MATERIALS LICENSE

Amendment No. 77

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, 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. 2. P.O. Box 191 New Brunswick, New Jersey 08903	In accordance with letter dated July 12, 1988, 3. License number 29-00139-02 is amended in its entirety to read as follows: 4. Expiration date March 31, 1989 (extended) 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. 1-83 inclusive, except Strontium 90	A. Any	A. 5 curies of each radionuclide, with a total possession limit of 1000 curies
B. Iodine 131	B. Any	B. 150 curies
C. Molybdenum 99/ Technetium 99m	C. Any	C. 2000 curies
D. Any byproduct material with Atomic Nos. 1-83 inclusive, except Strontium 90	D. Any	D. 200 millicuries of each radionuclide with a total possession limit of 5 curies
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. Nickel 63	H. Plated sources in detector cells	H. Not to exceed 15 millicuries per source
I. Any byproduct with Atomic Nos. 1-83 inclusive, except Strontium 90	I. Any	I. 10 millicuries of each radionuclide, with a total possession limit of 1 curie
J. Any byproduct material listed in Schedule B, 10 CFR 30.71	J. Any radioimmunoassay kit	J. Not to exceed limits specified for each radionuclide in Schedule B, 10 CFR 30.71

9. Authorized use

A., B., and C. (1) Research and development as defined in Section 30.4(q) of 10 CFR 30.
(2) For possession use and processing incident to the manufacture of radiochemicals and radiopharmaceuticals.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 29-00139-02
Docket or Reference number 030-05222
Amendment No. 77

(9. Continued)

(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 I. Research and development as defined in Section 30.4(q) of 10 CFR 30.
J. For demonstration by sales personnel at customer's facilities.

CONDITIONS

10. A. Licensed material in Items 6.A., B., C. and H. shall only be used at licensee's facilities at Rt. 1, North Brunswick, New Jersey.

B. Licensed material in Items 6.D., E., F., G. and H. shall only be used at licensee's facilities in Lawrenceville, New Jersey and 675 College Road East, Princeton Forrestal Center, Plainsboro, New Jersey.

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

D. Licensed material in Item 6.J. may be demonstrated at temporary job sites of the licensee anywhere in the United States where the Nuclear Regulatory Commission maintain jurisdiction for regulating the use of byproduct material.

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 Edward J. Truskowski.

12. A(1) Each sealed source or detector cell acquired from another person and containing licensed material, other than hydrogen 3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transferor indicating that a test has been made within 6 months before the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting materials or 10 microcuries or less of alpha emitting material.

(3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage before any use or transfer to another person unless they have been leak tested within 6 months before the date of use or transfer.

(12. Continued) CONDITIONS

B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.

C. Each sealed source or detector cell containing licensed material, other than hydrogen 3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months.

D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A 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, describing the equipment involved, the test results, and the corrective action taken.

13. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), of 10 CFR Part 20, 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 without a color requirement.

14. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Celsius.

15. Detector cells containing scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 325 degrees Celsius.

(Continued) CONDITIONS

16. 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 2 years from the date of each inventory.

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

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

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

20. This license does not authorize the distribution of byproduct material for medical use under general license pursuant to Paragraph 35.31, 10 CFR 35.

21. This license does not authorize the commercial distribution of exempt quantities of licensed material pursuant to Section 30.18, 10 CFR 30, and Section 32.18, 10 CFR 32.

22. The licensee shall maintain, and execute the response measures of his Radiological Contingency Plan submitted to the Commission on June 29, 1981, as revised on December 4, 1981, March 17, 1982, May 27, 1983, April 3, 1985, August 6, 1985, April 1, 1986, June 12, 1986, June 15, 1987, July 12, 1988 and February 27, 1989. The licensee shall also maintain implementing procedures for his Radiological Contingency Plan as necessary to implement the Plan. The licensee shall make no change in his Radiological 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 Contingency Plan without prior Commission approval if the changes do not decrease the response effectiveness of the Plan. The licensee shall maintain records of changes that are made to the Plan without prior approval for a period of two years from the date of the change and shall furnish the Chief, Material Licensing Branch, Division of Fuel Cycle and Material Safety, NMSS, U.S. Nuclear Regulatory Commission, Washington, D.C., 20555, and the appropriate NRC Regional office specified in Appendix D of 10 CFR Part 20, a report containing a description of each change within six months after the change is made.

