey State Bar Association symposium on At-Will Employment Law, New Brunswick, New Jersey

October, 1987	Attended New Jersey Institute for Continuing Legal Education seminar on Copyright, Trademark and Trade Secret Protection, Jamesburg, New Jersey
March, 1985	Attended New Jersey Institute for Continuing Legal Education seminar on Practical Estate Administration, Woodbridge, New Jersey
September, 1984	Attended Biotech 84 Conference, Washington, DC
August, 1984	Attended Kepner-Tregoe Decision Making and Problem Analysis course, Philadelphia, Pennsylvania
June, 1984	Attended Recent Developments in Licensing Law and Practice Conference, Hilton Head, South Carolina
February, 1983	Attended Patent Strategies for Biotechnology Products at the Center for Professional Advancement
March, 1982	Attended Genetic Engineering Worldwide: The Law and Business Conference, Key Biscayne, Florida
Summer, 1974 to Summer, 1978	Independent research, New Jersey Office of the Public Advocate. Critiqued chemical substances identification standards
October, 1974 to September, 1975	Advisor, Precision Polymers, New Jersey. Determined the feasibility of manufacturing and marketing a heart potential detector.
September, 1973	Attended AID mission to Columbia, South America
April, 1971	Attended UNIDO mission to northeast Brazil

Published a wide number of articles in professional scientific journals.

Invited to speak at professional scientific meetings and university seminars.

Memberships: American Bar Association, ABA Section of Corporate, Bank, and Business Law; ABA BioSciences Committee; New Jersey Bar Association; American Intellectual Property Law Association; American Association for the Advancement of Science; Licensing Executives Society; and, LES Biotechnology Transfer Committeee.

RESEARCH PUBLICATION

Tobia, A., Parker, R., Schildkraut, C. DNA replication in African green monkey cells synchronized by infection with SV40. 1975. Virology 66:82.

Ossowski, L., Unkeless, J., Tobia, A., Quigley, J., Rifkin, D., and Reich, E. 1973. An enzymatic function associated with transformation of fibroblasts by oncogenic viruses. II. Mammalian Fibroblast Culture Transformed by DNA and RNA Tumor Viruses. J. Exp. Med. 137:112. Reprinted in: Readings in Mammalian Cell Culture. Edited by R. Pollack, New York; Cold Spring Harbor Press, 1973.

Unkeless, J., Tobia, A., Ossowski, L., Quigley, J., Rifkin, D., and Reich, E. 1973. An enzymatic function associated with transformation of firbroblasts by oncogenic viruses. I. Chick Embryo Fibroblast Cultures Transformed by Avian RNA Tumor Viruses, J. Exp. Med. 137:85. Reprinted in: Readings in Mammalian Cell Culture. Edited by R. Pollack, New York; Cold Spring Harbor Press, 1973.

Tobia, A., Brown, E., Parker, R., Schildkraut, C., and Maio, J. 1972. DNA replication in synchronized cultured mammalian cells. IV. Anomalous synthesis of component alpha DNA in the African green monkey. Biochem. Biophys. Acta 277:256.

Tobia, A., Maio, J., Balaz, I., and Schildkraut, C. 1971. DNA replication in synchronized cultured mammalian cells in Drugs and Cell Regulation, E. Mihieh, editor, Academic Press, New York.

Tobia, A., Schildkraut, C., and Maio, J. 1971. DNA replication in synchronized cultured mammalian cells. III. Time of synthesis of the mouse satellite and main band DNAs. Biochem. Biophys. Acta 246:258.

Tobia, A., Schildkraut, C., and Maio, J. 1970. DNA replication in synchronized cultured mammalian cells. I. Time of synthesis of molecules of different average guanine plus cytosine content. J. Mol. Biol. 54:499.

SUSAN G. VOIGT
(b)(6)
(201) 519-2198 - Work

EXPERIENCE

E. R. SQUIBB AND SONS, INC., New Brunswick, NJ (1986 - Present)
Associate Director - Environmental, Health and Safety (Present). Direct the New Brunswick site environmental, industrial hygiene, safety, fire protection and workers' compensation functions for major pharmaceutical company.

Occupational Health/Environmental Department Head (1988-1989). Provide environmental/industrial hygiene services to international and domestic facilities.
Major responsibilities:
- Manage staff providing services in air, water and hazardous waste management.
- Coordinate and conduct industrial hygiene exposure monitoring studies.
- Supervise health and safety training programs.

EXXON CHEMICAL AMERICAS, Baton Rouge, LA (1980 - 1986)
Plant Industrial Hygienist. Provide industrial hygiene services at petrochemical manufacturing site (1,500 employees).
Major responsibilities:
- Evaluate chemical handling procedures, maintenance activities and chemical/physical stresses.
- Develop and conduct employee health training seminars.
- Auditor of Hearing Conservation and Respiratory Protection Programs.
- Coordinator of field monitoring studies.
- Review design specifications for industrial hygiene compatibility.
- Specify respiratory, hearing and other protective equipment.

EXXON CHEMICALS, U.S.A., Baton Rouge, LA (Summer, 1979)
Industrial Hygiene Intern. Participated in all aspects of comprehensive industrial hygiene program at the Baton Rouge Chemical Plant. Special emphasis on heat stress and laboratory ventilation systems.

WEIDLINGER ASSOC., CONSULTING ENGINEERS, New York (Summer, 1978)
Computer programmer. Projects included Economic Project Control.

EDUCATION

HARVARD SCHOOL OF PUBLIC HEALTH, Boston, MA (b)(6)
Master of Science - Industrial Hygiene and Air Pollution,
Courses included: Noise Control, Toxicology, Radiation, Ventilation, Epidemiology, Biostatistics, Air and Gas Cleaning, Identification and Measurement of Air Contaminants, Occupational Health Policy.
Honors: Recipient of NIOSH Traineeship Grant.

UNIVERSITY OF PENNSYLVANIA, Philadelphia, PA (b)(6)
Bachelor of Arts - Biology (Genetics & Microbiology), Cum Laude.
Courses included: Biochemistry, Organic and Inorganic Chemistry, Microbiology, Molecular and Cellular Biology, Molecular Genetics.

BRONX HIGH SCHOOL OF SCIENCE, Bronx, NY, (b)(6)

PROFESSIONAL CERTIFICATION AND AFFILIATIONS

American Board of Industrial Hygiene: CIH
American Industrial Hygiene Association: Full 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. Permagon Press, 1981.

030-05222

Squibb
Technical Operations

May 17, 1990

Mr. Francis M. Costello
Nuclear Materials Safety Section B
Division of Radiation Safety & Safeguards
US Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Re: License No. 29-00139-02

Dear Mr. Costello:

This is to confirm our telephone conversation of May 3, 1990.

As discussed, Mr. Edward Truskowski has resigned his position as Radiation Safety Officer for Bristol-Myers Squibb as of May 11, 1990.

Mr. Truskowski's replacement will be Mr. Daniel K. Balkunow, who until October 1988 had been the Radiation Safety Officer for the Company.

In reference to your letter of February 23, 1990 (License No. 29-00139-02, Document No. 030-05222, Control No. 110363), the information requested will be forwarded as soon as possible. I appreciate your consideration in this matter.

J. P. Gresh
Director
Bristol-Myers Squibb
Worldwide Quality Assurance Services

JPG:pcp

cc: Mr. D. K. Balkunow
Mr. L. Gaines
Dr. E. A. Gusmano
Radiation Safety Committee
Ms. D. Silva

110363

OFFICIAL RECORD COPY ML-10

MAY 21 1990

M5-16
K9

E.R. Squibb & Sons, Inc.

P.O. Box 191
New Brunswick, New Jersey 08903
201-545-1300

Cable: ERSQUIBB PRINCETON

March 30, 1990

Mr. Francis M. Costello
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

License # 29-00139-02
Docket # 030-05222
Control # 110363

Dear Mr. Costello:

As you agreed on March 15, 1990, enclosed please find the Radiological Contingency Plan in duplicate for E. R. Squibb & Sons. This references item #2 in your February 23, 1990 letter to the undersigned.

Edward J. Truskowski
Radiation Safety Officer

cc: Dr. P. Roets (E.R.S.)

EJT:pcp
DS\EJT0330.LET

'90 APR -6 P1:15

RECEIVED - REGION I

110363

OFFICIAL RECORD COPY ML 10

APR 06 1990

RADIOLOGICAL CONTINGENCY PLAN

E. R. Squibb & Sons, Inc.
New Brunswick, New Jersey
March 28, 1990

NOTIFICATION ACTION FORM

GROUP/PERSON	EMERGENCY CLASSIFICATION: UNUSUAL EVENT	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
Safety & Industrial Hygiene	yes	yes	yes
Alternate	opt	yes	yes
Maintenance	yes	yes	yes
Alternate	opt	yes	yes
Utility Services	yes	yes	yes
Alternate	opt	yes	yes
Radiodiagnostic Operations	yes	yes	yes
Alternate	opt	yes	yes
Plant Security	opt	yes	yes
Fire	through plant security if needed		
First Aid	through plant security if needed		
Robert Wood Johnson Hospital	through plant security if needed		
New Brunswick Police Dept	opt. through North Brunswick Police Dept.		
New Brunswick Fire Dept	opt. through North Brunswick Police Dept.		
North Brunswick Police Dept	through plant security if needed		
North Brunswick Fire Dept,	through plant security if needed		
HAZ MAT	opt	yes	yes
NBOEM	opt	yes	yes
EPA	opt	yes	yes
NJDEP	opt	yes	yes
NJSPOEM	opt	yes	yes
USNRC	opt	yes	yes

TABLE OF CONTENTS

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 80.1 acres primarily in the township of North Brunswick, at the crossroads of Route 1 and College Farm Road.

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 Broadscope License No. 29-00139-02 issued by the Nuclear Regulatory Commission. With the exception of a few research activities utilizing small quantities of radionuclides, the radiopharmaceutical manufacturing plant (Building 124) and storage facility (Building 122) are utilized for the processing and storage of the majority of radioactive materials received at the New Brunswick site. Both structures are located on the southwest end of the 80.1 acre site and occupy approximately 1.75 acres.

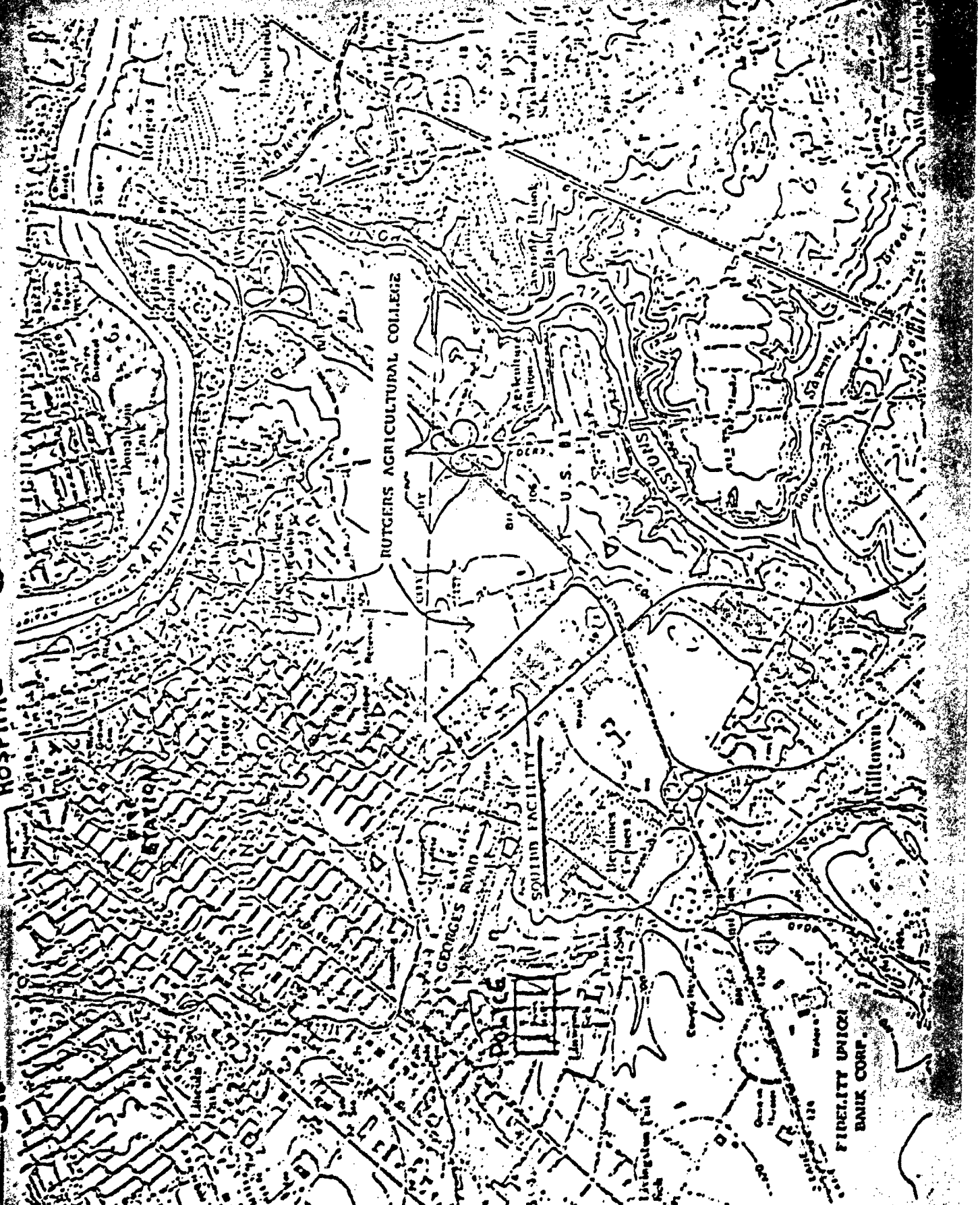
Only small quantities of hazardous chemicals are utilized in the processing and testing of radiopharmaceuticals in Building 124. Approved areas have been designated for the allocation and storage of such chemicals. Eyewash stations and showers are also provided near areas where hazardous chemicals are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

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.

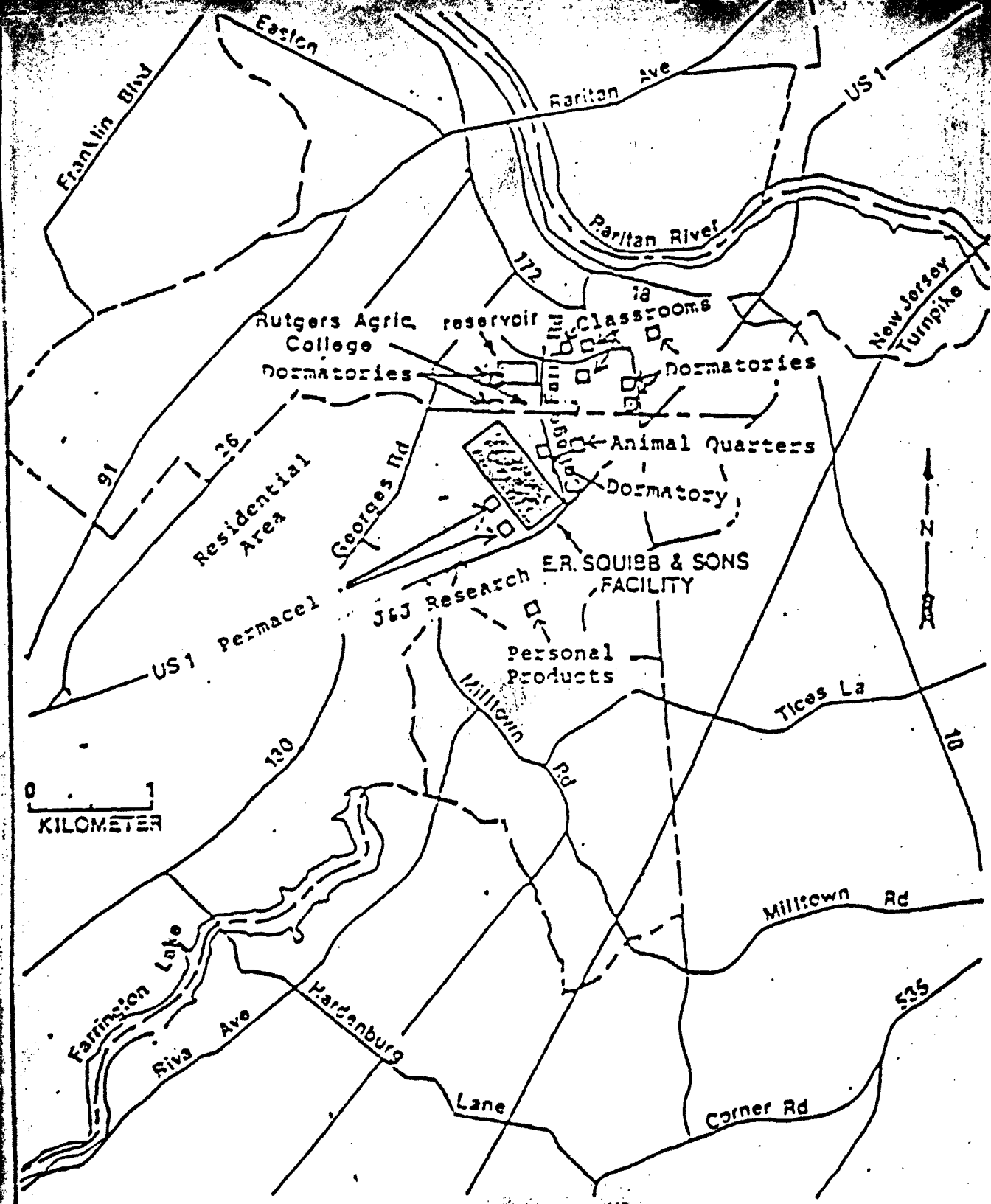
Population centers are identified by [ ] on the map labelled Figure 1a.

Figure 1



PORTION OF MIDDLESEX COUNTY, NEW JERSEY, SHOWING THE LOCATION OF THE E.R. SQUIBB & SONS FACILITY.