23. The licensee is authorized 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 29-00139-02

Docket or Reference number: 030-05222

Amendment No. 77

(Continued) CONDITIONS

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

A. Letter dated June 29, 1981
B. Letter dated December 4, 1981
C. Letter dated March 17, 1982
D. Letter dated June 22, 1982
E. Letter dated December 15, 1982
F. Application dated May 17, 1983
G. Letter dated May 27, 1983
H. Letter dated June 6, 1983
I. Letter dated July 11, 1983
J. Letter dated October 17, 1983
K. Letter dated December 14, 1983
L. Letter dated February 17, 1984
M. Letter dated September 10, 1984
N. Letter dated February 7, 1985
O. Letter dated April 3, 1985
P. Letter dated July 5, 1985
Q. Two letters dated August 5, 1985
R. Letter dated August 6, 1985
S. Letter dated December 4, 1985
T. Letter dated February 24, 1986
U. Letter dated April 1, 1986
V. Letter dated June 12, 1986
W. Letter dated July 29, 1986
X. Letter dated December 1, 1986
Y. Letter dated December 16, 1986
Z. Two letters dated February 16, 1987
AA. Letter dated June 15, 1987
BB. Letter dated January 22, 1988
CC. Letter dated September 26, 1988
DD. Letter dated November 21, 1988
EE. Letter dated December 27, 1988

For the U.S. Nuclear Regulatory Commission
Original Signed By:
Francis M. Costello

Date APR 13 1989

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

APR 13 1989

License No. 29-00139-02
Docket No. 030-05222
Control No. 109258

E. R. Squibb and Sons, Inc.
ATTN: Edward J. Truskowski
Radiation Safety Officer
P.O. Box 191
New Brunswick, New Jersey 08903

Gentlemen:

Please find enclosed an amendment to 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) 337-5239, 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.

~~OFFICIAL RECORD COPY~~ ML 29-00139-02/LTR A - 0001.0.0
03/30/89

ML 10

APR 10 1989

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

Sincerely,

Original Signed by:
Francis M. Costello

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

Enclosures:
1. Amendment No. 77
2. Requirements for Materials Licensees

RBP
DRSS:RI
Provencher/tlm
04/6/89

FMC
DRSS:RI
Kinneman
04/12/89

OFFICIAL RECORD COPY ML 29-00139-02/LTR A - 0002.0.0
03/30/89

CONVERSATION RECORD

TIME 9:00 | DATE 20 Mar 89

TYPE: ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE ☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Ed Truskowski	ER Squibb	201 519-2451

ROUTING

NAME/SYMBOL	INT

SUBJECT: Call Re: Changes to Radiological Contingency Plan.

SUMMARY

Mr. Truskowski indicated that changes to the RCP were made, as per our discussion on 6 Jan 89, and incorporated in the license renewal application dtd 27 February 1989.

ACTION REQUIRED

Finish action

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
R. Powers	R. Powers	20 Mar 89

ACTION TAKEN

~~"OFFICIAL RECORD COPY"~~ ML 10

SIGNATURE	TITLE	DATE

109258

CONVERSATION RECORD

TIME: 11[illegible]a | DATE: 6 Jan '89

TYPE: ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE ☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Ed Truskowski, RSO	E.R. SQUIBB	(201) 519-2451

ROUTING

NAME/SYMBOL	INT

SUBJECT: Discussion of changes to Radiological Contingency Plan dtd 7/12/88.

SUMMARY: Mr. Truskowsky, the newly designated RSO for SQUIBB, and I discussed several questions and comments I had during my review of their update to the RCP. The changes were of minor significance. We also discussed the results of the NRC team inspection conducted @ SQUIBB in Aug. '88 (Insp. Rpt. dtd 11/1/88), one of which was recommending that SQUIBB revise the RCP in its entirety to conform w/ NUREG-0654 (11/87). Since the licensee was actively pursing this major revision, I agreed that page changes were not immediately required; as long as the NRC comments be incorporated into the RCP during the Major Revision, and that SQUIBB address whether or not it agrees with our concerns and answers our questions discussed during the phone conversation through a written letter within 30 days.

ACTION REQUIRED: Send phone convo. letter to SQUIBB or Wait for reply.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
R. Provencher	Rick Provencher	6 Jan '89

ACTION TAKEN

"OFFICIAL RECORD COPY" ML 10

SIGNATURE	TITLE	DATE

50271-101 CONVERSATION RECORD OPTIONAL FORM 271 (12-76) DEPARTMENT OF DEFENSE

☆U.S. G.P.O. 1989-301-526/0348

109258

P.O. Box 4000
Princeton, NJ 08543-4000

030-05222

Squibb
Technical Operations

July 12, 1988

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

Subject: Contingency Plan Update

Dear Ms. Johansen:

Enclosed are six (6) copies of changes to update E. R. Squibb & Sons' Radiological Contingency Plan. Squibb's By-product Material License number is 29-00139-02.

Sincerely,

D. K. Balkunow
Radiation Safety Officer
E. R. Squibb & Sons

DKB/ldl

Enclosure:

RECEIVED BY LFMS
Date 8/3/88
Ltr Aug. 1
D. Balkunow
Date 12/12/88

FEE NOT REQUIRED
D. J. Nelson 11/30/88
reply re: Does not affect licensee

"OFFICIAL RECORD COPY" M18

19 JUL 1988

10925

Date Issued: 7/12/88

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Pages To Be Removed		New Pages To Be Issued	
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4	"	4	"
10	5/18/82	10	"
11	4/01/87	11	"
12	6/01/86	12	"
12a	4/01/87	12a	"
13	"	13	"
16	4/01/87	16	"
17	"	17	"
17a	"	17a	"
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43a	"	43a	"
44	"	44	"
44a	"	44a	"
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49	1/15/86	49	"
54	4/01/87	54	"
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--		Amendment #74 New Brunswick Police Letter	
--	3/24/80	SOP/GMP Radioactive Waste Disposal	2/27/87
--	6/12/81	Robert Wood Johnson Hospital Letter	7/03/87

OVERSIZE DOCUMENT PAGE PULLED

SEE APERTURE CARDS

NUMBER OF OVERSIZE PAGES FILMED ON APERTURE CARDS 1

APERTURE CARD/HARD COPY AVAILABLE FROM

RECORDS AND REPORTS MANAGEMENT BRANCH

RADIOLOGICAL CONTINGENCY PLAN

E. R. SQUIBB & SONS, INC.
NEW BRUNSWICK, NEW JERSEY
JULY 1, 1988

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 2000 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.

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.

Figure 3

Site Plan

of

E. R. Squibb & Sons, Inc.

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 quarterly 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.

• 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 operation 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.

2.1.2. Alarm Systems and release Prevention

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 provide information to persons entering these areas of any unusual conditions, thereby allowing them to minimize their own exposure. The instrumentation provided has the capability of detecting the highest anticipated radiation levels. To assure optimum coverage of all areas, the detector locations have been chosen with great care.

Each glove box 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 glove box. 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.

Any smoke released into the rooms will pass through the room filtering system and also be detected by the filter bank fire detectors.

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

The ventilation equipment not only provides separate filtering capabilities for various processes, but is also equipped with dampers and valves to preclude the spread of fire and automatically engage backup systems in the event of air failures.

In addition, there are six auxiliary systems available to service the twelve glove box systems to accommodate filter changes, maintenance or emergency situations. These are activated manually by maintenance personnel under the direction of Health Physics.

Should a fire occur, pyrotronic fire detectors located in each charcoal filter bank system will activate a valve to seal off the ventilation system in a glovebox and thereby contain the fire to the glovebox.

2.1.3 Support Systems

2.1.3.1 Structural Performance vs. Site Environmental Factors

2.1.3.1.1 Severe Natural Phenomena

The plant is a steel structure consisting of cinder block and brick constructed walls and a reinforced concrete floor. The geographical location of the plant is such that it is very unlikely to be subjected to a tornado; nor would it be likely that it's structure be seriously degraded by hurricane, flood, heavy snow loading, high winds or lightning.

2.1.3.1.2 Accidents at Neighboring Activities

Because of the types of activities conducted at neighboring facilities, it is highly improbable that our facility structure could be degraded as a result of fire or explosion at neighboring facilities. The facility nearest the Radiopharmaceutical manufacturing building is the parenteral filling and packaging facility. This structure, which is directly northeast of our facility does not use any highly explosive or combustible materials in its operation. Southwest of the Radiodiagnostics building is Permacel Avery, a tape manufacturer. Any fire or explosion at this site is not likely to affect our facility.

2.1.3.2 Confinement Barriers and Systems

The extensive use of glove boxes, hot cells and other well ventilated systems in conjunction with the design of the ventilation system itself serve as the prime defense against the intrusion into the air in the work areas of airborne radioactive materials. Alarms which indicate failure of some of these systems serve as a second line of defense in that they warn personnel in

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.M.P. diesel pump taking suction from a 16" city water main, which supplies the site.