Figure 1-A



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

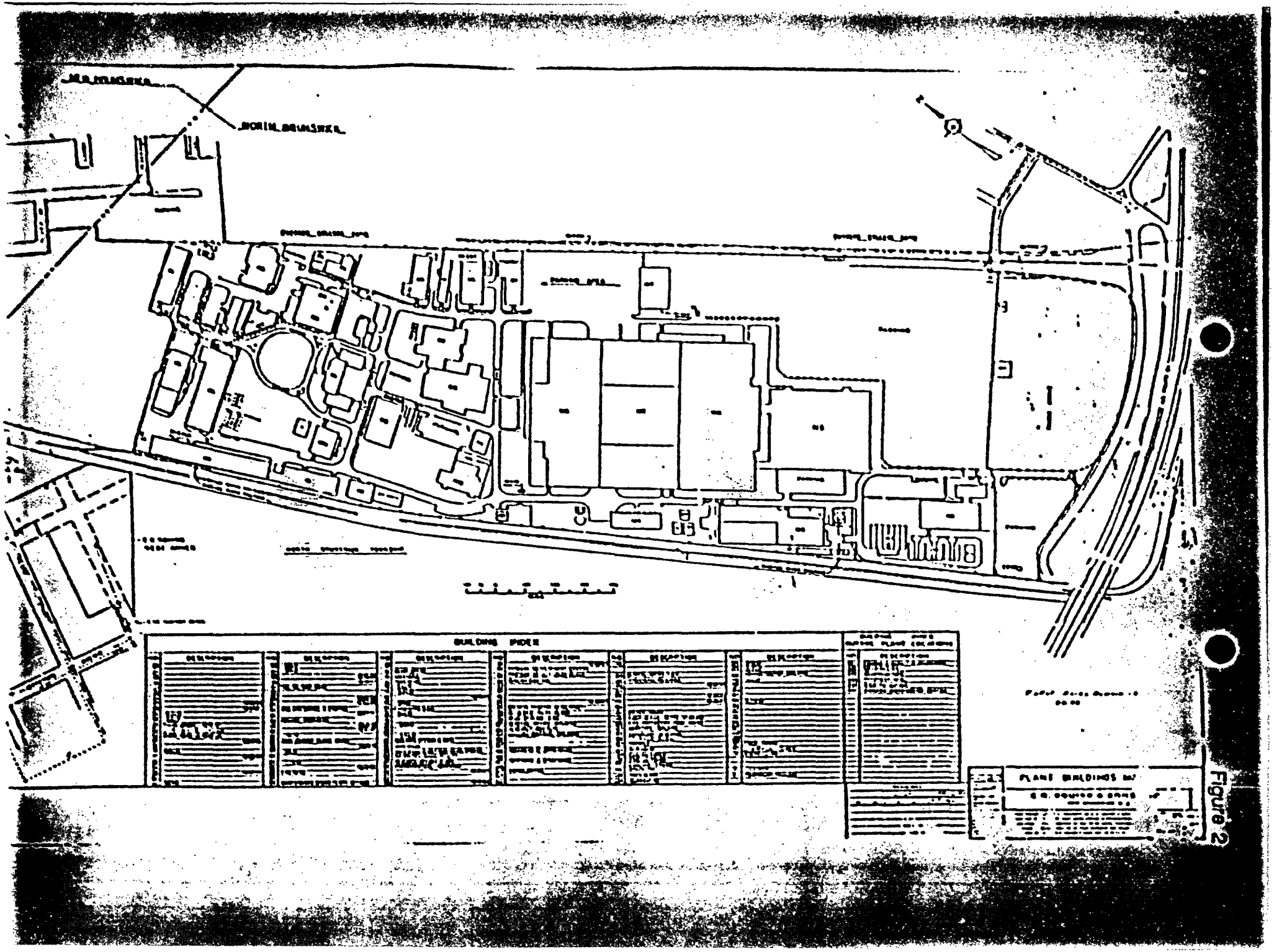
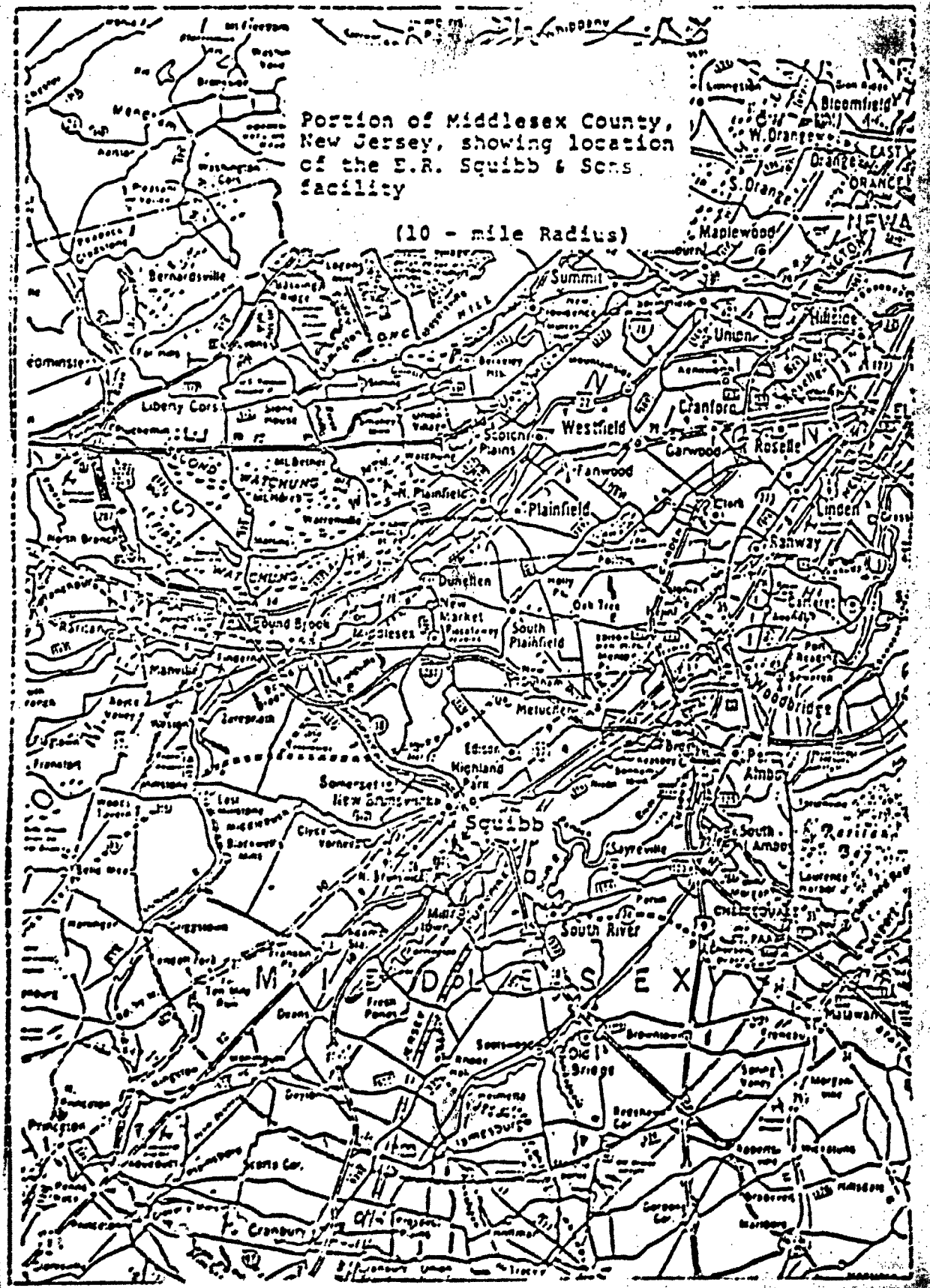


Figure 2

Figure 3


Portion of Middlesex County, New Jersey, showing location of the E.R. Squibb & Sons facility
(10 - mile Radius)
Squibb
MIDDLESEX

1.2 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 1a.

The location of offsite 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 157,000 individuals. This information is obtained from 1980 census data. Based on the 1980 County Planning Board & Census Bureau data, approximately 100,000 individuals are employed within a five mile radius and daily commuters passing the site total 80,000.

1.3 Description of Facility and Site

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 155 Curies. Specific isotopes and possession quantities normally possessed and processed are as follows:

Isotope	Maximum Inventory	Form
131I	65 Curies	Sodium Iodine
99Mo	155 Curies	Sodium Molybdate
82Sr	5 Curies	Strontium Chloride
85Sr	20 Curies	Strontium Chloride
201Tl	5 Curies	Thallous Chloride

1.3 Description of Facility and Site (Continued)

All processes within the site are protected by a looped and gridded fire protection water distributing system fed by independent pumped water sources. Two automatic 1,500-gallon pumps supplied by a 300,000-gallon above ground tank located on the south section of the site and 1,500 G.M.P. pump taking suction from 16" city water main, supplies the site.

The plant is provided with Class II interior one and one-half inch hose lines installed 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, which will serve as primary containment in the event of an explosion. The building and its charcoal filtration systems are considered secondary containments.

Shielding

Leaded glove boxes and hoods are used to manufacture and fill radio-pharmaceuticals 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 from 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 very unlikely that a fire or explosion would occur within these hot cells. Therefore, it is highly improbably that an accident would occur which would reduce the effectiveness of the shielding.

Process Systems

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 HEPA filter followed by a 1" high efficiency carbon filter to arrest any possible gaseous contaminant. The 99Mo- 99mTc 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.

Process Systems (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 exit 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 weekly 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 99Mo, etc. to the lowest practicable level.

All exhaust systems are discharged to the effluent exhaust stack. The system used for sampling exit air from the stack is comprised of six one-inch lines within the exit 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 exit 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 1.85 Cu. Ft. per minute and is changed daily.

The radioactivity collected in the sampler is constantly measured by the stack alarm detector which will sound an alarm in Health Physics operations area should the integrated activity representing the maximum permissible concentration for 24 hours for I-131 Iodine 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 assure isokinetic sampling.

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.")

Support Systems

Fire protection is provided at each branch connection to glove boxes and fume hoods, etc. by means of a spring-loaded fusible link fire damper. Carbon filters are monitored by means of ionization-type smoke 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. 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.

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.

Location of Communication and Assessment Centers

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

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.

Alternate Emergency Coordination Center

The Radiopharmaceutical Research & Development plant (Building 80/84) and the Site Safety Mobile Command Center have been designated as the alternate Emergency Coordination Centers. Both centers are equipped with emergency supplies, instruments and equipment to perform evaluations of radiological incidents that might occur within the license site. Telephones and portable walkie-talkies are available.

Any incident that requires temporary evacuation of the production plant and minor radiological incidents that occur within the site research facility will be coordinated and controlled from these locations. In addition, an emergency vehicle fully equipped with environmental monitoring supplies and communication equipment is available.

Communications Equipment

The on-site communication systems consist of telephones and walkie-talkies. Security, safety, and Health Physics personnel are equipped with walkie-talkie units which will be used to transmit vital information and instruction in the event of a radiological emergency. An intercom system is used throughout building 124 to immediately notify personnel of emergencies within the manufacturing area.

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 an alternate location will be used.

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.

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.

2.1 Description of Postulated Accidents

Condition I

The accident 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 175), 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 accident, 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 onsite and offsite personnel.

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.

2.2 Detection of Emergency Conditions

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.

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.

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.

3.0 Classification and Notification of Accidents

This section describes the classes of abnormal occurrences according to the severity and the potential impact of the radiological incident. 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 offsite 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 three classification systems are Unusual Event, Alert and Site Area Emergency. Examples of incidents for each class are as follows:

Unusual Event	Alert	Site Area Emergency
Evacuation of Radio-pharmaceutical plant for reasons other than false alarm. Projected releases are not expected to exceed a regulatory or license limit or cause offsite doses > 10% of EPA PAG levels.	Electrical Power failure for ~ 1 hour which results, or is projected to result in offsite doses > 10% but < 100% of EPA PAG levels.	Electrical Power failure for > 8 hours which does not or would not be projected to result in exposures exceeding 100% of the EPA PAG levels except near the site boundary.
Fire/explosion in a production area requiring only onsite fire brigade. Projected releases are not expected to exceed a regulatory or license limit or cause off site doses > 10% of EPA PAG levels.	Fire in production area re-quiring onsite or assistance from local authorities. Could result in offsite doses > 10% but < 100% of EPA PAG levels.	Explosion of propane tank at nearby facility or LPG line near site which does not or would not be pro-jected to result in exposures exceeding 100% of the EPA PAG levels except near the site boundary.
Flood near shipping area which results or is projected to result in a release greater than a regulatory or license limit and cause off site doses > 10% of EPA PAG levels.	Fire/major accident involving vehicle carrying 1 Ci of radioactive materials within the site. Could result in offsite doses > 10% but < 100% of EPA PAG levels.	Fire causing the burning of carbon filters which does not or would not be projected to result in exposures exceeding 100% of the EPA PAG levels except near the site boundary.
Thyroid detection of > 150 nCi from unknown source which results or is projected to result in a release > 10% of EPA PAG levels.	Two or more contaminated injured personnel requiring offsite hospital assistance could result in doses > 10% but < 100% of EPA PAG levels.	8 Ci of volatile Iodine spill in hallway. Exposures not expected to exceed 100% of the EPA PAG levels except near the site boundary.
Unusual Event	Alert	Site Area Emergency

Unusual Event	Alert	Site Area Emergency
Contaminated injured employee. Radioactive releases or exposures are not expected to exceed 10% of EPA PAG levels.	Dose rate at perimeter > 2 mR in any one hour period. Projected offsite doses > 10% but < 100% of EPA PAG levels.	Dose rate at perimeter > = 20 mR in any one hour period. Exposures are not projected to exceed 100% of EPA PAG levels near site boundary.
Stack concentration > two times MPC for 1 day average. Releases or exposures are not expected to exceed 10% of EPA PAG levels.	Stack releases > = 50 times MPC for a 1 day sampling. Offsite doses or releases are projected to exceed 10% but < than 100% of EPA PAG levels.	Stack concentration > = 5,000 times MPC for 1 day average. Exposures are not projected to exceed 100% of EPA PAG levels except near site boundary.

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

The Emergency Director (RSO) or his alternate has the authority and will be responsible for the following actions regarding incidents of a radiological nature:

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

The notification action form is to be utilized to aid the Emergency Director in the following: classification of accidents, activation of response personnel, initiation of protective actions and the performance of other essential duties necessary to control emergency situations.

3.3 Information to be Communicated

This section describes the type of information to be communicated when requesting offsite 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.

3.3 Information to be Communicated (Continued)

5. Plant status:

   a. Releases of radioactive or chemical material

   b. Injuries

   c. Recommendations for offsite 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.

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 onsite 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 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 Onsite Emergency Response Organization

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

All onsite emergency response personnel will be notified and provide assistance during production and non-production periods. The degree of assistance will depend solely on the nature of the incident (see organizational chart in 4.2.1, figure 4).

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

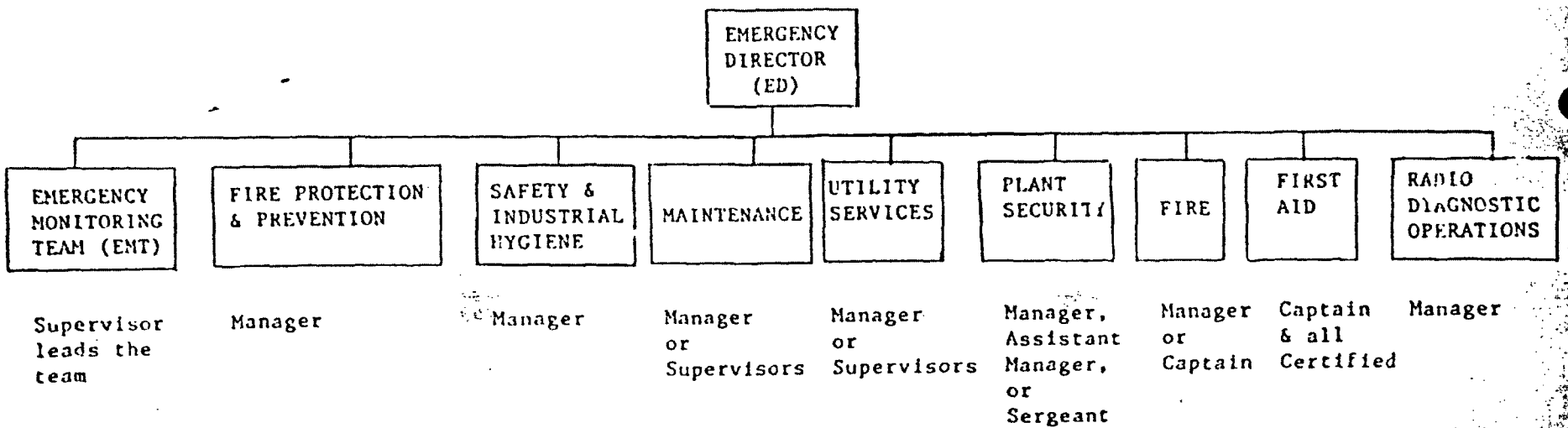
The responsibility and authority of onsite emergency plant staff are described as follows:

Emergency Director

The Emergency Director (ED) 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 ultimate authority to initiate, control and close out response operations for

FIGURE 4

PLANT EMERGENCY RESPONSE GROUP



Emergency Director (Continued)

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 emergency coordinator in cases of fire, injury or release requiring non-radiological emergency response groups. Upon this delegation the RSO or alternate assumes the role of radiological safety officer for the site response.

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 assess to hot 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.

Fire Protection & Prevention

The Fire Protection & Prevention Manager 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 onsite fire and first aid emergencies. In his absence, the captains of the plants' First Aid Squad and Fire Brigades are responsible for directing the actions of these groups. Only the Fire Protection and Prevention Manager, Plant Safety Director or their designee can authorize re-entry into the site after an emergency of a non-radiation hazard.

Environmental Compliance

The Environmental Compliance Manager is experienced in the area of emergency response and is knowledgeable of radiological emergency measures. This individual is a technical advisor to onsite and offsite emergency responding groups. He provides initial notification and maintains contact with local and state authorities regarding conditions at the license site. He also handles all environmental related issues.

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. One of four supervisory personnel oversee maintenance operations within the site on a 24-hour basis. 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 safety orientation and annual training.

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 two 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 through the plant paging system. The utility supervisor is responsible for overseeing the service of plant system operations, assisting in repair and damage control, and post assessment operations.

The RSO or Health Physics supervisors are responsible for notifying the manager or supervisors of this group should an incident involving emergency operations equipment and/or utilities occur within the Diagnostic Manufacturing Plant.

Plant Security

The role of the Plant Security Department in the event of a radiological emergency would include notification of onsite and offsite 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.

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.

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.

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 O.S.H.A. 1910 Subpart L. They receive annual training from various recognized training schools.

In the event of a fire, explosion or existence of other emergency incident that could result in the assistance of the fire brigade at the radiopharmaceutical plant, a call would be placed to the Building 111 Security Gate House. Upon receipt of the call by Security personnel, an evacuation signal is sounded for Building 124 and an interior fire alarm system is activated (continuous sounding of bells or sirens) to alert operations personnel to evacuate. The emergency radio paging alert would broadcast and the plant air whistle for zone 4, which designates the area of emergency within the site.

Plant fire brigade members respond to Building 81 (firehouse) and confirm location of alarm from guard by direct phone 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 Squibb's Emergency Management Plan. The Squibb Emergency Management Plan is written to include emergencies of a non-radiological nature.

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.

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

Plant First Aid Squad

The Squibb First Aid Squad is a member of the New Jersey State First Aid Council. It consists of approximately 18 full-time company employees who are all volunteer members. Each individual is a State Certified Emergency Medical Technician. The squad is responsible for responding to medical emergencies including life threatening activities within the site and for transporting injured personnel to outside medical facilities. This assistance is provided during production hours (7 a.m. - 4 p.m.). Personnel are alerted by the paging system that is initiated through the main security post, where all medical emergencies are reported by dedicated personnel. Coverage for offshift 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, such as a containment stretcher for the radiopharmaceutical manufacturing plant's use, are located throughout the plant site. Squad members receive training monthly during regular two-hour drill sessions.

4.3 Local Offsite Assistance to Facility

Medical Treatment Facility

Robert Wood Johnson Hospital has verbally agreed to provide treatment and care for employees involved in radiological accidents. The licensee is responsible for providing equipment, supplies, and radiation detection devices for use by hospital personnel. In addition, an individual from the licensee's monitoring team will accompany victims contaminated with radioactive substances.

The facility is located approximately two miles from the licensee site. A written agreement from the Robert Wood Johnson staff is still being pursued but has not been obtained.

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. Letters of agreement have been requested.

Fire Fighting

The North Brunswick Volunteer Fire Department agreed to assist the licensee's brigade in fire suppression assignments. This unit consists of three Engine Companies. Their locations vary from 1 to 3 miles from the licensee's site.

Fire Fighting (Continued)

The New Brunswick Fire Department will respond to emergencies at the license facility with whatever apparatus/equipment is requested by the North Brunswick Fire Department or Middlesex County Emergency Management. The responding station is located approximately 1.5 miles from the license site. Letters of agreement are on file.

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. Written agreements have been requested but not received. All groups providing emergency assistance will be invited to participate in annual 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 Emergency Director of this group 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 accidents of a radiological or chemical nature within the county of Middlesex. Their responsibilities include investigation, containment, over packing and response to basic hazardous material accidents. They interface with local, state and federal authorities during emergency situations.

4.4 Coordination with Participating Government Agencies (Continued)

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

The New Jersey State Police Office of Emergency Management 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 N.J. 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 offsite 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.

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)

5.4.2 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 ED.

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 Emergency Control Center.

5.4.3 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 Emergency Director.

Areas immediately outside the affected sections will serve as monitoring areas for onsite emergency personnel and volunteers.

The Plant Emergency Director 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 Plant Emergency Director must insure that:

- All re-entry and recovery teams have dosimeter and dose measuring instruments.

- Evaluation is made for the use of respiratory protection devices by all personnel within areas where air concentrations exceed MPC.

- In the recovery phase, all actions are carefully planned and reviewed.

- Comprehensive radiation surveys of site facilities have been conducted. All radiological problem areas defined.

- Radiation exposures of personnel who participate in recovery operations have been reviewed and additional personnel are used, if necessary.

Figure 5

Problem	Assessment Action	Corrective Action
1. Loss of electrical power to fans (also diesel generator backup does not work).	- Evacuate the building, communicate with maintenance, assay personnel for contamination. - If not corrected within one half hour, assay room concentrations - UNUSUAL EVENT. - 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 concentration surveys throughout the building.	- 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	- Evacuate building - call security to start RCP. - Survey personnel for contamination in 124 parking lot. - If not R/M - UNUSUAL EVENT. - If R/M involved in fire (e.g. truck with 1 Ci of I-131, glove box or fume hood filters) - ALERT - If fire needs outside assistance - ALERT.	- Assure personnel accountability. - Move personnel to alternative site as directed by E. D. (wind direction of a possible release) and fire chief (fire and explosion considerations). - Issue dosimetry to fire personnel and accompany them to scene with ion chamber. exposure limits are 5 rem to save property and 25 rem to save a life.