Building 67 provides water supply for building sprinkler systems and yard hydrants at a design pressure of 90 psi. All fire protection systems are maintained, tested and inspected in conformance with Factory Mutual Engineering requirements for secure properties, and the applicable provisions of subpart L of OSHA 1910 and NJAC 5:18.

Potable water is received on site through a 16" pipe from the New Brunswick water supply system and distributed via a looped and gridded system throughout the plant. The city water system in addition to domestic water supply, provides fire protection makeup water, and feeds a system of low pressure (54 psi) yard hydrants.

2.1.3.5 Shielding

The leaded glove boxes and hoods are used to manufacture and fill radiopharmaceuticals of different radioconcentrations. 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 as required 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 four inches of lead for I-131 Iodine and eight inches of lead for the 99Mo Molybdenum operations.

The steel and concrete used in the walls, flooring and ceiling of the hot cell's 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.

2.1.4 Control Operations

Plant engineered systems are monitored routinely by plant engineers and the Health Physics group to ensure proper performance.

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 emergency lighting and radioactive air sampling system for the plant.

Should the air system which supplies automatic controls fail, all filter intake and exhaust valves are designed to fail safe.

2.2.4 Control Operations

Verification that the filter bank systems are performing their intended functions at their maximum efficiencies is accomplished by continuously sampling air flow and collecting radioactivity. Each filter bank is equipped with samplers to analyze filter efficiencies. The samplers are checked on a weekly basis and assayed. Each of these filter banks are exhausted into a main duct which leaks to the breach of the stack. The combined effluents are sampled in the breach before being discharged to the stack. The releases from the facility are sampled continuously and analyzed at least once each day, except over the weekend. The weekend sampler is run from Friday to Monday and the measured radioactivity is averaged over this period of time.

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

3.0 CLASSES OF RADIOLOGICAL CONTINGENCIES

3.1 Classification System

The Squibb Radiological Contingency Plan is designed to handle emergency situations ranging from unusual events to general emergencies. These conditions have been categorized into four classes.

Class I

Unusual Event

Class I includes only those unusual events which indicate a potential degradation of the level of safety of the plant. The unusual event is confined to a specific area within the plant and would not require the evacuation of personnel from other areas of the plant unless further degradation of safety systems occur.

However, should an unusual event occur the Health Physics Department Head or his designee shall inform State, Federal and/or local offsite authorities of the nature of the unusual event.

The appropriate offices to be contacted are:

U.S. Nuclear Regulatory Commission	301-951-0550
Head Quarters Operations Center	301-427-4056
	301-492-8893
1. Identify: "E. R. Squibb & Sons, Inc."	301-427-4259
2. Give Emergency Class (Alert, Unusual event, site or general).	
3. You will be transferred to Region I Duty office.	
NJ State Department of Environmental Protection	609-292-7172
Radioactive Materials Section	609-530-4023
N. J. State Police	609-882-2000
24 hours ask for "Emergency Management Section."	

Class II

Alert

Radioactive releases that are contained within the plant, but require evacuation of the plant because of the possibility of widespread contamination. This alert condition involves an actual or potential substantial degradation of the level of safety of the plant.

The State, Federal and/or local authorities must be informed of an alert condition and the reason for the alert as soon as it is discovered.

The following authorities must be notified immediately by the Health Physics Department Head or his designee:

U.S. Nuclear Regulatory Commission	301-951-0550
Head Quarters Operations Center	301-427-4056
	301-492-8893
1. Identify: "E. R. Squibb & Sons, Inc."	301-427-4259
2. Give Emergency Class (Alert, Unusual event, site or general).	
3. You will be transferred to Region I Duty office.	

NJ State Department of Environmental Protection	609-292-7172
Radioactive Materials Section	609-530-4023
N. J. State Police	609-882-2000
24 hours ask for "Emergency Management Section."	

Class III

Site Emergency

Radioactive releases that are not contained within the plant and require evacuation of areas within the site. This site emergency involves actual or likely major failures of plant functions needed for protection of the public. Offsite releases are not expected to exceed EPA Protective Action Guidelines.

The State, Federal and/or local authorities must be informed of a site emergency condition and the reason for the site emergency as soon as it is discovered.

The following authorities must be notified immediately by the Health Physics Department Head or his designee:

U.S. Nuclear Regulatory Commission	301-951-0550
Head Quarters Operations Center	301-427-4056
	301-492-8893
1. Identify: "E. R. Squibb & Sons, Inc."	301-427-4259
2. Give Emergency Class (Alert, Unusual event, site or general).	
3. You will be transferred to Region I Duty office.	

NJ State Department of Environmental Protection	609-292-7172
Radioactive Materials Section	609-530-4023
N. J. State Police	609-882-2000
24 hours ask for "Emergency Management Section."	

Class IV

General

Radioactive releases beyond the site boundary. This condition will be considered a General Emergency which involves actual or imminent loss of confinement integrity. Releases can be expected to exceed EPA Protective Action Guidelines.

The State, Federal and/or local authorities must be informed of a general emergency condition and the reason for the general emergency as soon as it is discovered.

The following authorities must be notified immediately by the Health Physics Department Head or his designee:

U.S. Nuclear Regulatory Commission	301-951-0550
Head Quarters Operations Center	301-427-4056
	301-492-8893
1. Identify: "E. R. Squibb & Sons, Inc."	301-427-4259
2. Give Emergency Class (Alert, Unusual event, site or general).	
3. You will be transferred to Region I Duty office.	

NJ State Department of Environmental Protection	609-292-7172
Radioactive Materials Section	609-530-4023
N. J. State Police	609-882-2000
24 hours ask for "Emergency Management Section."	

3.2 Classification Scheme

Class I

NOTIFICATION OF UNUSUAL EVENT

Class Description

Unusual events are in process or have occurred which indicate a potential degradation of the level of safety of the plant. No releases of radioactive material requiring offsite response or monitoring are expected unless further degradation of safety systems occurs.

Purpose

Purpose of offsite notification is to (1) assure that the first step in any response later found to be necessary has been carried out, (2) bring the operating staff to a state of readiness, and (3) provide systematic handling of unusual events, information and decision making.

Actions

Inform State and/or local offsite authorities of the nature of unusual condition.

Augment on shift resources as needed.

Assess and respond. (See Addendum V, Use of Transparent Overlays for Determination of Ground Level Concentrations and Radiation Doses.)

Escalate to a more severe class, if appropriate.

or

Close out with verbal summary to offsite authorities, followed by written summary.

3.3 Range of Postulated Accidents

Class I

UNUSUAL EVENT

In this evaluation, it is postulated that a local fire has occurred in the facility and the fire has developed to the extent that the excess heat may cause the release of airborne radioactivity.

It is assumed that a fire has occurred in a glove box containing 4.0 curies of iodine I-131 (the largest batch size in radiopharmaceutical production). The iodine contained in the fraction of the liquid which flashes to steam represents the airborne source for this accident.

The fire in the box would release the fire damper located over each glovebox and prevent its spread 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 area of the charcoal filter by the pyrotronic fire detectors located in each charcoal filter bank. These smoke detectors will close valves on each side of the filter bank. Therefore, the airborne activity would be contained within the ducts of the ventilation system.

Any smoke released into the rooms will pass through the room filtering system and also be detected by the filter bank fire detectors.

Probability Considerations

The materials used in the manufacture of iodine I-131 products are nonflammable. All of the radioactive batches manufactured are aqueous solutions. No volatile solvents are used inside those areas containing iodine I-131. In addition, the hoods are provided with local fire dampers and each charcoal filter bank is provided with a smoke detector (pyrotronics) which controls two fire damper valves on each side of the filter bank. The only possible type of fire would be one in which there was an electrical failure of one of the devices inside the boxes (i.e., magnetic stirrer, heating mantles, pumps). A fire of this type should be of short duration with relatively low heat generation.

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 unusual event.

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

Should 4.0 Curies of I-131 Iodine in liquid form accidently spill in the work area, the radiation levels, one meter from the source, would measure approximately 880 mr/hr. Radiation exposures to the workers and teams responding to this emergency can easily be maintained below the permissible limits.

Because the I-131 Iodine is in an aqueous (NaOH or Na2 SO4) form, volatilization will occur primarily by evaporation.

Since the work areas are under negative pressure, all airborne radioactivity will be confined to the area of the spill and should not enter adjacent areas. The fire in the pass thru of the hot cell will cause the dampers in the exhaust ducts to close. The airborne radioactivity created by the spill, will be exhausted through the room's air exhaust system (Separate from the hot cell exhaust.)

Let's assume that half of the I-131 Iodine (4.0 Curies) has vaporized over a period of one hour before the spill is contained and shielded. Although it is felt that a significant amount of radioactivity would plate out and condense in the duct before it reaches the filters, we will theorize that this does not occur, and the filters are challenged with the entire 2.0 curies of airborne I-131 Iodine.

Effective filtration will remove 99.9% of the radioactivity, releasing the remaining 0.1% (2.00 millicuries) to the stack.