Figure 5a

Problem	Assessment Action	Corrective Action
2. Fire (Continued)	- If fire involves multi curies of I-131 and is out of the "cave" air system - SITE. - Explosion of propane tanker or LPG line near site - SITE.	
3. R/M spill > 1 mCi.	- Evacuate immediate area E.D. to be notified - UNUSUAL EVENT. If volatile by means of mix with acid of fire - ALERT.	- Assay and decontaminate personnel and equipment/shield material as appropriate.
4. R/M spill > 1 mCi with contaminated personnel	- Same as above and notify first aid through security. - Two or more contaminated persons needing offsite hospital assistance - ALERT.	- Same as above. - H.P. staff member or alternate to accompany contaminated employees to hospital to monitor for contamination with G.M. tube and ion chamber if appropriate.
5. Flood in or near controlled area.	- Assess closeness to R/M. - Notify maintenance for corrective measures.	- Maintenance with sump pump. - Move R/M away from potentially flooded area.

Figure 5a

Problem	Assessment Action	Corrective Action
6. Elevated air effluent emissions	- > 2 times MPC for 24 hours - UNUSUAL EVENT. - > 50 times MPC for 24 hours or > 2 mR in any hour on fenceline - ALERT. - > 5,000 times MPC for 24 hours or > 20 mR in any hour on fenceline - SITE.	- 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. - Same as above.

5.5 Exposure Control In Radiological Contingencies

5.5.1.1 Radiation Protection Program

The onsite 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 Plant 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 Plant Emergency Director or his alternate.

The Plant 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 520/1-75/001.

5.5.1.2 Exposure Guidelines

The exposure guidelines for onsite emergency teams, fire fighters, first aiders, medical doctors, nurses and rescue squad teams shall be limited to 5 rem whole body exposure for each emergency.

Exposure guidelines for thyroid dose due to inhalation from a passing plume is 5 rem for the general population and 100 rem for emergency workers.

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.

5.5.1.3 Monitoring

All emergency personnel and volunteers involved in any radiation emergency shall be required to submit to urinalysis testing and thyroid uptake measurements as directed by the Emergency Director or his alternate. These tests will be performed as specified by the Emergency Director 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 10CFR 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.

5.5.2 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.

6.2 Communication Equipment

6.2.1 Onsite Communications

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

6.2.2 Offsite Communications

The plant fire brigade performs daily checks with outside groups by means of short wave radio. This system of communication will be used as an alternate to the telephone for notification of emergencies and requests for assistance.

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 Plant Control Center. The direct line phone between the Building 111 Gate House, Control Center and the North Brunswick Police Headquarters will also be used.

6.4 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.

7.0 Maintenance of Emergency Preparedness Capability

7.1 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 onsite response group (Fire, First Aid, Security and Health Physics) shall be responsible for preparing and distributing emergency implementing procedures relating to their specific function. Original procedures and any changes to these procedures will be prepared by the manager of the response group and forwarded to the RSO for review and approval by the Plant Emergency Response Group (RSO, Site Safety, Fire, Maintenance, Security, etc.) Once approved, each person responsible for an emergency response function will receive a current copy and distribute to each member of his/her response group.

- The Radiation Safety Officer shall schedule annual meetings with all emergency response personnel to review function and provide radiation safety instructions.

7.2 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 extensive 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.
- Offsite organization communication drills. Table-top exercises.
- Full scale emergency exercise, including offsite response personnel, ~~twice yearly.~~

7.2 Training (Continued)

Emergency Monitoring Team will receive training on a quarterly basis for two hours. 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.
- Personal 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.
- Onsite emergency exercise.
- Full scale emergency exercise, including offsite response personnel, annually.
- Respirator training.

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

7.3.1 Annual Exercises

The Plant Emergency Response Group will plan and coordinate annual radiological emergency exercises. This group will be responsible for inviting offsite organizations to participate in annual exercises, and for the testing of procedures and equipment for notification and communication with local state and federal agencies. Annual exercise scenarios will be developed by the Plant Emergency Response Group and not be revealed to participants.

The regional office of the NRC shall be notified approximately one week prior to holding annual exercises. Notification to the NRC shall be given by the Radiation Safety Officer.

7.4 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 annual exercise critique. These individuals will receive additional training from various disciplines in the preparation and critiquing of exercises. They will act as nonparticipation observers who will evaluate the appropriateness of the emergency plan, its procedures, facilities, equipment, and personnel training.

7.4 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.

7.5 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, after any revisions, and semiannually 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 offsite letters of agreement annually and assure they are renewed at least every four years. They are also responsible for the selection of an individual who is well versed in the area of Health Physics and Industrial Hygiene to audit the corporation's emergency preparedness program.

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.

7.6 Maintenance and Inventory of Emergency Equipment, Instrumentation and Supplies

A physical inventory 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.

7.7 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. The Emergency Director will audit these documents semiannually.

8.0 Records of Reports

8.1 Records of 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. Included in the Radiological Contingency Plan Procedures are forms which are completed during the course of emergency response.

The recording and reporting of accidents and incidents of abnormal operation are logged on an Incident Investigation Report. This form documents the cause of the accident, personnel and/or equipment involved, the extent of injury and/or damage (onsite and offsite) 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 onsite and offsite assistance, notification and time of upgrade, downgrade and close out. All records shall be maintained until the license is terminated.

8.2 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 offsite support groups.
- Records of maintenance inventory of equipment, instruments and supplies.
- Drills and exercise.
- Offsite agreements.
- Radiation Safety Committee updates and distribution.
- Records of written reports to federal, state and local agencies.

9.0 Recovery

9.1 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.

9.1.2 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 allowable concentration 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.

9.1.3 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.

9.1.4 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 offsite authorities followed by written summary as required.

One Squibb Drive
PO Box 191
New Brunswick, NJ 08903-0191
(201) 519-2000

E.R. Squibb & Sons
United States

March 15, 1990

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

License #29-00139-02
Docket #030-05222
Control #110363

Dear Frank:

This is to confirm our phone conversation of today's date regarding the license renewal for E.R. Squibb and Sons. Your letter of February 23, 1990 requested response to the enclosed nineteen questions. Some of the items need additional time to respond properly. You have, therefore, agreed to accept our response by approximately the end of April 1990.

Since our Radiological Contingency Plan update is near completion, it will be sent to you by the end of March 1990, as you agreed.

Thank you again for your consideration.

Edward J. Truskowski
Radiation Safety Officer

cc: Dr. P. Roets (Squibb)

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110363

FEB 23 1990

License No. 29-00139-02
Docket No. 030-05222
Control No. 110363

E. R. Squibb and Sons, Inc.
ATTN: Edward J. Truskowski, RSO
Squibb Institute for Medical Research
One Squibb Drive, P.O. Box 191
New Brunswick, New Jersey 08903-0191

Gentlemen:

This is in reference to your application dated February 28, 1989 to renew License No. 29-00139-02. In order to continue our review, we need the following additional information:

1. Currently Condition 24, Amendment No. 78, License No. 29-00139-02, references document A-FF from June 29, 1981 thru June 16, 1989. Please note that we have limited our review of your renewal request to your current application dated February 28, 1989 and letter dated June 16, 1989. If there are other documents that you wish us to consider in reviewing your renewal request please identify them.

2. We note that you intended to submit a revision to your Radiological contingency plan using the Format of Regulatory Guide 0762, during 1989. Please provide this revised contingency plan as soon as possible so that we may incorporate it into your renewed license.

3. 10 CFR 20.1 states that NRC licensees should make every reasonable effort to maintain personnel radiation doses As Low As Reasonably Achievable (ALARA). Such a program should include a review of doses periodically and correction of dose problems identified by this review. ALARA programs establish investigational levels for dose based on the experience of doses received by specific work groups at your institution. Please describe your program for maintaining personnel doses ALARA and indicate the doses which will result in an investigation to determine the cause and corrective actions, if needed.

4. Please provide a description of the routine survey program, including the areas to be surveyed, the types and levels of radiation and contamination considered to be acceptable, and provisions for maintaining records of surveys. The individual user should supplement the surveys performed by the radiation staff. Regularly used laboratories should be surveyed for contamination at the end of each workday (except when quantities less than those in Appendix C to 10 CFR Part 20 are handled by an employee at any one time), and the user should maintain records of such surveys in units required by 10 CFR Part 20, even if only a single measurement is necessary.

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5. Please provide the flow rate and the collection efficiency for the room air samplers in your manufacturing facility.

6. Please provide the sensitivity of your portal contamination monitors and the basis for defining this sensitivity. What is the variation in the radiation background in the locations of your portal monitors and how dose this variation in background affect the sensitivity of the portal monitors?

7. Our recent inspection of your New Brunswick facility indicated that the area around your filter banks may become a high radiation area. Please describe in detail your plans to ensure that the controls for high radiation areas required by 10 CFR 20.203 are provided for the filter bank areas.

8. 10 CFR 30.32(g) requires that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either (1) identify the source or device by manufacturer and model number as registered with the NRC under 10 CFR 32.210 or with an Agreement State; or (2) contain the information identified in 10 CFR 32.210(c). Please provide this information for the sealed sources requested in your application.

9. Please provide procedures for examining incoming packages for leakage, contamination, or damage and for safely opening packages in accordance with 20.205 of 10 CFR Part 20. The monitoring should be performed as soon as practicable after receipt of the package of radioactive material. The procedures may vary depending upon the quantity of radioactive material received, but should, at a minimum, include instructions for surveying packages, wearing gloves while opening packages, and checking packing material for contamination. Even though 20.205 of 10 CFR Part 20 exempts certain packages from immediate monitoring, all packages should be monitored before they are opened.

10. 10 CFR 20.103(b)(2) requires that licensees make evaluations and take actions to assure against recurrence whenever an intake of radioactive materials exceeds the intake which would result from inhalation of such material for 40 hours at the concentration specified in 10 CFR 20, Appendix B, Table 1, Column 1. This intake of radioactive materials is frequently referred to as "40 MPC - hours". Please describe how your bioassay procedure will be able to detect an intake of 40 MPC-hours and confirm that, when such an intake is identified, you will make the required evaluation and take the actions necessary to assure against recurrence.

11. Please provide the following information regarding the leak-testing of your sealed sources:

    a. A description of the procedure for wipe-testing the source.

    b. The instrumentation used to measure activity on the wipe and the lower limit of detectability for this instrumentation.

If you elect to have another person to perform the leak-test, please submit the name of the person, the applicable NRC or Agreement State license number, and the model number of the commercial leak test kit.

12. Please describe your criteria for requiring thyroid monitoring for workers who use radioactive iodine in research and development.

13. Please describe the training provided to any contractors who may enter your restricted area.

14. In your application, you didn't describe a training program for ancillary personnel (maintenance, security, etc.) and personnel involved in radionuclide work. Please describe a program that it will:

    (a) be of sufficient scope to ensure that all personnel using radioactive materials receive proper instruction in accordance with 19.12 of 10 CFR Part 19 (enclosed);

    (b) provide for personnel to be properly instructed before assuming duties with, or in the vicinity of, radioactive materials with retraining as necessary.

    The training given to each group should be commensurate with the duties and responsibilities of the group and need not be the same for each group.

15. Please confirm that personnel will be instructed before beginning duties with, or in the vicinity of, radioactive materials and will be reinstructed whenever there is a significant change in duties, regulations, or the terms of the license.

16. In your application, you didn't specify the calibration of the instruments used for thyroid counts. Please confirm that you will be using a neck phantom when calibrating the instrumentation used for determining activity in the thyroid.

17. Please provide a copy of your laboratory instructions. Typical instructions should include:

    a) Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

    b) Wear disposable globes at all times while handling radioactive materials.

    c) Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area.

    d) Do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used.

e) Do not store food, drink, or personnel effects in areas where radioactive material is stored or used.

f) Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored.

g) Dispose of radioactive waste only in designated, labeled and properly shielded receptacles.

h) Never pipette by mouth.

i) Wipe-test radioactive material storage, preparation and use areas weekly from contamination. If necessary, decontaminate or secure the area for decay.

j) Refrigerators shall not be used jointly for foods and radioactive materials.

k) Confine radioactive solutions in shielded containers that are clearly labeled.

l) Secure all radioactive material when not under the constant surveillance and immediate control of the authorized users.

18. Please describe the criteria which will by your Radiation Safety Committee to approve proposed users and uses of licensed materials.

19. Your applications request that the Radiation Safety Officer be authorized to approved users of licensed material at facilities other than your New Brunswick, New Jersey facility. Please confirm that the approvals would be reported to the Radiation Safety Committee at the next Committee meeting.

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. 110363.

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:
Francis M. Costello
Francis M. Costello
Nuclear Materials Safety Section B
Division of Radiation Safety
and Safeguards

FMC
RI:DRSS
Costello/bj/pmb/tlm

2/23/90

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02/15/90

030-05222

9-0

E.R. Squibb & Sons, Inc.

P.O. Box 191
New Brunswick, New Jersey 08903
201-545-1300

Cable ERSQUIBB PRINCETON

December 13, 1989

Ms. Betsy Ullrich
U.S. Nuclear Regulatory Commission
Nuclear Materials Safety Section B
475 Allendale Road
King of Prussia, PA 19406

Re: Renewal Application: Control #110363
License No. 29-00139-02 for E. R. Squibb & Sons, Inc.

Dear Ms. Ullrich:

This is to confirm today's phone conversation regarding submission of a revised Radiological Contingency Plan for E.R. Squibb & Sons, Inc. As stated in section 10.6 of our February 27, 1989 license renewal application, "A revision in the Radiological Contingency Plan from E.R. Squibb & Sons in the format of Reg. Guide 0762 is expected to be completed and submitted during 1989."

I informed you and Mr. John Jensen of your office that we are behind anticipated completion date and expect the plan to be submitted by the end of the first quarter, 1990.

In addition, Mr. Jensen stated that he expects to send a confirming letter next week regarding Squibb's October 4, 1989 request to change the frequency of calibration for radiation detection instrumentation from every 3 months to every 6 months.

Thank you for your assistance,

Edward Truskowski
Radiation Safety Officer

cc: Mr. John Jensen, NRC
Dr. P. Roets, E.R. Squibb & Sons, Inc.

110363

ET/dmj
ullrich.d13

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DEC 16 1989

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

MAR 21 1989

E.R. Squibb & Sons
ATTN: Dr. R. Abdou
Vice President
One Squibb Drive
P.O. Box 191
New Brunswick, New Jersey 08903-0191

DOCKET NO. 030-05222
LICENSE NO. 29-00139-02
CONTROL NO. 110363

SUBJECT: LICENSE RENEWAL APPLICATION

Gentlemen:

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

Any correspondence regarding the renewal application should reference the control number specified and your license number.

Sincerely,

Original Signed By:
Doris J. Foster

Doris J. Foster, Chief
Licensing Assistant Section
Division of Radiation Safety
and Safeguards

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Route 1 at College Farm Road
PO Box 191
New Brunswick, NJ 08903-0191
(201) 818-2401

Louis T. DiFazio, Ph.D.
President

030-05222

Squibb
Technical Operations

February 27, 1989

Dr. L. Friedman
U.S. Nuclear Regulatory Commission
Nuclear Materials Safety Section B
475 Allendale Road
King of Prussia, PA 19406

Dr. Friedman:

This letter and accompanying documentation and fee is to request a renewal of NRC License No. 29-00139-02 for E. R. Squibb and Sons, that is due to expire on March 31, 1989.

Please respond with a timely renewal acknowledgement letter for our records.

for Dr. L.T. DiFazio
President, Squibb Technical Operations

H. M. Abdou

Dr. H. Abdou
Vice-President
Worldwide Pharmaceutical Operations

HA/ldm

Enclosure

License Fee Information on application

119363

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MAR 01 1989

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

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB
3150-0120
Expires 6-30-90

030-05222

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

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH

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

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

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

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

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

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

IF YOU ARE LOCATED IN

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

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

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

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

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

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

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

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

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 29-00139-02

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

E.R. Squibb & Sons
One Squibb Drive
P.O. Box 191
New Brunswick, NJ 08903-0191

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

See Addendum 1

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Edward J. Truskowski, Radiation Safety Officer

TELEPHONE NUMBER: 201-519-3158

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

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time: See Addendum 2

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
See Addendum 3

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE
See Addendum 4

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

9. FACILITIES AND EQUIPMENT
See Addendum 5

10. RADIATION SAFETY PROGRAM.
See Addendum 6

11. WASTE MANAGEMENT
See Addendum 8

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)
FEE CATEGORY: By-Product Material
AMOUNT ENCLOSED: $ 700.00

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

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

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

SIGNATURE-CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
[signature]	Dr. H. Abdou For Dr. L.T. DiFazio	V.P. Worldwide Pharm. Op. For Pres., Squibb Tech. Op.	2/23/89

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
Ltr	Mar. 9-1	3A	1110363	[signature]
AMOUNT RECEIVED	CHECK NUMBER			DATE
$700	320490			3/6/89

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MAR 01 1989

ADDENDUM 1
Page 1

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 and Provinceline Road
Lawrenceville, NJ
P.O. Box 4000
Princeton, NJ 08543-4000

C. E.R. Squibb & Sons
Clinical Laboratory
Princeton House
905 Herrontown Road
Princeton, NJ 08540

D. E.R. Squibb & Sons
675 College Road East
Princeton Forrestal Center
Plainsboro, NJ 08543

ADDENDUM 2
Page 1

Item #5: Radioactive Material

Material	Chemical/physical form	Possession limit
Location A		
- Any byproduct material with atomic numbers 1-83 inclusive except strontium 90	any	5 Curies of each radionuclide, with a total possession limit of 1000 curies
- iodine 131	any	150 Curies
- molybdenum 99/ Technetium 99m	any	1000 Curies
- nickel 63	plated sources in detector cells	not to exceed 15 millicuries per source
Location B		
- Any byproduct material with atomic numbers 1-83 inclusive except except strontium 90	any	200 millicuries of each radionuclide with a total possession limit of 5 Curies
- hydrogen 3	any	2 Curies
- carbon 14	any	4 Curies
- sulfur 35	any	2 Curies
- nickel 63	plated sources in detector cells	not to exceed 15 millicuries per source
Location C		
- any byproduct material with atomic numbers of 1-83 inclusive except strontium 90	any	10 millicuries of each radionuclide, with a total possession limit of 1 Curie
- nickel 63	plated sources in detector cells	not to exceed 15 millicuries per source

Location D

- phosphorous 32	any	100 millicuries
- sulfur 35	any	100 millicuries
- carbon 14	any	40 millicuries
- iodine 125	any	20 millicuries
- hydrogen 3	any	40 millicuries
- nickel 63	plated sources in detector cells	not to exceed 15 millicuries per source

NRC License
E.R. Squibb & Sons 2/27/89

ADDENDUM 3
Page 1

Item #6: Purposes for which licensed material will be used.

In Location A:

1. Research and development as defined in Section 30.4(q) of 10CFR 30 (March 31, 1987)

2. Processing or manufacture for distribution to authorized recipients.

In Locations B, C and D.

1. Research and development as defined in Section 30.4(q) of 10CFR30 (March 31, 1987).

ADDENDUM 4
Page 1

Item #7: Individuals responsible for radiation safety program and their training and experience.

Radiation Safety Officer

The radiation safety officer at E.R. Squibb & Sons is a full-time employee who is supported by a staff of technical supervisors and union technicians. The RSO also serves as secretary to the Radiation Safety Committee. Mr. Edward Truskowski, the RSO, has a masters in radiation science and has worked with radioactive materials since 1976. A listing of his training and experience is found on his resume; see attached.

Radiation Safety Committee

The radiation safety committee is composed of the following members. Their resumes are attached.