Taking into consideration the fact that the exhaust velocity from the stack is 75,000 cfm, the air concentration from the stack for one hour would be 1.59 E-8 uCi/cc.

$$\frac{2.0\ E03\ uCi}{(2.8\ E04\ cm2/ft3)\ (75{,}000\ ft3/min)\ (60\ min)}$$

Assuming that no additional radioactivity will be released to the stack, the average air concentration for a 24-hour period would be approximately 6.6 E-10 uCi/cc.

$$\frac{2.0\ E03\ uCi}{(2.8\ E04\ cm3/ft3)\ (75{,}000\ ft3/min)\ (60\ min)\ (24\ hours)}$$

4.2.1.1 EMERGENCY ORGANIZATION - CHAIN OF COMMAND
EMERGENCY MONITORING TEAM PERSONNEL

PLANT EMERGENCY DIRECTOR

Health Physics Department Head
or Alternate

#2	#3
Health Physics Supervisor or Alternate	Health Physics Supervisor or Alternate

Plant Emergency Director Alternates

One Health Physics Supervisor, or
Radiodiagnostic Department Head, or
Radiodiagnostic Quality Control and Distribution Manager

Emergency Team Alternates

One (1) Radiodiagnostic Manufacturing Section Head, or
Four (4) Radiodiagnostic Manufacturing Shift Supervisors
and/or Radiodiagnostic Quality Control Shift Supervisors.

4.2.1.2 Authority and Reponsibilities

Radiopharmaceutical Plant Emergency Director

A. Notification of Unusual Event Follow-up Actions

- Evaluate the emergency through the emergency assistance group and as quickly as possible, determine if the incident is causing the release of radioactivity beyond the restricted area of the radiopharmaceutical production building.

- Designate Health Physics personnel to proceed to the scene with appropriate monitoring and emergency equipment.

- Proceed to and take charge of the Emergency Coordination Center (Health Physics Office).

- Inform all radiopharmaceutical manufacturing personnel of the incident.

- Establish barricades around the site of the incident.

- Direct the actions necessary to bring the emergency under control.

- Notify Medical Assistance Group, if necessary.

- Promptly notify local or state offsite agencies.

B. Alert Condition Follow-up Actions

- Proceed to take charge of the Emergency Coordination Center (Health Physics office).

- Evaluate the emergency as per A above.

- Designate personnel to proceed to the scene of the emergency with the emergency kit.

- Notify the Radiodiagnostic Production Manager.

- Direct the survey of all personnel for contamination.

- Supervise collection of all data necessary for the emergency monitoring log.

- Dispatch monitoring teams to survey the radiopharmaceutical production area boundary.

- Notify Federal, State and Local offsite agencies.

- Direct the actions necessary to bring the emergency under control.

- Establish the appropriate barricade to restrict access to the site of the incident.

- Account for all plant personnel and visitors.

C. Site Emergency Follow-up Actions

- Proceed to take charge of the Alternate Emergency Coordination Center.

4.2.2.11 Fire Department

A. Fire Chief

The Fire Chief is responsible for the training of fire fighting personnel, the purchase and maintenance of fire fighting equipment in the plant and pre-plan of emergencies which might occur at the facility. His responsibilites include:

- A complete knowledge of the over-all plant layout, including construction, location of personnel hazardous areas, location of entrances and exits, and plant conditions requiring special fire fighting techniques.
- The organization and training of the fire brigade.
- The maintenance of fire fighting equipment.
- The direction of all fire fighting activities.
- An over-all knowledge of primary and secondary fire protection water systems in and immediately adjacent to the plant.
- Liaison with municipal, county and state fire fighting organizations.
- A knowledge of the duties of the other elements which make up the Disaster Organization to permit the maximum coordination in an emergency.

B. Fire Department Functions

In the event of fire, explosion, or existence of other emergency, a call is placed to the Building 111 Security Gate House by dialing Ext. 3011. Upon report of the emergency, the guard sounds the proper building evacuation signal. The personnel in the building (Radiodiagnostic Bldg. 124) are evacuated by an interior fire alarm system (continuous sounding of bells or sirens). The emergency radio paging alert is broadcast and the plant air whistle for zone 4, designates the area of emergency within the site.