Dr. E. Nickoloff - Chairman
Director, Administrative Resources for Science and Technology
R&D representative

Mr. E. Truskowski - Secretary
Manager of Health Physics
Radiation Safety Officer

Dr. E. Eaton
Associate Corporate Medical Director
Medical Respresentative

Mr. H. Harrison
Vice-President, Regulatory Counsel (Corporate)
Legal Representative

Dr. P. Roets
Director of WW Occupational/Environmental Safety
Safety Representative

Mr. G. Thompson
Director of Radiopharmaceutical Operations and Productivity
Diagnostic Division Representative

Edward J. Truskowski

(b)(6)

EXPERIENCE:

E.R. Squibb & Sons New Brunswick, N.J. Nov 1988 - present	Radiation Safety Officer: Supervise the department of Health Physics, which monitors the proper handling of all radioactive materials and ionizing radiation producing machines (e.g. X-ray machines) at E.R. Squibb & Sons. The department's charge is to keep all appropriate environmental releases and personnel exposures ALARA (as low as reasonably achievable) and to satisfy federal and state regulations and public concerns. This is accomplished through training, recordkeeping, auditing and especially direct personal communication.
E.R. Squibb & Sons New Brunswick, N.J. June 1977 - Nov 1988	Health Physics Supervisor: Evaluate and audit radiopharmaceutical manufacturing and research and development procedures for compliance with radiation safety practices in accordance with federal and state regulations. Supervise union Health Physics technicians. Prepare and update personal computer programs for: storage and analysis of individual's radiation exposure history; daily health physics surveys and assays; and updating radiation safety, waste management, ALARA, and radiological contingency plan procedures manuals. Set up and maintained GeLi detection and analysis system for product and environmental samples. Develop and implement training programs on radiation safety procedures and emergency drills.
Rutgers University New Brunswick, N.J. Nov 1981 - Dec 1984	Radiation Science Instructor: teach operational Health Physics course for the Coordinating Council on Radiation Science. This course is offered at power reactors to upgrade employees to Health Physcis technicians.
E.R. Squibb & Sons New Brunswick, N.J. Dec 1976 - June 1977	Analytical Chemist: Medotope Division - Analyze and prepare standards from NBS. Perform radiochemical purity and bio-efficacy tests on radiochemical products.

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Rutgers University New Brunswick, N.J. Aug 1976 - Dec 1976	Health Physics Assistant: Assist university's radiation safety officer in: surveying x-ray machines in local hospitals material inventory. Supervision of health physics safety procedures for radioactive iodine labeling of protein. Electron beam dose calculations from an 18Mev accelerator using Fricke dosimeter and TLD's. Supervision of undergraduate applied health physics laboratory.
Brookhaven Nat. Lab Upton, N.Y. June 1976 - Aug 1976	Health Physics Graduate Student Fellow: Concentrated my work as an operational Health Physicist at the high flux beam reactor. Also participated in projects in almost every department with health physics concerns on the site.
ATI/Chem-Spray 5 Taft Rd. Totowa, N.J. 1973 - June 1976	Supervisor of Cost and Inventory: Supervise proper flow of paperwork for all billings and inventory analysis. Compute all job cost estimates for new business quotes. Set up and maintain cost system for over 500 aerosol and cosmetic products.
1971-1973	Inventory Control Supervisor: Set up perpetual inventory system dealing with thousands of components having a large turnover. Improved customer relations concerning the handling of their inventories.
Manhattan College Physics Dept. 1970 - 1971	Laboratory Assistant: Assisted in construction, set up and maintenance of Physics Laboratory.

EDUCATION:

Rutgers University New Brunswick, N.J. (b)(6)	Master of Science: Radiation Science: Radiation: Physics, Chemistry, Biology, Instrumentation and Dosimetry; Micrometeorology; Special Topics in Health Physics; Environmental Impact Statement and Analysis; Air Sampling and Analysis; Nuclear Energy Technology.
Manhattan College Bronx, N.Y. (b)(6)	Bachelor of Science Degree: Physics including Modern Physics, Atomic and Nuclear, Waves and Vibrations, Mechanics, Electromagnetic Radiation, Quantum Mechanics, and Solid State; Mathematics: including Honors Calculus, Linear Algebra, and Complex Variables; Chemistry: Organic and Organic Laboratory.

EILEEN L. NICKOLOFF, Ph.D.
(b)(6)

PROFESSIONAL EXPERIENCE:

1/80 - Present **Squibb Institute for Medical Research, Princeton, NJ**

5/87 - Present **Director, Administrative Resources for Science & Technology.** Act as liaison with Facilities and Engineering Departments for all new Science & Technology buildings, in Lawrenceville, New Brunswick and offsite. Act as coordinator for interim space needs for all S&T areas. Overall directorship of departments of Science Information and Scientific Information Systems. Chairman, Radiation Safety Committee since 1/89; member of Committee since 1987.

9/85 - 5/87 **Director, Science Information Resources.** Responsible for acting as liaison for new R&D expansion facilities. Overall directorship of departments of Science Information and Scientific Information Systems.

9/84 - 9/85 **Administrative Director, Diagnostics R&D.** Responsible for all budgetary, personnel and scientific administrative functions for 65 scientists. Introduced computer networking within the division; handled all radiation safety issues.

1/80 - 9/85 **Director, Clinical Assay R&D.** Responsible for introducing 13 immunoassay kits to market. Developed research assays for in-house use, including drugs, prostaglandins, bradykinin and complement factors, using I125, H3 and C14.

9/74 - 1/80 **Director, In-Vitro Laboratory & Radiopharmacy**
The Johns Hopkins Hospital, Baltimore, MD
Directed Nuclear Medicine in-vitro laboratory and increased the number of assays performed from 200 to 2500 per month in four years. Supervised preparation and quality control testing for all clinical and research imaging agents, using Tc99m, I131, Tl 201, and other isotopes.

8/71 - 9/74 **Clinical Chemist**
Harrisburg Hospital, Harrisburg, PA
Directed all clinical chemistry, dialysis, toxicology and urinalysis functions for 500 + bed hospital.

6/70 - 8/71 **Supervisor, Core Laboratory**
Thorndike Laboratory, Harvard Medical Unit
Boston City Hospital, Boston, MA
Directed Core Laboratory, setting up research assays. Validated assays for use in measuring blood changes during transcendental meditation.

PUBLICATIONS: Twenty nine abstracts
Twelve book chapters
Thirteen papers

BOARD CERTIFICATION:
American Board of Clinical Chemistry, 1976

EDUCATION: University of New Hampshire, Durham, NH
Ph.D., Organic Chemistry, (b)(6)

St. Josephs College, Brooklyn, NY
B.A., Chemistry, (b)(6)

RESUME

EARL H. EXTON, M. D.
E. R. Squibb & Sons, Inc.
New Brunswick, N. J. 08903

Date of Birth: (b)(6)

SEPTEMBER (b)(6)	Graduated from New York Medical College in New York City, New York. M. D. Degree.
OCTOBER 1944 TO JUNE 1945	Internship U. S. Naval Hospital, Sampson Naval Training Center, Geneva, New York.
JULY 1945	U. S. Marine Corp. Field Medical Services School, Camp Lejeune, North Carolina.
AUGUST 1945 to MAY 1946	Medical Officer, First Medical Battalion, First Marine Division, Fleet Marine Forces in the Pacific. Served ten months in the Battalion Hospital, Tientsin, China.
MAY 24, 1946	Rleleased from active duty.
SUMMER 1946	Performed locum tenens for J. F. Lintz, M. D. West 59th Street, New York City, New York, for three months.
OCTOBER, NOVEMBER, DECEMBER 1946	Postgraduate courses in Pediatrics, Orthopedics, and Gynecology in New York City, New York.
JANUARY, FEBRUARY MARCH 1947	Postgraduate course in Obstetrics at Margaret Hague Miternity Hospital, Jersey City, New Jersey.
APRIL AND MAY 1947	Unemployed while searching for town in which to practice.
JUNE 1947 to DECEMBER 1952	General practice, Cobleskill, New York. Served as President of County Medical Society, served as school physician, Cobleskill School.
JANUARY 1953 to JUNE 1953	Attended Naval School of Aviation Medicine, Pensacola, Florida. Certified as flight surgeon May 1953 U. S. Navy.
JULY 1953 to JULY 1954	Medical Officer, N. S. Midway Islands.
AUGUST 1954 to JUNE 1955	Served as a Senior Medical Officer, Naval Auxilliary Air Station, Brown Field, Chula Vista, California.
JUNE 1955	Resigned commission as Lt. Commander, MC, U. S. Naval Reserve.
JULY 1955 to AUGUST 1972	Resumed private practice of medicine, Cobleskill, New York. On Medical staff of Community Hospital from date of its opening in 1956. At various times served on different hospital staff committees. Served as chief of Obstetrical Department, served one term as President of Medical Staff. Had part-time employment as college physician at Cobleskill Agricultural and Technical College. Served as a number of the County Board of Health and an adviser to the American Cancer Society and on the Board of Directors of the local Council of the Boy Scouts, and was a member of the Board of Directors of Blue Shield of Northeastern New York 1959 to 1972 in Albany, New York.

RESUME

SEPTEMBER 1972 to JUNE 1976	Assumed position as Medical Director of Blue Shield of Northeastern New York, Albany, New York until 1976.
JULY 1976 to JULY 1983	Assumed position of Medical Care Director, Life Savers, Inc., Canajoharie, New York, providing occupational medical care and care for personal illnesses for employees of Life Savers, Inc., Beech-Nut Nutrition Corp. and the Milupa Corporation of Fort Plain. Also provided medical care for retirees of the three companies.

While practicing in Schoharie County, I was a member of the Schoharie County Medical Society, New York Medical Society and American Medical Association.

While practicing in Canajoharie, New York, I was a member of the Montgomery County Medical Society and New York State Medical Society and American Medical Association.

JULY 1, 1983	Position of full-time physician discontinued by Life Savers, Inc., Canajoharie, New York.
JULY 5, 1983	Employed as full time physician by E. R. Squibb and Sons, New Brunswick, New Jersey.

HOWARD R. HARRISON - BIOGRAPHY

SQUIBB CORPORATION
Worldwide Headquarters
P. O. Box 4000, Princeton, New Jersey 08540

1988 - Present: Vice President, Regulatory Counsel (Corporate)

1986 - 1988: Senior Vice President and Counsel, Science and Technology

E. R. SQUIBB & SONS, INC.

1981 - 1985: Vice President, Regulatory Counsel

1978 - 1980: Regulatory Counsel

1975 - 1977: Regulatory Counsel and Director, Quality Assurance and Product Release

1972 - 1974: Regulatory Counsel

1970 - 1971: Associate Regulatory Counsel

1969 - 1970: Assistant Regulatory Counsel

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
FOOD AND DRUG ADMINISTRATION (now HHS)
Washington, D.C.

1966 - 1969: Trial Attorney, General Counsel's Office

FLETCHER, HEALD, ROWELL, KENEHAN & HILDRETH
Washington, D. C.

1964 - 1966: Associate

EDUCATION:

JD, Columbia University School of Law, (b)(6)
AB, Princeton University, (b)(6)

BAR ADMISSIONS:

District of Columbia, 1965
Connecticut, 1964

PERSONAL DATA:

Philip Petrus Roets

(b)(6)

Date of Birth: (b)(6)
Height:
Marital Status:
Dependents:

EDUCATION:

University of Pittsburgh, Pennsylvania (b)(6)
D.Sc. (Hyg) in Industrial Hygiene -
M.Sc. (Hyg) in Industrial Hygiene -

University of Pretoria, Republic of South Africa (b)(6)
M.Sc. Majoring in Physiology, Anatomy and Biochemistry -
B.Sc. Majoring in Physiology, Anatomy and Biochemistry -

Membership to Scientific Associations and Governmental Committee:

National:
South African Institute of Public Health
•South African Clean Air Society
•South African Bureau of Standards, Advisory Committee of Acoustics
•Ad Hoc Committee on Occupational Health Education
•Ad Hoc Committee on Environmental Emissions Control in the South African Steel Industry
•South African Department of Mines Risk Committee on Occupational Diseases in Mines and Works
#Member of a four-man commission of Inquiry appointed by Parliament to prepare a report for the South African President on research, training and legal aspects of occupational health

International:
British Occupational Hygiene Society
Permanent Commission and International Association on Occupational Health
American Industrial Hygiene Association
American Society for Testing and Materials - D-22
South African representative on the International Iron and Steel Institute's Committee on Environmental Emissions Control

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• Resigned active participation on moving to the U.S.A. November, 1975.

Final report submitted December 16, 1975, published by South African Government - April, 1976

E.R. Squibb & Sons, Inc., New Brunswick, N.J.
1978-1988 Manager, Industrial Hygiene & Safety
1988-Present Director, Worldwide Occupational/Environmental Safety

Quinnipiac College, Hamden, Connecticut
1975-1977 Associate Professor in Industrial Hygiene
1977-1978 Associate Dean, School of Allied Health and Natural Sciences

The South African Iron and Steel Industrial Corporation Ltd., (ISCOR)
1970-1975 Head of the Industrial Hygiene Department
1967-1970 Senior Industrial Hygienist
1964-1967 On study leave at the University of Pittsburgh
1962-1964 Assistant Industrial Hygienist

University of Pretoria, Republic of South Africa
1968-1975 Adjunct Professor in Industrial Physiology (part time)
1961-1962 Head of technical staff, Department of Anatomy
1960-1961 Microtechnician and histology demonstrator, Department of Anatomy
1958-1960 Technical Assistant, Department of Bacteriology

University of Pittsburgh, Pennsylvania
1965-1967 Assistant Professor in Occupational Health (part time)

COURSES TAUGHT:

Physiology I, University of Pretoria, 1968-1975
Industrial Physiology, University of Pretoria, 1968-1975
On the Job Training of Industrial Hygiene Personnel, ISCOR, 1968-1975
Introduction to Industrial Hygiene, Institute of Public Health, 1974
Industrial Hygiene for General Electric and St. Regis, Quinnipiac College, 1975-1976
Ch 437 Toxicity and Detoxication, Quinnipiac College, 1975-1976
IH 310 Introduction to Industrial Hygiene, Quinnipiac College, 1975-1976
IH 330 Industrial Hygiene I, Quinnipiac College, 1975-1976
BI 211 Anatomy and Physiology, Quinnipiac College, 1976-1977
BI 295 Applied Physiology, Quinnipiac College, 1976-1977
BI 456 Environmental Health Practices I, Quinnipiac College, 1976-1977
IH 312 Particulates and Mists, Quinnipiac College, 1978-present
BI/Ch 325 Principles of Toxicology, Quinnipiac College, 1978-present

PUBLICATIONS:

1. The Influence of Hypothermia on the Blood Glucose and Liver Glycogen of the White Rat. Roets, Philip P.,.M.Sc. Thesis, University of Pretoria, 1963.

2. Reduction of Local Sweating by Cooling at the Same Site. P.P. Roets, FASEB Abstract, Atlantic City, 1966, 273.

3. Quantitative Aspects of the Local Response of Sweat Glands to Local Alteration of Skin Temperature. P.P. Roets, D.Sc. Thesis, University of Pittsburgh, U.S.A., 1967.

4. Environmental Hygiene in South African Iron and Steel Works, Second Air Pollution Conference Organized by the Department of Health. P.P. Roets, October 1970.

5. Industrial Hygiene at the South African Iron and Steel Industrial Corporation. P.P. Roets, 17th International Congress on Occupational Health, Buenos Aires, September, 1972.

6. Industrial Hygiene - A New Science in South Africa and at ISCOR. P.P. Roets, Biennial Health Congress organized by the Institute of Public Health, Port Elizabeth, November, 1972.

7. An Afrikaans translation of this paper was also published in: Bedryfshigiene 'n Nuwe Wetenskap in Suid-Afrika en by USKOR. Public Health Vol. 73(2), pp. 53-62, February, 1973. (above mentioned paper)

8. Some Meteorological Aspects of Planning of a New Plant Site at Saldanha Bay, South Africa. P.P. Roets and A.T. Holmes. Symposium on Environmental Control in the Steel Industry organized by the International Iron and Steel Institute, (IISI), Tokyo, Japan, February 18-21, 1974. Vol. 1, Sec. 7/E/101/0-Annex 16.

9. Continuous Measurement of Dust in Waste Gases. A.T. Holmes and P.P. Roets, Ibid IISI, Tokyo, Japan, 1974. Vol. 1, Sec. 2/E/108/0.

10. Aerological data in the first two hundred metres of air above the Saldanha Bay Development Region. N. Boegman, E.C. Halliday, W.S. Louw, P.P. Roets and J.J. Taljaard, CSIR Report APRG/75/10, May 1975.

11. Verslag van die Kommissie van Ondersoek, na Bedryfsgesondheid, December, 1975. (English translation published April, 1976).

ADMINISTRATIVE SKILLS - 1970-PRESENT

1. Managed and directed Industrial Hygiene program for ISCOR. Directly responsible for a staff of 14 scientists (see attached organization chart). With staff responsible for Industrial Hygiene function at 3 steel mills, 7 mines, 2 quarries, 60,000 employees.

2. Trained in management principles by ISCOR - Louis Allen "Management by Objectives" program. Several courses and seminars.

3. Organized and chaired an ad hoc committee on Occupational Health Education under auspices of the South African Institute of Public Health. Pressure from this committee led to a Government Commission of Inquiry into Occupational Health Legislation.

4. Appointed by South African President to above mentioned commission (see publication 11).

5. Organized and chaired an ad hoc committee on Environmental Emissions Control in the South African Steel Industry. Appointed the South African representative at the International Iron and Steel Institute's Committee on Environmental Emissions Control. (IISI/Env.)

6. Represented South Africa at IISI/Env. biannually at Brussels 1973-1975. Assisted in organizing a symposium in Tokyo. Developed 2 papers for the symposium (see publications 8 and 9). Delivered a paper at the symposium (8).

7. Instrumental in organizing a research program between the South African Department of Health, South African Weather Bureau, South African Council for Scientific and Industrial Research and ISCOR to investigate the feasibility of industrialization of the Saldanha Bay area (see publications 8 and 10). Result and recommendations of this research to the South African Department of Planning & Environment led to present plan of development for this area accepted by the South African Parliament in 1975. Largest export iron ore harbor on the African continent now in operation at this site.

8. As Associate Dean, share in the responsibility of managing and directing the School of Allied Health and Natural Sciences. A job description of this function is attached. The School of Allied Health and Natural Sciences has 70 faculty members, 1,044 students and offers 6 associate degrees, 16 baccalaureate degrees and 3 graduate degrees.

9. Manage and direct E.R. Squibb Industrial Hygiene program, domestic programs. Consultant to E.R. Squibb for Safety and Health Internationally. (1978-1988)

10. Direct E. R. Squibb worldwide and domestic Occupational/Environmental Safety programs. (Present)

Date	Subject	Centre
Jan.1974	Interim report on dust and SO_2 conditions in Bantu Hospital	Pretoria works
Jan.1974	Re-estimation of pneumoconiosis risk	Newcastle works
Feb.1974	Report on overseas visit to Italy, USA and Japan	Headquarters
Feb.1974	Ammonia vapours in plan production room	Headquarters
Feb.1974	Risk classification of Steelworkers in dusty occupations	Pretoria works
Mar.1974	Detailed dust survey	Pretoria works
Mar.1974	Radiation Safety - Belt weighers	Pretoria works
Apr.1974	Placing of loudspeakers in panoramic offices for equal sound distribution	Headquarters
Apr.1974	Sound and vibration isolation between offices	Pretoria works
May.1974	Noise survey	Pretoria works
May.1974	Noise survey	Rooiplaas quarry
May.1974	Dust survey	Rooiplaas quarry
June.1974	Detailed air pollution survey (SO_2, Smoke and settling dust 6-monthly report)	Newcastle works
June.1974	Use and misuse of Carbontetrachloride	Corporation wide
July.1974	Lighting of workbenches - guideline and specification	Headquarters
Aug.1974	Guideline in Legal consequences of being a controlled mine under occupational diseases Act	Uis Tin Mine
Sept.1974	Air pollution at a possible site for a new works	Headquarters
Oct.1974	Noise surveys at 3 of Iscor's subsidiary companies where the major work completed during this month	Headquarters

Iscor has a headquarters in Pretoria, 3 works; Pretoria, Newcastle and Vanderbijlpark, 2 iron ore mines; Thabazimbi and Sishen, one coal mine;

of the training program, beginning with the [illegible] information given and follow the same general format for each person.

NAME	POSITION	BIRTHDATE (Month, Day, Year)
Philip P. Roets	Associate Professor	(b)(6)

CITIZENSHIP (See instructions)			SEX
	U.S. Citizen or U.S. National	(b)(6)	☒ Male ☐ Female
	(If "NO," Permanent Resident)		

EDUCATION (Begin with baccalaureate and include postdoctoral training)

INSTITUTION AND LOCATION	DEGREE	YEAR COMPLETED	PROFESSIONAL FIELD
University of Pretoria, South Africa	B.Sc.	(b)(6)	Physiology, Anatomy and Biochemistry
University of Pretoria, South Africa	M.Sc.		Physiology, Anatomy and Biochemistry
University of Pittsburgh, Pennsylvania	M.Sc. (Hyg)		Industrial Hygiene
University of Pittsburgh, Pennsylvania	D.Sc. (Hyg)		Industrial Hygiene

HONORS

MAJOR PROFESSIONAL INTEREST	ROLE IN PROPOSED PROGRAM
	Faculty

TRAINING AND RELATED SUPPORT (See instructions)

PROFESSIONAL EXPERIENCE: (Starting with present position, list training and experience relevant to area of proposed program. List selectively publications that are most relevant to the training program)

GEORGE F. THOMPSON

Present Position Director, Radiodiagnostic Operations and Productivity

Education

Wilkes College - B. A. Biology, (b)(6)
U. S. Public Health Service
Course in Basic Radiological Health, 1968

Experience

E. R. Squibb & Sons, Inc.
Chemical Technician - Quality Control, 1964 - 1966
Production Coordinator - Quality Control, 1966 - 1967
Supervisor - Radiopharmaceutical Q. C., 1967 - 1969
Bulk Supervisor - Radiopharmaceutical Mfg., 1969 - 1971
Section Head - Radiopharmaceutical Mfg., 1971 - 1980
Department Manager - Radiopharmaceutical Mfg., 1980 - 1988
Director - Radiodiagnostic Operations and Productivity, 1988 to Present

Societies

Health Physics Society - Full Member
Society of Nuclear Medicine - Associate Member

ADDENDUM 5
Page 1

Item #9: Facilities and equipment.

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 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 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 Mo-99 Molybdenum 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 nonradioactive 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.

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 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 100 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 nonrecirculating 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 HEPA filter followed by a 1" high efficiency carbon filter to arrest any possible gaseous contaminant. The Mo-99 - Tc-99m cave is exhausted through an F-85 and a HEPA filter and three 1" charcoal filters. Other manufacturing gloveboxes, where less volatile radionuclides are processed, are exhausted through an F-85 and a HEPA filter followed by 2 one-inch high efficiency carbon filters.

Each of the twelve fume hood system filter bank 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, three Flanders HEPA and nine one-inch equivalent MSA 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 weekly 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 other radionuclides such as Mo-99, etc. to the lowest practicable level.

All exhaust systems are discharged to the effluent exhaust stack. The system used for sampling exit air from the stack is comprised of six one-inch lines within the exit duct. Each of these 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 exit 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 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.

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 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 and emergency lighting for the plant.

Additional facilities at the New Brunswick site include laboratories for sterility and pyrogen testing and research and development laboratories.

All ventilation is supplied by non-recirculating air. Carbon filtration is utilized in areas where unbound iodine I-125 is processed. See Figure 2 for the diagram of the iodination lab: Room 207A, Building 80. Breathing zone air samplers are also available in this

room. Effluent air is continuously monitored. Air concentrations in areas housing unbound iodine are also continuously monitored. No unbound iodine I-131 is processed outside of the manufacturing building.

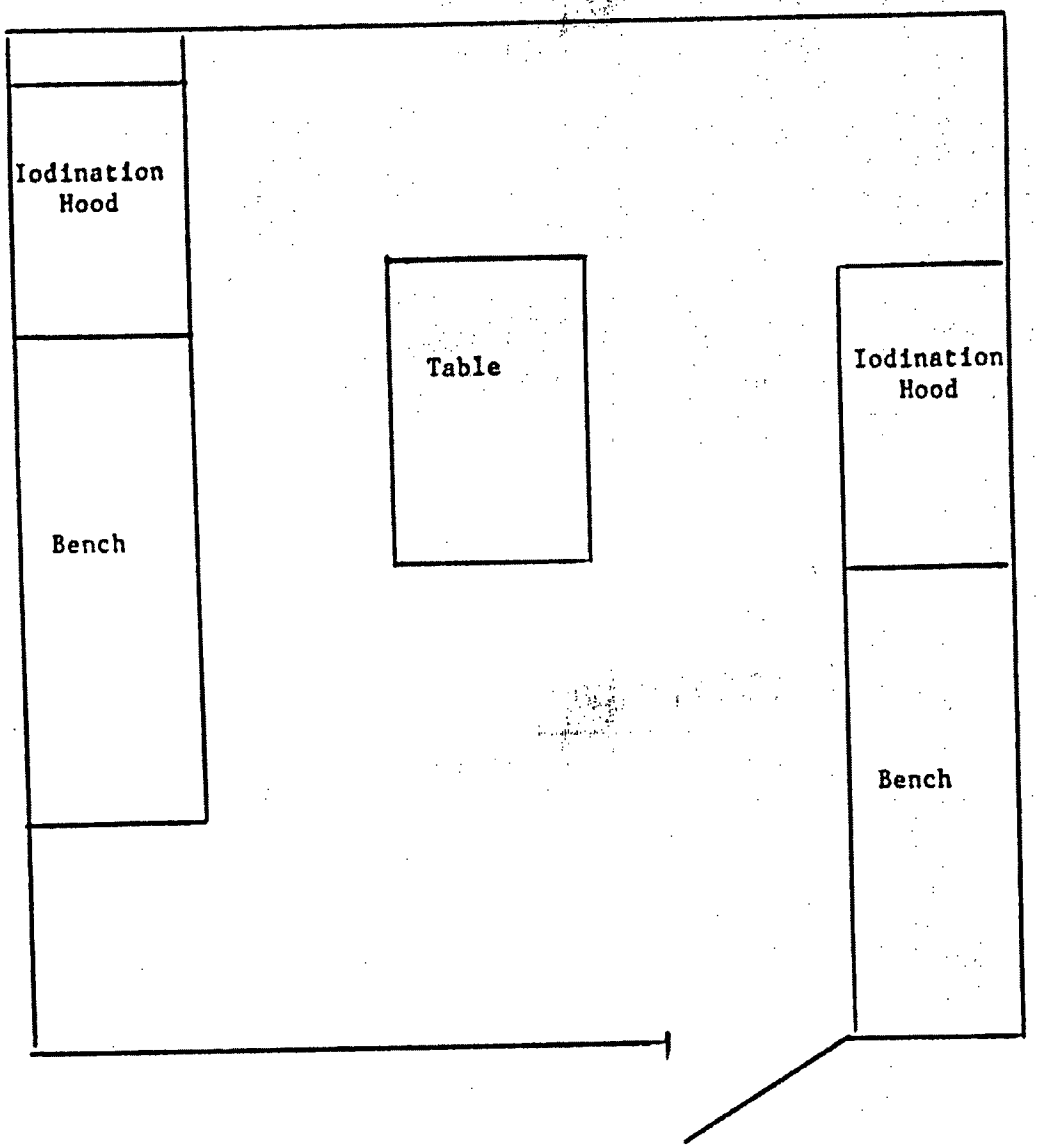
Holding tanks are provided for the cage washing area of the pyrogen testing facility.

The Lawrenceville, Princeton House and Forrestal facilities all utilize non-recirculating air for the ventilation systems for all areas possessing radioactive materials. No unbound iodine is used in any of these facilities.

Low density shielding is extensively used in areas housing significant quantities of Phosphorous P-32. Eye protection is also utilized in areas using greater than 10 mCi of P-32.

Figure 1
Manufacturing Facility Building 124

Figure 2
R&D Iodination Laboratory
Room 207A, Building 80



Item #10: Radiation Safety Program.

10.1 Previous Licenses

This application requests a continuation of activities that are presently licensed under License Number 29-00139-02. As of this date, our license includes Amendment No. 76, which references letters from E.R. Squibb & Sons dated November 21 and December 27, 1988.

The amendment requested in a letter from E.R. Squibb & Sons dated January 16, 1989 regarding the approval of users and uses of radioactive material at all sites not part of the New Brunswick, NJ site, is included in the description of the radiation safety committee responsibilities in this application.

In addition, the renewal application incorporates all amendments of License No. 29-00139-02, which will expire on March 31, 1989 except for the radiological contingency plan. Updates of this plan are included in Addendum 7 of this application.

Aside from the changes to the radiological contingency plan the primary changes in this license application that have not been previously addressed by an amendment request are:

1. the list of members of the radiation safety committee (Section 10.2),
2. possession limit for Mo-99/Tc-99 m in New Brunswick from 2,000 Curies to 1,000 Curies (Item 5),
3. radioactive waste procedures (Item 11),
4. elimination of radioimmunoassay kit demonstrations at temporary job sites, and
5. calibration of detection instruments at least bi-annually as per NRC Reg Guide 8:21 ("Health Physics Surveys for By-Product Material at NRC-Licensed Processing and Manufacturing Plants")

10.2 Radiation Safety Committee

The Radiation Safety Committee is responsible for assuring that all operations involving radioactive materials are carried out in total conformance with our overall radiation safety program which is administered and enforced by the Radiation Safety Officer 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 Radiation Safety Officer the responsibility and authority to approve individual uses and users of radioactive material at sites not in the New Brunswick location. These sites (presently Lawrenceville, Princeton House and Forrestal Greens) possess quantities of radioactive material that would qualify for a Type B broad scope license as specified by NRC 10CFR33.11. For a Type B broad scope license the Radiation Safety Officer is the proper authority to approve or disapprove all users and uses of radioactive material. This stipulation is considerably more protective than having a Type B broad scope license because the Radiation Safety Officer has the obligation to report to the committee for review any new location, major equipment change, new department or generic process at these locations. In addition, any radioactive material use or user request that is questionable to the Radiation Safety Officer must be brought before the committee for final review.

Since quantities of radioactive material possessed at the New Brunswick site are considerably higher than that of the New Brunswick site, the committee will review uses of radioactive material at the New Brunswick site.

Periodic audits of the radiation safety program will be conducted. 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.

Committee meetings will be held at least quarterly. The quorum for a meeting is at least half of permanent members or their designated alternates. Minutes of each meeting are kept by the secretary and copies of these minutes are distributed to members.

10.3 Radiation Safety Officer

The RSO is responsible for the day-to-day coordination and management of the radiation safety program at E.R. Squibb & Sons. He/she ensures compliance with conditions of the license and NRC regulations applicable to radiation safety.

The RSO currently reports to the Director of Quality/Productivity and Health Physics. This director reports to the Vice-President of Worldwide Pharmaceutical Operations. This reporting structure, along with the support of the Radiation Safety Committee gives the RSO access to all levels of the organization and authority to immediately terminate a project that is found to be a threat to health, safety or property.

The RSO is a full-time employee whose charge is to manage the Health Physics organization. This organization is presently staffed by two technical supervisors, four union technicians and one clerk.

The responsbilities and duties of the RSO include, but are not limited to the following:

1. Prepare, with the supervisory staff, safety evaluations of all proposed uses of radioactive material and present them to the RSC as appropriate.
2. Oversee all activites involving radioactive material, including but not limited to:

   a. Routine contamination and exposure rate surveys of all areas in which radioactive material is used. Surveys are routinely performed by the Health Physics staff at intervals at least as frequent as specified by NRC Reg Guide 8.21, and

   b. The RSO or his/her management 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. Frequent informal monitoring by the Radiation Safety Officer and staff is also performed.

3. Compliance with rules and regulations, license conditions and RSC's project conditions are accomplished through the Health Physics staff's scheduled monitoring, scheduled and unscheduled audits, inventory records, dosimetry record audits and feedback from users concerned about their own or their neighbor's radiation safety practices. That is, the philosophy of ALARA is not only practiced by the Health Physics staff but by all persons working in restricted areas.

4. All incoming radioactive material packages above limits specified in 10CFR 20.205 (May 31, 1984) are appropriately surveyed for contamination and external exposure rates. All receipts of radioactive material are logged into the license's inventory.

5. All site's 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.

6. The radioactive material waste disposal program is coordinated through the Health Physics department. Certain departments that generate large amounts of waste staff their own consolidation and shipping operations. These staffs are trained and audited by the Health Physics staff.

   All gaseous and liquid effluents are monitored by the Health Physics staff.

7. Radioactive material not in current use, including wastes, 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.

8. Personnel monitoring is achieved through our contractor Siemans Gammasonics in Des Plaines, IL. Personnel stationed in the manufacturing facility are issued weekly film badge dosimeters and TLD rings as determined by the Health Physics staff. All other occupational workers are issued appropriate monthly dosimetry. Users of Phosphorous P-32 in quantities greater than 1 mCi utilize TLD ring dosimetry.

   Personnel handling significant quantities of potential volatile iodine monitor their thyroid when working with this material. Personnel in the manufacturing facility monitor their thyroid at least each week. All exposure records and thyroid assay records are evaluated and kept by the Health Physics staff. Variations over the normal reading in an individual's history are investigated and corrective actions are undertaken.

9. Health Physics coordinates the calibration of all geiger counter and NaI detectors with scalers and ion chambers with our contractor, The NDL Organization of Peekskill, NY. Instruments in use are calibrated at least every six months. They are marked with a calibration date and calibration certificates are reviewed and kept by Health Physics.

10. Every six months leak tests are performed on all sealed sources, as required.

11. Each occupational worker is trained by Health Physics on the appropriate procedures in radiation safety for that person's job function before they work with radioactive material. In addition, support groups that could be considered visitors with temporary dosimetry attend group training.

12. Health Physics maintains an open door policy as a consultant to all users of radioactive material and all support groups and visitors who frequent or are near areas where radioactive material is kept. This policy is directed through the Health Physics staff's ability and eagerness to converse with levels in the company from service workers to the highest ranking members of management.

13. Carbon filter systems are employed wherever iodination procedures are performed.

14. The Health Physics staff supervises all clean up of significant radioactive material contamination.

15. Records specified by 10CFR 20.401 and 10CFR 30.51 are also kept by Health Physics for a duration not less than specified under these regulations.

10.4 Administrative Procedures

10.4.1 Control of Procurement and Use

All purchases of radioactive material are processed through one purchasing agent who is at the New Brunswick, NJ site. He will not process an order unless the Health Physics Department has initialed the Purchase Order. Health Physics verifies that the isotope and quantity ordered is consistent with our license requirements and that the person is authorized to use this material.

10.4.2 Safety Evaluations of Proposed Uses

Before any use of radioactive material, an application is completed by the principal radiation user. Considerations in this application include but are not limited to:

1. location of storage of material,
2. location of use of material,
3. proper shielding,
4. proper ventilation,
5. proper monitoring capabilities,
6. previous experience and education,
7. detection equipment available,
8. proper dosimetry,
9. generation of radioactive waste,
10. animal use, and
11. specific training in radiation safety/ALARA.

These applications will be maintained on file.

10.5 Bioassays

Thyroid bioassays are scheduled at least weekly for all occupational personnel stationed in the controlled area of the manufacturing facility (Building 124). All other personnel, after handling significant quantities of potential volatile iodine, monitor their thyroid.

Currently no person uses tritium in such quantities that bioassay measurements are recommended by NUREG-0938, "Information for Establishing Bioassay Measurements and Evaluations of Tritium Exposure", 1983.

10.6 Emergency Procedures

All occupational workers are instructed in emergency procedures involving radioactive materials. Attached is the emergency procedure from the "E.R. Squibb & Sons Radiation Safety Standard Operating Procedures" manual. This procedures is posted.

In addition, there is a radiological contingency plan for our manufacturing facility. The amended pages are in Addendum 7. These changes do not attempt to include the format of Reg Guide 0762 "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities", 1987, but are meant to update data relating to recent organizational, equipment and procedural changes. A revision in the Radiological Contingency Plan from E.R. Squibb & Sons in the format of Reg Guide 0762 is expected to be completed and submitted during 1989.

Part III - Emergency

Radiation Emergency Procedure:

I. PURPOSE - Outline radiation emergency procedure for radioactive spills and major catastrophes.

II. RESPONSIBILITY - It is the responsibility of all individuals working in radiation controlled areas to adhere to all these procedures.

III. GENERAL PROCEDURES

A. General Rules

1. The individual's first responsibility is his/her own safety.

2. Evacuate the area immediately.

3. Notify Health Physics & supervision immediately.

B. Specific Rules

1. Minor spills outside enclosures (less than one millicurie).

a. Vacate area immediately, holding breath, if possible.

b. Contact Health Physics and supervision immediately.

c. Monitor clothing and body for contamination, removing contaminated clothing.

d. Follow decontamination procedure outlined by Health Physics or supervision.

2. Major spills outside enclosure (more than one millicurie).

a. Vacate area immediately, holding breath.

b. Remove lab coat, if contaminated.

c. Notify Health Physics and supervision immediately.

d. Seal off area and mark each entrance with a warning sign indicating the hazard.

e. Monitor body, shoes, clothing for contamination. If grossly contaminated, remove clothing and shower immediately. Notify supervision.

f. Do not enter the area without Health Physics approval.

g. Follow decontamination procedures as outlined by Health Physics.

3. Fires, explosions, major catastrophes.

a. Evacuate all personnel immediately.

b. Sound fire alarm and notify Health Physics and supervision.

c. Follow Health Physics's instruction.

d. Do not leave area (general vicinity of building) without first being monitored for radioactive contamination.

NRC License
E.R. Squibb & Sons 2/27/89

ADDENDUM 7
Page 1

Changes in Radiological Contingency Plan

As stated in 10.6 of Addendum 6, the radiological contingency plan for the By-product Material License No. 29-00139-02 for E.R. Squibb & Sons is being updated as follows:

Pages to be Removed	Page to be Inserted
Page 1	Page 1, 2/23/89
Page 4	Page 4, 2/23/89
Page 8	Page 8, 2/23/89
Page 9	Page 9, 2/23/89
Pages 12 and 12a	Pages 12 and 12a, 2/23/89
Page 15	Page 15, 2/23/89
Page 25	Page 25, 2/23/89
Page 26a	Page 26a, 04/01/87
Page 38	Page 38, 2/23/89
Page 39	Page 39, 2/23/89
Page 40	Page 40, 2/23/89
Pages 43, 43a and 43b	Pages 43, 43a, 43b, and 43c 2/23/89
Pages 44, 44a and 44b	Pages 44, 44a and 44b, 2/23/89
Pages 45 and 45a	Pages 45 and 45a, 2/23/89
Page 46	Page 46, 2/23/89
Page 48	Page 48, 2/23/89
Page 54	Page 54, 2/23/89
Page 62	Page 62, 2/23/89
Page 63	Page 63, 2/23/89

Six copies of this addendum are attached.

1.0 GENERAL DESCRIPTION OF PLANT/LICENSED ACTIVITY

1.1 Licensed Activity Description

E. R. Squibb and Sons, Inc. of New Brunswick, New Jersey is the holder of Materials License No. 29-00139-02 issued by the Nuclear Regulatory Commission for its radiopharmaceutical operations. The license includes authorization for the possession and use of byproduct materials of any form, with atomic numbers 1-83 inclusive, except Strontium 90. The maximum total quantity of radionuclides in this atomic number range is 5 curies of each radionuclide with a total possession limit of 1000 curies except: 150 curies of Iodine-131, and 1000 curies of molybdenum-99/technetium-99m. The license authorizes the use of the materials in research and development, and processing for distribution to authorized recipients. With the exception of a few research activities utilizing small quantities of radioactive materials, manufacturing operations are performed in the Medotopes building (Bldg. 124). (See Addendum I for license.)

1.2 General Description of the Plant/Licensed Activity

E. R. Squibb & Sons, Inc. owns and operates a pharmaceutical manufacturing and research facility in Middlesex County, New Jersey. Physically, the site occupies about 94.8 acres in the township of North Brunswick and New Brunswick.

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 close to 120 feet above sea level are found near the center of the site; 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. Site coverage for each ranges between 5,000 and 150,000 square feet. Uses include warehousing of raw materials and finished products, animal study facilities, analytical and pilot plant laboratories, utilities and maintenance services, bulk chemical processing finished product processing and packaging, and administrative offices.

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.

Control apparatus consist of steel filter enclosures with particulate filters of varying efficiency and activated carbon filters on the suction side of fans discharging to the stack.

The reduction in the radioactive iodine concentration through the material used at our facility is at a minimum factor of 5 per centimeter of bed depth for radioiodine as methyl iodide at a flow rate of 40 fpm, 70% relative humidity and air temperature of 25 degrees C. For this reason, the theoretical filtration efficiency is approximately 99.9%.

Data accumulated at the Radiopharmaceutical Manufacturing facility shows that over the course of a year, approximately 0.4% of the amount of I-131 that is used in the facility is presented to the air handling system.

For practical purposes in our calculations, the theoretical efficiency has been assumed to be 99%. On this basis, the total radioiodine transmitted to the atmosphere should not exceed .004% of the radioiodine handled, or less than 50 microcuries per Curie of radioiodine used in the facility.