SOP-PB-02
Effective 3/22/83
PLANT FIRE BRIGADE ORGANIZATION
1

Authorization:

_____

CHIEF: _____

Brigade Command

CAPTAIN: _____

LIEUTENANT: _____

ENGINEER: _____

Support-Water Supply Systems
Operate Engine

FIREFIGHTER: _____

FIREFIGHTER: _____

FIREFIGHTER: _____

FIREFIGHTER: _____

Sprinkler
System Valves

Chain of Command:

Chief
Captain
Lieutenant
Engineer
Firefighter

- 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. Radiodiagnostic Department 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 Manager

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: 63 or 60

Telephone: 2160, 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: 17 or 60

Telephone: 2451, 3158 or 3721

	Office	Home
Daniel K. Balkunow	2451	(b)(6)
Edward Truskowski	3158	
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. Radiopharmaceutical Department Head

	Office	Home
G. Thompson or designee	3061	(b)(6)
C. Forberg	3063	

3. 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.

4. 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.

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 Department Head shall notify:

V. P. & General Mgr., Sq. Diagnostics

	Office	Home
Dr. K. Loberg	609-987-1816	(b)(6)

E. The Health Physics Department Head shall notify:

V. P. of World Wide Quality Control and Quality Assurance

Dr. F. A. Gusmano	3191	(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
   or
   Intercom 60 or 63

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
D. K. Balkunow or designee,	2451	(b)(6)
E. Truskowski	3158	
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 Department Head or designee:

	Office	Home
G. Thompson or designee,	3061	(b)(6)
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: "F. 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 Health Physics Department head shall notify:

V. P. & General Mgr., Sq. Diagnostics

	Office	Home
Dr. M. Loberg	609-987-1816	(b)(6)

7. Radiopharmaceutical Department Head or designee:

	Office	Home
G. Thompson or designee,	3061	(b)(6)
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 Department Head shall notify:

V. P. & General Mgr., Sq. Diagnostics

	Office	Home
Dr. E. Loberg	609-987-1816	(b)(6)

E. The Health Physics Department Head shall notify:

V. P. of World Wide Quality Control and Quality Assurance

	Office	Home
Dr. E. A. Gusmano	3191	(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 Department Head

F. Notify the following members of management:

- Radiodiagnostic Manufacturing Department Head
- Squibb Plant Manager
- Diagnostics Quality Control 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

- Plant Security Head

- Plant Medical Department Head

- Other personnel as required

C. Determine if the Emergency Coordination Center is in a safe condition through the use of portable survey instruments.

D. Proceed to take charge of the Emergency Coordination Center.

E. Dispatch a monitoring team to scene of the emergency to evaluate the extent and magnitude of the emergency.

F. Evaluate the emergency and, as quickly as possible, using meteorological data, overlay and area maps, determine the extent of the offsite release of radioactivity. See Addendum V for methodology and parameters used in calculating atmospheric dispersion and dose rates to individuals.

G. If there are any injured personnel, assign the Senior Medical Representative to administer first aid and prepare the patient(s) for transfer to the hospital.

H. Provide a Health Physics representative to accompany the patient(s) to the hospital with the ambulance emergency kit, to maintain radiological control in the hospital.

I. Evaluate monitoring data from survey teams as it becomes available.

J. Provide monitoring team for State Department of Environmental Protection.

K. Inform company management, State Department of Environmental Protection and Nuclear Regulatory Commission of offsite radiological conditions.

5.4 Protective Actions

Unusual Event

A. If an unusual event should occur, an individual's first responsibility is his own safety. All persons shall evacuate the emergency area immediately, holding their breath, if possible.

E. R. SQUIBB & SONS, INC.

EMERGENCY CALL LIST

Title	Squibb Extension
V.P. and General Manager Dianostics Division	609-987-1816
Dir. Diagnostics Operation & Productivity	2806
Dir. Engineering & Maintenance	3045
Radiopharmaceutical Mfg Dept Head	3061
VP World Wide Quality Control and Quality Assurance	3191
Health Physics Department Head	2451
Health Physics Supervisor	3721
Health Physics General Supervisor	3158
Plant Security Head	2101
Director Personnel & Ind Rel	3034
Director Employee Health	2486
Manager 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 — 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.

04/01/88

54a

NJ State Department of Environmental Protection
Radioactive Materials Section

609-292-7172
609-530-4023

609-882-2000

N. J. State Police
24 hours ask for "Emergency Management Section"

6.0 EQUIPMENT AND FACILITIES

6.1 Control Point

Two areas are defined for control and coordination of on-site activities following an emergency.

6.1.1 Alternate Health Physics Office

The Alternate Health Physics Office is located immediately outside the restricted area of the radiodiagnostic manufacturing facility. Located within the room is the communication system for all rooms and areas around the radiopharmaceutical production plant. All on-site activities shall be directed from this room.