The combination of particulate and gaseous filters described serves to reduce the effluent of other radionuclides such as Mo-99, etc. to the lowest practicable level.

Confinement Systems (Liquid)

Liquids with low-level radioactivity, e.g., glassware washing water and water from hand sinks in materials handling areas, are collected in holdup tanks. There are four separate tanks, each having a capacity of 3.8 E04 liters. Current liquid generation rates permit approximately a three-month decay of the holdup tank effluent. Tanks are sampled as necessary and released to the sanitary drain, if contents satisfy the concentration limits for such release. The remainder of the liquid wastes (approximately 1.0 E06 liter/day) from the site is sanitary waste and is released without treatment or monitoring.

Alarm Systems

The manufacturing areas in building 124 are equipped with remote monitoring detectors. These are calibrated at least bi-annually to produce a blue warning light and an audible alarm in the work area and a blue warning light in the Health Physics operations area should background radiation levels reach 10 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 panel.

SQUIBB PROCESS FLOW DIAGRAM / I-131

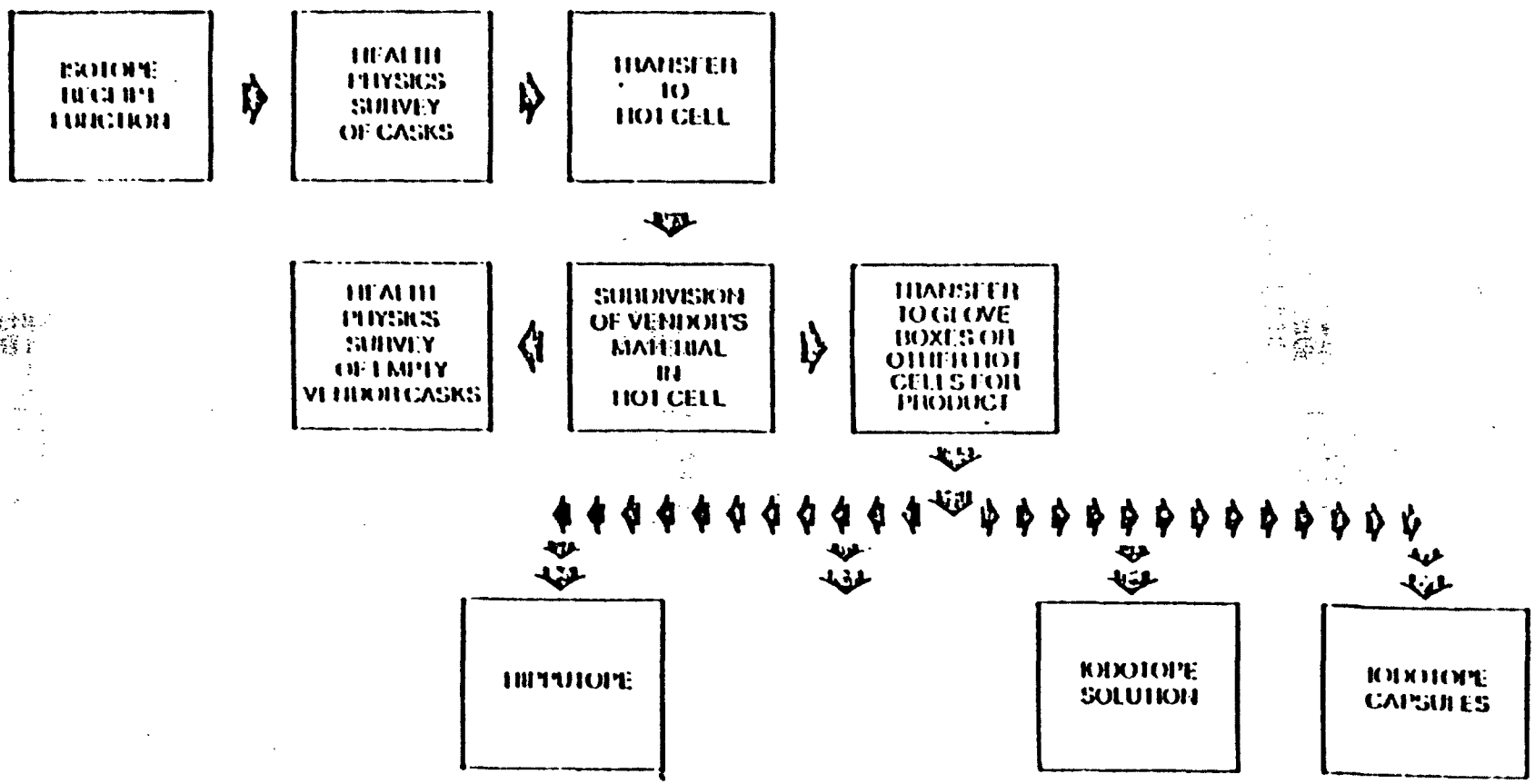


Figure 5

8

2/23/89

This isotope is diluted to the desired radioactive concentration and the solution pH checked and adjusted, if necessary. A calculated volume of the diluted isotope is loaded onto nonradioactive support columns to achieve the desired activity. These columns are placed into shielded containers and removed from the hot cell. Each unit is checked for total activity and placed into an appropriately labeled plastic container. This unit is packaged into a shipper and transferred to the distribution area for subsequent delivery to a customer.

1.3.2 I-131 Process Flow (Figure 5)

Iodine I-131 is supplied by a contracted vendor on a weekly basis. At the time of receipt, the isotope is logged in and assigned an identification number. The cask is then checked by Health Physics for radiation level and external contamination. After Health Physics's approval, the cask is transferred to a hot cell. The shielded container is transferred into the hot cell where the prime container is removed. The shielded container is then removed from the cave and the cask checked by Health Physics prior to return to the vendor. Based on radioactive concentration, the vendor's isotope is allocated to various product processes requiring I-131. The required activity is measured out in the hot cell and placed into a glass bottle. The bottle is placed in a bulk transfer pig and then taken from the hot cell to the glovebox or hot cell designated for that particular product preparation. At this time, Iodine I-131 is subdivided for the preparation of Hipputope, Iodotope Solution, and Iodotope Capsules.

2.0 ENGINEERED PROVISIONS FOR ABNORMAL OPERATIONS

2.1 Criteria for Accommodation of Abnormal Operations

The design criteria of the plant are based on state of the art technology to ensure prompt detection of abnormal conditions and to limit releases of radioactive materials in the event of a radiological emergency.

2.1.1 Process Systems

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 nonradioactive materials areas.

2.1.3.3 Access and Egress of Operating Personnel and Emergency Response Teams

2.1.3.3.1 Onsite

The radiopharmaceutical operations are conducted on the ground floor of the plant making access and egress for the evacuation of personnel an easy task. 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.

In addition to the exits used routinely, the plant is also equipped with alarmed emergency exits.

The access control system has been designed to prohibit inadvertent or unauthorized access to high radiation areas and to provide personnel with the knowledge of the presence of radiation or radioactive materials. The access control system eliminates unnecessary exposure and assures exposures are maintained within regulatory limits.

One of the first indications to personnel of a potential hazard is the presence of caution signs at the entrance to radiation areas and labels on the containers of radioactive materials.

2.1.3.3.2 Near Site

Access and egress including the offsite evacuation of personnel as well as for onsite response by offsite based emergency response participants have been established at three site locations; 1) the Ward Street, 2) the US #1 entrances, and 3) the Georges Road entrances.

2.1.3.4 Fire and Explosion Resistance and Suppression

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.

The plant is provided with Class II interior 1 1/2" hose lines installed 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. It is expected that the hot cells which are constructed of steel, concrete and lead, equivalent to 4 to 8 inches of lead will serve as primary containment following an explosion. The building and the building's charcoal filtration systems are considered secondary containments.

It should be noted, however, that it is highly improbable that an explosion of any magnitude could occur since no explosive or combustible compounds or reagents are used in the hot cells during the manufacture of I-131 Therapeutic Oral Solutions or 99Mo-99mTc generators.

The building and processes within the site are protected by a looped and gridded fire protection water distributory system, fed by independent pumped water sources. Two automatic 1500 gallon pumps one electric and one diesel supplied by a 300,000 gallon above ground tank located on the south section of the site and 1500 G.P.M. diesel pump taking suction from a 16" city water main, which supplies the site.

The combination of particulate and gaseous filters described serves to reduce the effluent of other radionuclides such as 99Mo, etc. to the lowest practicable level.

All exhaust systems are discharged to the effluent exhaust stack. The system used for sampling exit air from the stack is comprised of six one-inch lines within the exit duct. Each of these 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 exit 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 1.85 Cu. Ft. per minute and is changed daily.

The radioactivity collected in the sampler is constantly measured by the stack alarm detector which will sound an alarm in Health Physics operations area should the maximum allowable activity for I-131 Iodine 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. The sampling system has been designed to assure isokinetic sampling in the main duct.

2.2.2 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,
- Running indication for all systems,
- "Air failure" alarm and indication for all critical systems, 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.")

Air balance is maintained by means of constant volume regulators in each branch duct connection to glove boxes, fume hoods, etc.

2.2.3 Support Systems

Fire protection is provided at each branch connection to glove boxes and fume hoods, etc. by means of a spring-loaded fusible link fire damper. Carbon filters are monitored by means of ionization-type detectors in the duct work. Generally, detectors will isolate a filter fire from the air stream by closing

Class II

ALERT

Certain manufacturing processes require the allocation of curie amounts of 131-I iodine into shielded vials for transfer to gloveboxes within the plant. Although the containers used are sealed, it is possible, that through human error or carelessness, an incident might occur during the transfer which may be considered an alert.

Let us assume that a lead shield containing 4.0 curies of I-131 Iodine which is to be transported to a glovebox topples over when being removed from the hot cell. It strikes a small electrical box in the hot cell pass thru causing the electrical wires to short circuit and crash to the floor. The lead container and vial of iodine upon impact are damaged and the iodine is released onto the floor. An electrical fire results from the short circuit but there is no significant release of airborne radioactivity.

In this case, the spill would immediately be detected by the room monitor and an alarm would notify the individuals in the immediate area to evacuate. At the same time, an alarm would also be indicated in the Health Physics operational office.

The pyrotronic fire detectors would release a fire damper in the air ventilation duct and contain the fire in the hot cell pass thru. Any smoke released into the room will pass through the room filtering system and also be detected by the filter bank fire detectors. When this occurs, a fire alarm will sound in the Health Physics operational area and at the main gate security station.

Within minutes, Health Physics personnel, the Fire Department and Security will respond to the alarms. Upon assessing the incident, the emergency director shall proceed to implement the contingency plan and promptly notify state and/or local monitoring agencies of the incident.

Consequences

The 22.5 millicuries would be diluted before it leaves the stack by the plant's ventilation system (75,000 cfm.)

The air concetration for a release time of two hours would therefore be calculated to be:

$$\frac{2.25\ E + 04\ uCi}{(2.8\ E+04\ cm3/ft3)\ (75{,}000\ ft3/min)\ (120\ min)}$$

$$\frac{2.25\ E+04}{2.52\ E + 011} = 8.9\ E-08\ uCi/cc$$

The average air concentration for twenty four hours (assuming no addition releases) would be:

7.4 E-09 uCi/cc

The plant fire brigade members respond to Bldg. 63 (fire house) and confirm the location of the alarm from the guard by direct phone from the gate house. The brigade responds with the engine and squad vehicle to the alarm location. The Zone Engineers on duty for the pump houses will report to and attend the sprinkler system fire pumps. In the event a building sprinkler head is discharging water on the fire, a fire pump will automatically start sending a signal to the guard house which notifies the fire brigade and the zone engineer. Water flow from sprinkler heads initiates the building's local sprinkler water motor gong. The senior fire officer on duty will assume immediate command of all fire fighting activities. Should he decide that a site emergency exists, he immediately intitates the Emergency Management Plan.

The officer in charge will keep the 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.

When a disaster exists, all Production Personnel will begin shut-down and evacuation procedures as directed by Plant Management. Areas remote from the disaster area may continue to discontinue operations as directed by Plant Management.

4.2.2.12 First Aid Squad

The Squibb First Aid Squad is a member of the New Jersey State First Aid Council and conforms to the 5 point statewide minimum training and proficiency standards. The squad manning of approximately 19 people cover 1st and 2nd shifts and are alerted by paging radios initiated through the main security post, where all medical emergencies are reported by dedicated extension 3033. Coverage for the 3rd shift and weekends is provided by the local community first aid squad.

Certain First Aid personnel are assigned to respond to all calls with the Squad's fully equipped ambulance. The site is divided into four zones with first aid personnel assigned within those zones responsing directly to the scene of medical emergencies within their zone. First aid kits and certain other equipment, such as a containment stretcher for the radiopharmaceutical manufacturing plants use, are located throughout the plant site. Squad members receive training monthly during regular two hour drill sessions.

4.2.2.13 Fire Brigade

The plant maintains an organized Fire Brigade currently consisting of 1 full-time and 8 volunteer fire protection people.

The five man engine assignment and two man squad complement respond to regular shift fire alarms which are transmitted by radio page, and air horn from the main security post where fire system alarm and dedicated fire reporting phone (ext. 3011) calls are received. The Fire Brigade members are equipped with personal protective equipment conforming to O.S.H.A. 1910 subpart L. They receive training at the NJ State Fire College and during regular work hours, in-house monthly training drills. During off-shift periods, the North Brunswick Volunteer Fire Department are first due for site fire emergencies.

4.2.2.14 Radiation Emergency Plan-Security Department

A. Purpose

The purpose of this section is to provide guidance to plant security personnel concerning their responsibilities during a plant radiation emergency.

B. Scope

The Security Department shall endeavor to safeguard the health and safety of company employees/visitors and take all necessary action in accordance with instructions received from the Plant Emergency Director or his designee.

C. Procedure

- Establish radio communications between the security office and the Plant Emergency Director's Control Room.
- Sound the necessary building evacuation alarms and direct employees to areas of safety.
- Alert the North Brunswick Police and Fire Departments and the New Brunswick Police Department to initiate their respective prearranged plans.
- Notify the Director of Engineering and Maintenance, Personnel Manager and Industrial Hygiene and Safety Manager.
- Recall all available uniformed security personnel.
- Prohibit all routine vehicular and pedestrian egress and ingress to plant.

- Provide assistance to plant fire and first aid units as well as any municipal or state agency rendering assistance.

- Continue to secure plant and enforce all company rules and regulations.

- Monitor local radio station (WCTC-1450 kc).

- Refer all requests for information from the news media to the Squibb Public Relations Staff. Security Personnel will divulge NO information at any time.

- If necessary, supplement security department with predesignated supervisory personnel.

- During an off-shift emergency, the NCO in charge will immediately initiate the following recall:

  1. Plant Emergency Director or Assistant Director
  2. Diagnostic Operation and Productivity Director
  3. Security Manager or Assistant Manager
  4. Director of Engineering and Maintenance
  5. Director of Human Resources
  6. Personnel Manager
  7. Industrial Hygiene and Safety Director

During an off-shift radiation emergency, the NCO in charge will initiate the procedures listed above in accordance with instructions received from the Security or Assistant Security Manager.

All activity, phone calls and information related to the emergency will be noted and maintained in a separate emergency log.

4.3 Offsite Assistance to Facility

The following are the provisions and arrangements which have been established for assistance to onsite personnel during and after a radiological emergency (See Addendum IV - Letters of Agreement).

3. Releases within the site boundary which cause dose rates in unrestricted areas to exceed 10 mr/hr but do not exceed EPA Protective Action Guideline exposure levels outside the site boundary.

B. A major fire in the radiopharmaceutical production building (#124.)

A general emergency exists when:

A. Any condition which threatens to cause the release of radioactive material beyond the site boundary in quantites expected to exceed EPA Protection Action Guideline exposure levels offsite.

1. Events are in process or have occurred which involve actual imminent loss of confinement integrity.

2. A radiation dose rate of 10 mr/hr at the site boundary or concentration of radioactive material greater than MPC beyond the site boundary.

B. A major fire involving the release of large amounts of radioactive material.

5.2 Assessment Actions

5.2.1 Notification of Unusual Event

A. When an unusual event occurs, the following procedures should be implemented to alert response personnel and to notify management of the incident.

The individual (s) suspecting that an unusual event has occurred shall notify Health Physics personnel immediately, by telephone, plant intercom system and/or in person.

Intercom: 60

Telephone: 2168, 3158, 2451, 3721

Health Physics personnel shall immediately notify the Health Physics Department Head or his designee by intercom, telephone and/or in person.

Intercom: 60

Telephone: 2451, 3158 or 3721

	Office	Home
Edward Truskowski	3158	(b)(6)
Larry Gaines	3721	

The Health Physics Department Head shall notify:

	Extension
1. Squibb Medical	3033
Squibb Fire	3011
Squibb Police	2111
Robert Wood Johnson Hospital	201-937-8000 ext. 2222 (if required)

2. Director of Quality Productivity/Health Physics

	Office	Home
Mr. J. Reinhardt	2001	(b)(6)

3. V. P. of World Wide Pharmaceutical Operations

	Office	Home
Dr. H. Abdou	2582	(b)(6)

4. Radiopharmaceutical Department Head/Director

	Office	Home
G. Thompson or designee	3076	(b)(6)
K. Sosnowski	3063	
C. Forberg	3063	

5. U.S. Nuclear Regulatory Commission Head Quarters Operations Center
301-951-0550
301-427-4056
301-492-8893
301-427-4259

a. Identify: "E. R. Squibb & Sons, Inc."
b. Give Emergency Class (Alert, Unusual event, site or general).
c. You will be transferred to Region I Duty office.

6. NJ State Department of Environmental Protection — 609-292-7172
   Radioactive Materials Section — 609-530-4023

5. N. J. State Police — 609-882-2000
   24 hours ask for Emergency Management Section

B. The emergency assistance team or alternate shall proceed to the immediate area of emergency with special monitoring equipment and determine the extent of the emergency.

C. The affected area shall be isolated with a barricade and warning signs shall be placed on all entrances leading to the emergency area.

D. All personnel not immediately involved with the emergency shall report to an area designated by the emergency team or alternate.

5.2.2 Alert

A. Persons discovering the emergency condition shall notify the Health Physics office by the most expeditious means available (Telephone 2168, 2451, 3158 or 3721; Intercom 60)

B. Health Physics personnel or shift supervisors sounds the appropriate alarm within the plant and notify the Health Physics Department Head or his designee:

Health Physics Department Head:	Office	Home
E. Truskowski or designee	3158	(b)(6)
L. Gaines	3721	

C. The Health Physics Department Head shall notify:

1. Medical	3033	
2. Fire	3011	
3. Police	2111	
4. Robert Wood Johnson Hospital	201-937-8000, ext. 2222	
5. New Brunswick Police	201-745-5200	
6. North Brunswick Police	201-545-4300	

7. Radiopharmaceutical Director or designee:

	Office	Home
G. Thompson or designee,	3076	(b)(6)
K. Sosnowski	3063	
C. Forberg	3068	

8. U.S. Nuclear Regulatory Commission — 301-951-0550
   Head Quarters Operations Center — 301-427-4056
   301-492-8893
   301-427-4259
   a. Identify: "E. R. Squibb & Sons, Inc."
   b. Give Emergency Class (Alert, Unusual event, site or general).
   c. You will be transferred to Region I Duty office.

9. NJ State Department of Environmental Protection — 609-292-7172
   Radioactive Materials Section — 609-530-4023

10. N. J. State Police — 609-882-2000
    24 hours ask for Emergency Management Section

D. The Radiodiagnostic Director or designee shall notify:

President, Sq. Diagnostics	Office	Home
Dr. M. Loberg	609-987-1816	(b)(6)

E. The Health Physics Department Head shall notify:

Director of Quality Productivity/Health Physics		
Mr. J. Reinhardt	2001	(b)(6)
V. P. of World Wide Pharmaceutical Operations		
Dr. H. Abdou	2582	(b)(6)

F. Persons in the immediate area of the emergency condition shall take appropriate action to limit the extent of the incident with available means to the extent possible, then retreat to a safe location and await assistance.

G. All shift personnel, not immediately involved with the incident, shall report to the area designated by the Health Physics or shift supervisors.

5.2.3 Site Area Emergency

A. Persons discovering the emergency condition shall immediately notify the Health Physics Office by the most expeditious means available.

B. Telephone ext. 2168, 3158, 2451 or 3721; Intercom 60

C. Health Physics personnel or shift supervisors sound the appropriate alarm (horn) within the radiopharmaceutical production building and notify the Health Physics Department Head or his designee:

Health Physics Department Head:	Office	Home
E. Truskowski or designee	3158	(b)(6)
L. Gaines	3721	

D. The Health Physics Department Head shall notify:

1. Medical	3033	
2. Fire	3011	
3. Police	2111	
4. Robert Wood Johnson Hospital		201-937-8000, ext. 2222
5. New Brunswick Police		201-745-5200
6. North Brunswick Police		201-545-4300

7. Radiodiagnostic Director or designee:

	Office	Home
G. Thompson or designee,	3076	(b)(6)
K. Sosnowski	3063	
C. Forberg	3063	

8. U.S. Nuclear Regulatory Commission Head Quarters Operations Center
   301-951-0550
   301-427-4056
   301-492-8893
   301-427-4259

   a. Identify: "E. R. Squibb & Sons, Inc."
   b. Give Emergency Class (Alert, Unusual event, site or general).
   c. You will be transferred to Region I Duty office.

9. NJ State Department of Environmental Protection Radioactive Materials Section — 609-292-7172, 609-530-4023

10. N. J. State Police — 609-882-2000

E. The Radiodiagnostic Director or designee shall notify:

President, Squibb Diagnostics

	Office	Home
Dr. M. Loberg	609-987-1816	(b)(6)

1100363

F. The Health Physics Department Head shall notify:

	Office	Home
Director of Quality Productivity/Health Physics		
Mr. John Reinhardt	2001	(b)(6)
V. P. of World Wide Pharmaceutical Operations		
Dr. H. Abdou	2582	(b)(6)

G. Persons in the immediate area of the emergency condition shall take appropriate action to limit the extent of the incident with available means to the extent possible, then retreat to a safe location and await assistance.

H. Shift operating personnel, not immediately involved with the incident, report to the Health Physics Office.

5.2.4 General Emergency

A. Person(s) discovering the emergency condition shall immediately notify the Health Physics Office by the most expeditious means available (Tel. 2168, 3158, 2451 or 3721; Intercom 60.)

B. Health Physics personnel or shift supervisors sound the appropriate alarm within the radiopharmaceutical production building and notify the Health Physics Department Head or his designee:

Health Physics Department Head:	Office	Home
E. Truskowski or designee	3158	(b)(6)
L. Gaines	3721	

C. The Health Physics Department Head will notify:

1.	Medical	3033
2.	Fire	3011
3.	Police	2111
4.	Robert Wood Johnson Hospital	201-937-8000, ext. 2222
5.	New Brunswick Police	201-745-5200
6.	North Brunswick Police	201-545-4300

7. Radiopharmaceutical Director or designee:

	Office	Home
G. Thompson or designee,	3076	(b)(6)
K. Sosnowski	3063	
C. Forberg	3068	

8. U.S. Nuclear Regulatory Commission — 301-951-0550
   Head Quarters Operations Center — 301-427-4056, 301-492-8893, 301-427-4259
   a. Identify: "E. R. Squibb & Sons, Inc."
   b. Give Emergency Class (Alert, Unusual event, site or general).
   c. You will be transferred to Region I Duty office.

9. NJ State Department of Environmental Protection, Radioactive Materials Section — 609-292-7172, 609-530-4023

10. N. J. State Police — 609-882-2000
    24 hours ask for "Emergency Management Section"

D. The Radiodiagnostic Director shall notify:

President, Squibb Diagnostics

	Office	Home
Dr. M. Loberg	609-987-1816	(b)(6)

E. The Health Physics Department Head shall notify:

	Office	Home
Director of Quality Productivity/Health Physics		
John Reinhardt	2001	(b)(6)
V. P. of World Wide Pharmaceutical Operations		
Dr. H. Abdou	2582	(b)(6)

F. Persons in the immediate area of the emergency condition shall take appropriate action to limit the extent of the incident with available means, to the extent possible, then retreat to a safe location and await assistance.

5.3 Corrective Actions

5.3.1 Notification of Unusual Event

A. The Emergency Director shall designate personnel to proceed to the scene of the emergency with the necessary equipment to meet the emergency. These persons will evaluate the extent and magnitude of the emergency, determine if radiation hazards exist and report their findings to the Emergency Director.

B. The Emergency Director shall direct actions necessary to bring the emergency under control with the help of the emergency assistance team and/or the designated alternates.

C. Surveys and bioassays for personnel involved with the emergency will be instituted immediately.

5.3.2 Alert Condition

Plant Emergency Director

A. Proceed to and take charge of the Emergency Coordination Center.

B. Determine if the assembly point is in a safe area through the use of portable survey instruments.

C. Evaluate the emergency as quickly as possible, and determine if the incident is causing a release of activity outside the plant which could result in a site emergency.

D. Dispatch monitoring team to the scene of the emergency with the emergency kit to evaluate the extent and magnitude of the emergency and survey the area along the boundary.

E. Direct Radiopharmaceutical Production Supervisors to a check of time card rack and visitors log book to determine what personnel other than the emergency team personnel have not left the plant.

F. Notify the following members of management:

- Radiodiagnostic Manufacturing Department Head
- Squibb Plant Manager
- Diagnostics Quality Control/Distribution Department Head

F. Notify the following members of management:

- Radiodiagnostic Manufacturing Department Head
- Squibb Plant Manager
- Diagnostics Quality Control/Distribution Department Head
- Plant Security Head
- Plant Medical Department Head
- Other personnel as required

G. Set up necessary auxiliary communications (walkie-talkie), if necessary.

H. Establish barricades with Plant Security force at the site boundary gate houses to restrict access to the site.

I. Evaluate the emergency and, as quickly as possible, determine the release of radioactivity. Refer to Addendum V for methodology and parameters used in calculating atmospheric dispersion and dose rates to individuals.

J. If there are injured personnel, notify the senior Medical Representative.

K. Provide a Health Physics representative to accompany the patient(s) to the hospital with the ambulance emergency kit, to maintain radiological controls in the hospital.

L. Supervise collection of emergency data in the Contingency Monitoring Log.

M. Notify Plant Security to institute site industrial emergency and disaster control plan, if necessary.

5.3.4 General Emergency

A. Note the wind direction, instruct security to evacuate onsite personnel, if necessary, through the upwind exits of the site and sound the evacuation alarms.

B. Notify the following members of Squibb Management:

- General Manager Diagnostics Division
- Diagnostics Quality Control and Distribution Manager

E. R. SQUIBB & SONS, INC.

EMERGENCY CALL LIST

Title	Squibb Extension
President, Diagnostics Division	609-987-1816
Dir. Diagnostics Operation & Productivity	3076
Dir. Engineering & Maintenance	3045
Radiopharmaceutical Mfg Dept Head	3063
VP World Wide Pharmaceutical Operations	2582
Health Physics Department Head	3158
Health Physics General Supervisor	3721
Plant Security Head	2101
Director Personnel & Ind Rel	3034
Director Employee Health	2486
Director Ind Hygiene and Safety	2885
Diagnostic Quality Control/Distribution Manager	2361

NOTE: An updated emergency list of home addresses and telephone #'s are maintained by Security and Health Physics.

U.S. Nuclear Regulatory Commission
Head Quarters Operations Center

301-951-0550
301-427-4056
301-492-8893
301-427-4259

a. Identify: "E. R. Squibb & Sons, Inc."
b. Give Emergency Class (Alert, Unusual event, site or general).
c. You will be transferred to Region I Duty office.

If the number of patients require it, the guard will call the North Brunswick Squad and other back-up squads as needed.

If not in the plant the Medical Director or his assistant is to be called.

D. The nurse on duty from 3:00 p.m. to 11:00 p.m. will follow the instructions outlined above.

E. From 11:00 p.m. Friday, until 7:00 a.m. Monday, or anytime when there isn't a nurse or doctor on duty, the guards and first aid groups will follow first aid instructions and assit in getting the ill or injured person to a hospital or doctor.

6.5 Emergency Monitoring Equipment

The following is a list of emergency equipment that will be available for personnel and area monitoring as well as that for assessing the release of radioactive materials into the environment:

6.5.1. Model 22A Portable Scaler Rate Meter with Single Channel Analyzer

This equipment is to be used for immediate assessments of radioactive samples. It is portable and therefore convenient and practical for inplant and out of plant operations.

6.5.2 Eberline "Teletector Survey Monitor"

This equipment is to be used for assessing radiation and high radiation areas. Its detector can be extended approximately ten feet to allow emergency personnel to obtain accurate measurements while minimizing radiation exposures to themselves.

6.5.3 G.M. Portable Survey Meter

This equipment is to be used to detect low level external contamination when monitoring operating personnel.

6.5.4 Two (2) Acceptable and Calibrated Survey Monitors

This equipment will be used for radiation survey measurements during a radiological emergency.

6.5.5 Canberra Auto-Gamma Spectrometer

This equipment will be used for accurate analysis of air,

liquid and vegetation samples collected during a radiation emergency condition.

All equipment is calibrated at least bi-annually. Back up monitoring equipment will be available in the Health Physics operations area and in the Manufacturing storage area. All equipment described will be stored in an emergency cabinet in the control coordination area except for the portable survey monitors and the Canberra Auto-gamma spectrometer. The spectrometer is located in the Health Physics operational office and the survey monitors in the vicinity of the emergency control coordination area.

A meterological station is located in the emergency control coordination area and will be used in emergency conditions to provide pertinenet meteorological information.

The following is a list of equipment which will be stored in the vicinity of the emergency control coordination office:

- Model 22A Portable Scater rate meter with single channel analyzer (1)
- Eberline "teletector survey monitor" (1)
- G. M. Portable Survey Meter (1)
- High range dosimeter (5)
- Area Maps & Overlays (1)
- Walkie Talkie (1)
- Information notebook (1)
- Emergency log book (1)
- Pen and/or pencils (4)
- Felt tip marker (1)
- Coveralls (4 sets)
- Air Sampler Cartridges (filter and charcoal) (10)
- Air Sampler, Battery (1)
- Smear Papers (2 boxes)

ADDENDUM 8
Page 1

Item #11: Waste Management

1. All radioactive waste that is shipped to approved burial sites from E.R. Squibb & Sons is transported by our waste contractor: The NDL Organization of Peekskill, NY (NRC License No. 3112000-2, New York State License No. 12261422, DEC License No. LLNY 3002).

   Radioactive waste is segregated, processed and shipped according to the attached section of E.R. Squibb & Sons Radiation Safety Standard Operating Procedures", Aug. 1988.

2. Liquid waste is either shipped to burial sites via the NDL Organization or released into the sanitary sewer. In areas where there is release into the sanitary sewer:

   a. all releases are in conformance with 10CFR 20.303,
   b. all material is appropriately assayed before release. This includes aliquots of holding tank contents or small volumes of research material, and
   c. all assay results are recorded by Health Physics.

3. All releases to the environment are in conformance to 10CFR 20.106. Ventillation systems exhausting potentially volatile radioactive material are monitored for environmental release. At present this includes the exhaust stack of the manufacturing facility and the exhaust stacks from the iodination laboratory and corresponding laboratory. These systems are described in Item 9 of this application. An additional monitored exhaust system services the sterility testing suite in which samples of I-131 product are tested. All assays are performed with NBS traceable standards.

   Our current gaseous effluent concentration at the exit port of the stack of the manufacturing facility has been approximately 25% of MPC (Maximum Permissible Concentration) specified in 10CFR Part 20.

   Our action level is 75% MPC averaged over one week at which time the following corrective action is taken:

   a. Health Physics conducts an investigation and performs surveys to determine the source and/or cause of the air concentrations.

   b. Individual air systems as well as the stack effluent will be closely monitored and filter efficiency evaluations will be made.

c. Air filter system(s) which are found to be contributing a major portion of the airborne radioactivity to the main discharge ducts will be shut down and their exhaust air will be diverted to the auxiliary standby system while filter changes are being made.

d. Filter changes will be made until gaseous effluent releases measured in the breach of the stack are maintained below our action level.

4. There is no treatment or disposal by incineration of any material considered to be radioactive.

5. Disposal without regard to the radioactivity of H-3 and C-14 is in conformance with 10CFR 20.306.

6. Radioactive material with a physical half-life of less than 65 days is held for decay-in-storage before disposal in ordinary trash provided:

a. radioactive waste to be disposed of in this manner is held for decay for a minimum of 10 half-lives.

b. before disposal as normal waste, radioactive waste is surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels are removed or obliterated.

E.R. Squibb & Sons Radiation Safety Standard Operating Procedures
August, 1988

Radioactive Waste Categorizing and Disposal Procedures:

I. PURPOSE - To assure that all radioactive waste materials generated in the manufacturing, testing and research areas are properly packaged, labelled and controlled in accordance with regulations and guidelines prescribed by the Nuclear Regulatory Commission, the Department of Transportation, burial sites and the waste contractor.

II. RESPONSIBILITY - It is the responsibility of all individuals using radioactive materials to be thoroughly familiar with the standard operating procedures regarding the proper disposition of radioactive waste. It shall be the responsibility of these individuals to segregate, label, and monitor radioactive waste. The individual shall certify that the waste does not contain "RCRA" waste (see page 63).

III. GENERAL PROCEDURES

A. Storage

1. There will be central locations in New Brunswick where dry waste will be stored and packaged for transfer to the burial sites. Waste materials generated from R&D and Radiopharmaceutical Mfg. service departments operating in buildings other than Building #124 will be delivered to central locations convenient to their operations. Radioactive waste from Building #124 will be stored in the waste storage area, which is Building #122. R&D will provide the manpower needed to handle the dry waste in their centralized locations and Radiopharmaceutical Manufacturing will assign a "barn" person to assume this responsibility in Building #122.

2. All radioactive waste must be sealed in plastic 4 mil liners and delivered in 5 gallon pails to these waste areas and must be properly identified with isotope, amounts of radioactivity and the date of assay. Radioactive waste will not be accepted unless the type and category of radioactive waste is affixed to the container. In addition, the container shall indicate the radiation levels measured on its surface and shall identify the department from which it was generated. Radiation levels should not exceed 100 mR/hr at the surface of these 5 gallon pails.

3. Each radioactive waste container will have a Radioactive Disposal Record Card attached. Each time radioactive waste is transferred from a 5 gallon container into 30 or 55 gallon drums, an entry which describes the isotope, approximate activity in millicuries (mCi), date of assay, and other required information, must be logged on a separate Radioactive Disposal Record card to the drum. (See addendum #8).

4. Every effort should be made to allow shortlived isotopes (less than 65 days) to decay for approximately 10 half-lives before packaging. Strontium (Sr-82, Sr-85) should be segregated from other isotopes because of its relatively long half-life and radioconcentration.

5. All properly prepared absorbed liquids and biological waste containers will be picked up by the waste collection contractor in each department or as specified by the Health Physics Department. These are not to be transferred to the central waste locations unless authorized by Health Physics.

6. Radioactive waste recepticles cannot contain radioactive RCRA waste or RCRA hazardous waste mixed with radioactive waste.

B. Disposal of Waste

1. When a 55 gallon drum is filled, the responsible waste area person must perform a radiation survey. The radiation dose rate must not exceed 200 mR/hr on the surface of the drum and 10 mR/hr at one meter from any point on the drum. If the drum exceeds these limits, the drum must be allowed to decay before shipment. This procedure must be verified by a responsible supervisor or Health Physics.

2. If the drum reading is below these radiation limits, the plastic liner must then be sealed.

3. The amount of each isotope entered on the Radioactive Disposal Record Card must be totalled and decayed to the date of shipment by the responsible supervisor. A copy of the Radioactive Disposal Record should be kept on file along with a sheet verifying that the drum does <u>NOT</u> contain RCRA waste.

4. The responsible waste person shall check the drum lid to insure the gasket is functional, secure the lid with a retainer ring and tighten the bolt. In addition, he shall determine the radiation dose at one meter and at the surface of the drum. If the surface reading is over 200 mR/hr or the one meter reading is over 10 mR/hr, the drum must be repacked or placed back in the storage area until the radiation readings are below these levels. Health Physics should verify these measurements.

5. Based on the surface and one meter readings (known as the Transport Index or TI), the barn person will select one of the following three types of DOT labels:

	White-I (mR/hr)	Yellow-II (mR/hr)	Yellow-III (mR/hr)
Surface Reading	< 0.5	< 50	< 200
Transport Index	0	< 1	< 10

The "barn" person shall prepare two DOT labels of the proper category. Record the TI in the proper space on the label. He shall record each radioisotope on the DOT label of the "Contents" line and the total activity of each radionuclides on the "Number of Curics" line, decayed to the time of shipment. Apply the DOT labels on opposite sides of the container (180 degrees apart). Health Physics should verify the selection of labels and the TI readings.

6. Prior to acceptance by the waste contractor, each drum must also be labelled to indicate the proper waste category (e.g. D, V, L, SR or R), U.S. NRC waste class (class "A" only), and "non-stable." (See addendum #9 for limits).

7. The barn person shall weigh each container. If the weight is in excess of 110 lbs (50 kg), it must have its gross weight plainly and durably marked on the outside of the package.

8. The barn person shall place a security seal bearing Squibb's code, name or logo identification.

9. The radioactive manifest and disposal receipt must be filled out completely by the supervisor of the waste storage area (see attached examples). These forms should be completed prior to the arrival of the waste contractor's driver-service man who will verify the container numbers, count, size, category and label compliance.

10. Category SR liquid scintillation media disposal must be accompanied by a Hazardous Waste Manifest in addition to a Radioactive Waste Manifest. Forms are supplied by our waste contractor.

11. Upon verification of proper completion of the radioactive manifest and disposal receipt, including the required signature, the waste representative will sign the manifest accepting the waste on the contractor's behalf. Within one week of the acceptance date, a verification copy of the manifest will be returned to the generator's representative responsible for radioactive waste. This will signify the receipt of the waste at the waste contractor's facility. Should the verification copy not be received within 20 days of the contractor's pickup, an investigation must be performed (according to 10 CFR 20.311L).

****
* *
* The waste contractor will not accept any waste *
* without the paperwork completed and the con- *
* tainers properly labelled by the generator. *
* *
****

IV. CONTAMINATION SURVEY - Health Physics shall perform a wipe test to ensure that there is no significant removable contamination on the exterior of the container. Removable (nonfixed) contamination, for a wipe(s) of a major portion of the container (assume 300 sq. cm.), must not be over the following limits:

	Maximum Permissible Level	
Contaminant	uCi/sq. cm.	dpm/sq. cm.
Beta-gamma emitting radionuclides; all radionuclides with half-lives less than ten days.....	1 E-05	22
All other Alpha emitting nuclides..	1 E-06	2.2

V. AUTHORIZED RADIONUCLIDES - DOT CONTAINER LIMITS

A. Except as noted below, the waste contractor will accept radionuclides with atomic numbers 1 to 104 inclusive. The single radionuclide activity for type A container is the A2 value listed on the back of the Radioactive Manifest and Disposal Sheet (49 CFR 173.435). For mixed nuclides where the identity and activity of each is known, the activity of each radionuclide R1,R2,...Rn must be such that F1+F2+...Fn is not greater than unity when:

$$F1 = \frac{\text{Total activity of R1}}{A2(R1)} \qquad (A2 = 0.4 \text{ Ci.})$$

$$F2 = \frac{\text{Total activity of R2}}{A2(R2)}$$

$$Fn = \frac{\text{Total activity of Rn}}{A2(Rn)}$$

B. Exceptions for radioactive waste not being accepted by waste contractor:

1. The identity or activity is unknown.

2. Radionuclides in excess of the A2 limit or 1 Ci., whichever is less.

3. Radioactive waste in Class B or C.

4. Any amount of Radium-226.

5. Gaseous radioactive material.

C. Chemical form:

1. No amount or mixture of RCRA, chemically hazardous waste will be accepted.

2. Chelating agents (eg. EDTA, DTPA, citric acid, carbolic acid, etc.) can not constitute more than 0.10% of the radioactive waste by weight. The weight percentage must be estimated and recorded on the manifest.

VI. CATEGORIZATION OF RADIOACTIVE WASTE

A. Category D (Dry Waste)

1. Definition

Solid dry waste with no absorbed or pourable liquid of any kind, no animal carcasses and no organic solvent contamination. Dry waste may include aqueous solutions properly solidified in cement or other approved media. Also see page 74 for "Handling Procedure for Radioactive Dry Waste to be Compacted."

2. Category D Container

This category CANNOT contain any RCRA waste (ex: lead). Dry waste may only be placed in DOT approved 5, 30 or 55 gallon containers, lined with a clear 4 mil plastic liner. As materials are added to the drum, the isotope, amount of activity (in mCi) and date of entry must be recorded on an inventory sheet. The inventory sheet should also include any other information that describes the waste in the container including certification that the drum contains NO RCRA waste (class, chemical form, category, etc.).

B. Category SR (Liquid Scintillation Vials)

1. Definition

a. Waste consisting entirely of vials containing media used for liquid scintillation counting. There must be no other radioactive waste of any kind.

b. To dispose of scintillation media that contains deregulated quantities of Carbon 14 (C-14) and tritium (H-3) (less than .05 uCi/g) only, see Squibb's Health & Safety Manual procedure SNB#16 "Hazardous Waste Management".

c. The radioactivity requirements of this category is 0.05 uCi or less per gram of medium of C-14 and/or H-3 and/or 300 uCi or less per gram of medium of P-32, S-35, Ca-45, Cr-51, Fe-59, I-125, Co-57, Na-22, Zn-65, Ru-86, Ga-67, In-111, Cl-36, and/or Hg-203.

d. Plastic and glass vials must not be in the same container.

e. For any other isotope or greater quantities of these isotopes, notify Health Physics before generating this type of radioactive waste.

2. Category SR Container

a. Liquid scintillation vials may only be placed in approved DOT containers with a 4 mil liner with:

1. 12 inches of approved absorbent in a 55 gallon drum.

2. 9 inches of approved absorbent in a 30 gallon drum.

3. 6 inches of approved absorbent in a 5 gallon drum.

b. Scintillation vials may be added according to the following formulae, but in no case beyond one inch from top:

55 gallon.....Number of vials allowed = $\frac{17600}{X}$

30 gallon.....Number of vials allowed = $\frac{8680}{X}$

5 gallon.....Number of vials allowed = $\frac{2100}{X}$

X = amount of liquid/vial in cc.

c. One half of the required absorbant shall be in the liner and one half in the drum.

d. Scintillation and only scintillation vials may be placed in the 4 mil liner.

e. The container must be properly labelled and the liner sealed.

f. Category SR requires a hazardous waste manifest in addition to a radioactive waste manifest.

C. Category L (Absorbed Liquid)

1. Definition

Liquid waste with pH between 6 and 9 and properly absorbed in an approved absorbent. Liquid waste may not include scintillation liquid or ANY OTHER RCRA waste, but may include excreta. There must be no other radioactive waste of any kind.

2. Category L Container

a. Approved DOT outer containers with approved inner containers that are filled with approved absorbent.

b. Sufficient absorbent must be added to outer container to provide at least a total of two times the amount of absorbent necessary to absorb the liquid, taking into account the absorbent already in the inner container.

c. No liquid is allowed in the absorbent between the inner and outer containers.

d. The maximum permissible amount of liquid allowed cannot exceed the following volume for the containers listed and a record of additions must be kept with the drum.

1. 55 gallon overpack with a 30 gallon inner container -- 37.85 liters (10 gallons).

2. 30 gallon overpack with a 5 gallon inner container -- 12 liters.

3. 5 gallon overpack (available through waste contractor only) -- 1.5 liters.

e. The outside container must be legibly marked "THIS END UP" to indicate the upward position of the inside packaging.

f. The inner containers must be surrounded by approved absorbents.

D. Category R (Biological Radioactive Waste)

1. Definition

Waste consisting entirely of biological material including solid excreta, pads used in trays to collect excreta and animal carcasses. There must be NO radioactive waste of any other category or RCRA waste.

2. Category R Container

a. DOT specification metal 55 gallon outer container with DOT specification 30 gallon inner container with at least 4" of approved absorbent in the bottom of the outer container.

b. 4-mil liner in inner container.

c. Biological material shall be placed in the inner container and thoroughly layered in a ratio of 30 parts biological material to at least 1 part slaked lime and 10 parts approved absorbent. The addition of formaldehyde is strictly prohibited. Preservative must be in direct contact with carcasses.

d. The top 6 inches is to be filled with 2 inches of slaked lime then 4 inches of approved absorbent.

e. Close the liner and remove as much of the entrapped air as possible. Twist the top and seal the liner with tape, tying or heat. Check to ensure that the gasket of the lid is NOT damaged before sealing the inner container with closing tool or ring and bolt.

f. Seal inner container with closing tool or ring and bolt.

g. Entirely surround inner container, including bottom, with approved absorbent and fill to the top of the drum and seal outer container.

h. Record date of sealing on Category R label.

i. The presence of etiologic agents requires container labelling pursuant to 49 CFR 173.388.

E. Category V (Small vials only)

1. Definition

a. Liquid waste in vials or units not exceeding 50 ml. There must be no scintillation vials. Waste in this category may include biological waste (excluding animal carcasses). Pathogenic/infectious material must be rendered non-viable prior to placement in container.

b. No amount of RCRA, chemically hazardous, waste will be accepted.

2. Category V Container

a. DOT specification 55 gallon outer container with 15 gallons of approved absorbent. Place approved 30 gallon inner container, filled to 9 inches from bottom with approved absorbent. The 30 gallon inner container must contain a 4 mil plastic liner.

b. Vials may be added according to the formula but in no case beyond one inch from top.

$$\text{Number of vials allowed} = \frac{21460}{X}$$

where X = amount in cc's of liquid/vial.

Other allowed waste may be included <u>but no absorbent may be removed</u>.

c. Approved absorbent to completely fill space between inner and outer containers.

d. No liquid or other material is allowed in the space between containers.

e. The outside container must be legibly marked "THIS END UP" to indicate the upward position of the inside packaging.

ADDENDUM #8

The NDL Organization, Inc.

Instructions For Completing the NDL Radioactive Manifest And Disposal Receipt:

General

1. It is your decision as to whether only 1 manifest (page 1 plus necessary contination sheets) shall be used for all waste pick ups at an entire facility or 1 manifest for each lab or waste storage location services. Whatever is convenient for your record keeping purposes is acceptable to us.

2. PLEASE USE A BALL POINT PEN (NO PENCILS OR SOFT TIP PENS PLEASE) WHEN FILLING OUT THE MANIFEST AND PRESS HARD. YOU ARE MAKING FIVE CARBON COPIES!

3. Do not separate manifest copies - This is to be done by NDL Driver/Service man.

Specific

1. Show your NDL-assigned Customer number. The number may be obtained from any recent invoice or by contacting the NDL office.

2. The NDL representative will write in the date of actual pick up.

3. It is important that the telephone number of the person to be contacted regarding the waste listed on the manifest be shown.

4. In addition to the name and address of the waste generating facility, the lab or other location such as a waste room where the waste was picked up should be shown.

5. Show total number of containers shipped, according to proper DOT shipping name. The shipping name on container must match name on manifest. If in doubt, check the waste container. For use of shipping names other than radioactive material NOS, contact NDL first.

6. For NDL use.

7. The drum container number if the number shown on Radioactive Waste Disposal Record (blue card). Do not supply

ADDENDUM #8 (continued)

your own numbers. Should the card be missing, request a new one from the NDL office or the NDL Driver/Service man.

8. Show container size in gallons for pails and drums and cubic feet for wooden crates.

9. Show NDL category. Refer to Waste Acceptance Criteria or back of manifest.

10. Show best estimate of container weight. If more than 110 lbs., mark on container lid with indelible marker.

11. Show solid, liquid. For gas contact NDL office first.

    a. Show whether plastic or glass for category SR.

12. Describe waste, typical waste descriptions are shown.

13. Show none if no absorbent or solidification agent was used. For NDL-supplied Vermiculite show RADLITE. If NDL cement bottles were used to solidify liquids, show cement bottle and list Portland cement as a part of principal chemical form.

14. Show only the principal chemical form of the waste. Do not be too specific. Some acceptable typical entries are shown. For chelating agents exceeding 0.1% by weight, show agent and percent by weight.

15. Show N for nonstable unless waste complies with all NRC requirements for stable waste (refer to 10CFR61.56b).

16. Show Class A if Class A limits are not exceeded (refer to Waste Acceptance Criteria). Contact NDL office before listing Class B or C waste.

17. List each radionuclide in each container with one nuclide per line.

18. Show activity in millicuries. Do not use arrows, ditto marks or less than. Show a number for every radionuclide entry.

19. Show whether the DOT A1 or A2 value was used to determine container limits. (Refer to back of manifest) Do not use A1 value without proper consultation with NDL. For mixtures of more than one nuclide in a container, use the sum of fractions rule to determine compliance.

ADDENDUM #8 (continued)

20. Show quantity in grams of Special Nuclear Material (SNM) or kilograms of source material. For material defined as fissile, contact NDL office.

21. Show highest reading at surface and at one meter from each container. These readings will be confirmed by the NDL representative prior to acceptance.

22. Show which DOT labels were applied to each container. For limited quantity or Low Specific Activity, show L.Q. or L.S.A.

23. Show the maximum removable activity on containers listed. Results must be less than DOT limits. Show NA where there are no alpha emitters.

24. Name of representative or agent of waste generator taking responsibility for certifying waste.

25. For NDL use at time of pick up.

26. Do not write in this space. Within seven days of acceptance a signed verification copy of the manifest will be returned to the customer/generator.

27. A continuation sheet shall be used after page one has been completely filled in. Show name and customer number on each continuation sheet used.

28. Copy manifest number from page one on each continuation sheet used.

29. Show maximum removable activity on drums listed on continuation sheet. See Item #23.

30. Each continuation sheet must be signed as specified in Items #24 and 25. At time of pick up, after NDL representative verifies certain entrees on all copies of manifest, determines acceptability of radionuclides and activity and confirms radiation levels and proper labelling, the customer representative will be given copy two of each page of the manifest.

31. No amount of RCRA, chemically hazardous, waste will be accepted.

RADIOACTIVE WASTE ADDENDM # 8

PLACE CATEGORY LABEL HERE

NUCLEAR DIAGNOSTIC LABORATORIES

PEEKSKILL, N.Y. 10566
RADIOACTIVE DISPOSAL SERVICE

N D L

E 483

RADIOACTIVE DISPOSAL RECORD

The following information to be filled in by customer:

ISOTOPE	CHEMICAL FORM	mCi	DATE

Removable activity on surface of container less than 22 dpm/cm^2:

yes ☐ no ☐

Waste category:

D W L S R V

DO NOT WRITE BELOW THIS LINE – FOR NDL USE ONLY.

Container Survey Results:

mr/hr at surface _____

mr/hr at 3 feet _____

Container Size:

55 gal. ☐

30 gal. ☐

5 gal. ☐

Other _____

Date Received _____

Weight _____

E 483

CLASS A WASTE LIMITS

Radionuclide[1]	10CFR61.55		Dry Solid Waste Container Limit[2] (Categories D, W & R[3]) in mCi			Liquid Waste[5] Concentration Limit (Categories L,S & V) μCi/ml
	Listed in Table 1	Concentration limit Ci/m³	55 Gal[4]	30 Gal[4]	5 Gal[4]	
C-14	1	0.8	166.557	90.849	15.141	0.8
C-14 in activated metal	1	8.0	1665.576	908.496	151.416	8.0
Ni-59 in activated metal	1	22.0	45803.34	2498.364	416.394	22.0
Nb-94 in activated metal	1	0.02	4.163	2.271	0.378	0.02
Tc-99	1	0.3	62.459	34.068	5.678	0.3
I-129	1	0.008	1.665	0.908	0.151	0.008
Sum of Trans-uranics with T½ > 5 years	1	10 nCi/gm				
Pu-241	1	350 nCi/gm				
Cm-242	1	2000 nCi/gm				
Ra-226	(6)	(6)				
Sum of all radionuclides w T½ < 5 years	2	700.0	145.737 Ci	79.493 Ci	13.248 Ci	700.0
H-3	2	40.0	8327.88	4542.48	757.08	40.0
Co-60	2	700.0	145.737 Ci	79.493 Ci	13.248 Ci	700.0
Ni-63	2	3.5	728.689	397.467	66.244	3.5
Ni-63 in activated metal	2	35.0	7286.895	3974.67	662.445	35.0
Sr-90	2	0.04	8.327	4.542	0.757	0.04
Cs-137	2	1.0	208.197	113.562	18.927	1.0

(1)

RADIOACTIVE WASTE ADDENDUM # 1

Continuation Sheet (27)

Customer Generator: XYZ Institute

Customer No: 106

Manifest No:	30803	page 2 of 2

(28)

Container Number	Container Volume (cu ft)	Waste Category	Container Weight (lbs)	Physical Form	Waste Description	Solidification or Absorbent Media	Principal Chemical Form (Show % Chelating Agent)	Stable/Unstable	Waste Class	Radionuclide	Activity (mCi)	A1/A2	Shield Source	Radiation Level mR/hr Surface	Radiation Level mR/hr at 1m	D.O.T. Label Used
[illegible]	30	S	80	liquid	Scint Vials	[illegible]	Toluene	N	A	H-3	1.0	A2	NA	.02	.02	Radioactive - white I
—										C-14	0.5	A2				Radioactive -
—										S-35	0.001	A2				Radioactive -
[illegible]	55	N	225	Solid	Animal Carc.	[illegible]	Tissue & lime	N	A	C-14	5.0	A2	NA	.02	.02	Radioactive - white I
[illegible]	30	W	56	Solid	gears	None	Sealed Sources	N	A	Cs-137	100.0	A1	NA	450	6.5	Radioactive - yellow II
[illegible]	55	V	250	liquid	vials	[illegible]	[illegible]	N	A	C-14	1.4	A2	NA	.02	.02	Radioactive - white I
[illegible]	55	L	250	liquid	absorbed	[illegible]	[illegible]	N	A	Th-nat	0.22	A2	[illegible]	.6	.04	Radioactive - yellow II
[illegible]	30	W	150	Solid	Sealed Source	None	Special Form	N	A	Co-60	1.00	A1	NA	.1	.02	Radioactive - white I
																Radioactive -
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(27)

The above containers have been checked for removable contamination; Results: Alpha ≤ 2.2 dpm/cm² Beta Gamma ≤ 22.0 dpm/cm²

*See Other Side

I, ______ (30) ______ (please print), as an authorized agent for above customer generator, hereby transfer title and/or ownership of the above named materials to The HDL ORGANIZATION and disclaim all rights to recover said materials. I certify that the above named materials are packaged and category labelled according to the HDL ORGANIZATION'S current Radioactive Waste Acceptance Criteria. I further certify that the above named materials are properly classified, described, packaged, marked and labelled and are in proper condition for transportation according to applicable regulations of the Department of Transportation.

Signature ______ (30) ______

Q/A COPY

I, ______ (30) ______ (please print), as an authorized agent for The HDL ORGANIZATION declare that the above named materials were received by me on the date shown on page 1 of this manifest. I further certify, based on customer generator certification as to contents and packaging, that the above named materials are properly classified, described, packaged, marked and labelled and are in proper condition for transportation according to applicable regulations of the Department of Transportation.

Signature: ______ (30) ______

(26)

EXHIBIT L

Radioactive Waste License Nos:
SUNC 31-12000-2
NYS 1228-1422

RADIOACTIVE WASTE ADDENDUM # 1

NDL Organization, Inc.

post office box 701 (914) 737 1330 peekskill new york 10566

Manifest No: 30803 page 1 of 2

Name of Generator XYZ Institute (2) Customer No 106 Date 12/27/83 (1)

Address 454 Main St Smithbury NY 10561 Telephone No 914 555-1000 x113

Attn/Bldg No R&D Lab - 201 (3)

RADIOACTIVE MANIFEST and DISPOSAL RECEIPT

Shipper: The NDL Organization Inc. Address: Peekskill, N.Y. | Via: The NDL Organization Inc. Vehicle No Y- (6)

Total Quantity Shipped

- Containers — Radioactive Material, L S A, N O S — Radioactive Material — ID# 2912
- 10 Containers — Radioactive Material, N O S — Radioactive Material — ID# 2982
- Containers — Radioactive Material, Special Form, N O S — Radioactive Material — ID# 2974
- Containers — Radioactive Material, Limited Quantity, N O S — Radioactive Material — ID# 2910

(4) (5) (8) (9) (10) (11) (12) (13) (14) (15) (16) (17) (18) (19) (20) (21) (22) (23)

Container Number	Container Volume cu ft	NRC Waste Category	Container Weight Net	Physical Form	Waste Description	Solidification or Treatment Media	Principal Chemical Form (Show % Chelating Agent if any)	Stabilized (Y/N)	Waste Class	Radiation Rate	Activity (mCi)	A1/A2	Special Source (Y/N)	Radiation Level mR/hr Surface	Radiation Level mR/hr @ 1m	DOT Label Used
1111	55	B	175	Solid	Lab trash	none	paper, plastic, glass	N	A	0.05	10	A2	NA	.02	.02	Radioactive - [illegible]
1112	30	B	150	Solid	Soil	none	Soil	N	A	0.01	90.0	A2	NA	.02	.02	Radioactive - [illegible]
1163	5	B	20	liquid	absorbed	cellulose	Soil Material	N	A	0.001	0.5	A2	NA	.02	.02	Radioactive - [illegible]
										0.057	0.5	A2				Radioactive -
1188	55	B	175	Solid	solidified by cement	cement	solidified aqueous lab trash	N	A	0.3	15.0	A2	NA	.02	.02	Radioactive - [illegible]
					lab trash	cellite	paper, plastic, glass									Radioactive -
1251	5	B	17	Solid	lab trash	none	paper, glass, metal	N	A	0.04	1.0	A2	NA	.02	.02	Radioactive - [illegible]
																Radioactive -
																Radioactive -
																Radioactive -
																Radioactive -
																Radioactive -
																Radioactive -
																Radioactive -

(24) (25) (26) (27)

The above containers have been checked for removable contamination. Results: Alpha N/A dpm/cm² Beta gamma < 200 dpm/cm²

I, Peter Soto (24), as an authorized agent for above listed generator, hereby transfer title and/or ownership of the above named waste to the NDL ORGANIZATION and declare all rights to recover said waste. I certify that the above named materials are packaged and category listed according to the NDL ORGANIZATIONS' Current Radioactive Waste Licensure Criteria. I further certify that the above named materials are properly classified, described, packaged, marked and labelled and are in proper condition for transportation according to applicable regulations of the Department of Transportation.

Signature: (24)

I, (25), as an authorized agent for The NDL ORGANIZATION declare that the above named materials were received by me on the date shown above. I further certify, based on customer generator certification as to contents and packaging, that the above named materials are properly classified, described, packaged, marked and labelled and are in proper condition for transportation according to applicable regulations of the Department of Transportation.

Signature: (25)

(26)

11113613

ADDENDUM #3

ML 10

OFFICIAL RECORD COPY

MAR 01 1989

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03211
STATUS CODE: 2
FEE CATEGORY: 3A
EXP. DATE: 19890331
FEE COMMENTS: ----------

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: E. R. SQUIBB & SONS, INC.
RECEIVED DATE: 900604
DOCKET NO: 3005222
CONTROL NO.: 112622
LICENSE NO.: 29-00139-02
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: $120.00
CHECK NO.: 453816

3. COMMENTS

SIGNED [signature]
DATE 6-8-90

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED

1. FEE CATEGORY AND AMOUNT: 3A (120)

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ✓
RENEWAL ----------
LICENSE ----------

3. OTHER ----------

SIGNED [signature]
DATE 6/11/90

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03211
STATUS CODE: 2
FEE CATEGORY: 3A
EXP. DATE: 19890331
FEE COMMENTS: _____

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: E. R. SQUIBB & SONS, INC.
RECEIVED DATE: 890301
DOCKET NO: 3005222
CONTROL NO.: 110363
LICENSE NO.: 29-00139-02
ACTION TYPE: RENEWAL

2. FEE ATTACHED
AMOUNT: $700.00
CHECK NO.: 320496

3. COMMENTS

SIGNED R. F. Brown
DATE 89-03-02

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED / _

1. FEE CATEGORY AND AMOUNT: 3A ($700)

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT _____
RENEWAL ✓
LICENSE _____

3. OTHER _____
_____

SIGNED [illegible]
DATE 3/8/89

VOID SHEET

TO: License Fee Management Branch

FROM: REGION I

SUBJECT: VOIDED APPLICATION

Control Number: 112622

Applicant: E.R. Squibb + Sons, Inc.

Date Voided: 29 JUNE 1990

Reason for Void: ACTION IS AN RESPONSE TO A DEFICIENCY LETTER - DATED 23 FEBRUARY 1990. THIS IS NOT A NEW ACTION.

EMW 6-29-90
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

Refund Authorized and processed

No Refund Due

Fee Exempt or Fee Not Required

Comments: Site Review -- See attached new information/request 5/17/90 Letter

Log completed

Processed by:

OFFICIAL RECORD COPY ML 10