6.1.2 Alternate Emergency Coordination Center

The Alternate Emergency Coordination Center will be the Radiopharmaceutical Research and Development building. It is equipped with the necessary monitoring equipment to perform the evaluations of the environmental monitoring on-site samples and contains a telephone communications system. An alternate portable communications system (Walkie Talkies) will be provided and the emergency kit will be kept in the emergency vehicle.

6.2 Communications Equipment

The on-site communication systems consist of telephones and walkie-talkies. Security personnel 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.

6.3 Facility for Assessment Teams

The facility designated for use by staff performing post-accident and recovery assessment and protective action functions is the office area and/or conference room in building 124.

6.4 Onsite Medical Facilities

6.4.1 Medical Emergency Plan For Bldg. 124

In all cases of Medical Emergencies the Squibb Medical Department (Ext. 3033) must be notified. The extent of contamination should be determined as quickly as possible. The judgement as to whether the injuries take precedence over contamination control or whether decontamination should be attempted before further treatment must be made by the senior medical representative available.

7.2 Training

Selected plant personnel will be trained in emergency procedures and monitoring duties in order to provide an adequate number of emergency monitoring personnel.

Health Physics Supervision, Radiodiagnostic Manufacturing Supervision and Radiodiagnostic Quality Control Supervision will be trained in the supervision of monitoring teams, interpretation of data, use of map overlays, etc.

Health Physics Supervisors and Technicians will be trained in onsite air activity determinations and familiarization with the emergency procedures.

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 30 people, covers all shifts and are alerted by paging radios initiated through the main security post, where all medical emergencies are reported by dedicated extension 3033.

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. The first aid personnel assigned within these zones respond directly to the scene of medical emergencies within their zone. First aid kits and certain other equipment, such as a contaminent stretcher for radiopharmaceutical use, are located throughout the plant site. Squad members receive training monthly during regular two hour drill sessions.

MATERIALS LICENSE

Amendment No. 74

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, 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. Squibb Institute for Medical Research 2. Georges Road New Brunswick, New Jersey 08903	In accordance with letter dated January 22, 1988, 3. License number 29-00139-02 is amended in its entirety to read as follows: 4. Expiration date March 31, 1989 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. 1-83, inclusive, except Strontium 90	A. Any	A. 5 curies of each radionuclide, with a total possession limit of 1000 curies
B. Iodine 131	B. Any	B. 150 curies
C. Molybdenum 99/ Technetium 99m	C. Any	C. 2000 curies
D. Any byproduct material with Atomic Nos. 1-83 inclusive, except Strontium 90	D. Any	D. 200 millicuries of each radionuclide with a total possession limit of 5 curies
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. Nickel	H. Plated sources in detector cells	H. Not to exceed 15 millicuries per source
I. Any byproduct with Atomic Nos. 1-83 inclusive, except Strontium 90	I. Any	I. 10 millicuries of each radionuclide, with a total possession limit of 1 curie
J. Any byproduct material listed in Schedule B, 10 CFR 30.71	J. Any radioimmunoassay kit	J. Not to exceed limits specified for each radionuclide in Schedule B, 10 CFR 30.71

9. Authorized use

A., B., and C. (1) Research and development as defined in Section 30.4(q) of 10 CFR 30.
(2) For possession use and processing incident to the manufacture of radiochemicals and radiopharmaceuticals.

(9. Continued)

(3) For storage prior to distribution of manufactured radiochemicals a 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 I. Research and development as defined in Section 30.4(q) of 10 CFR 30.

J. For demonstration by sales personnel at customer's facilities.

CONDITIONS

10. A. Licensed material in Items 6.A., B., C. and H. shall only be used at licensee's facilities at Rt. 1, North Brunswick, New Jersey.

B. Licensed material in Items 6.D., E., F., G. and H. shall only be used at licensee's facilities, Lawrenceville, New Jersey.

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

D. Licensed material in Item 6.J. may be demonstrated at temporary job sites of the licensee anywhere in the United States where the Nuclear Regulatory Commission maintain jurisdiction for regulating the use of byproduct material.

11. Licensed material shall be used by, or under the supervision of, individuals designated by the licensee's Radiation Safety Committee.

12. A(1) Each sealed source or detector cell acquired from another person and containing licensed material, other than hydrogen 3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transferor indicating that a test has been made within 6 months before the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting materials or 10 microcuries or less of alpha emitting material.

(3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage before any use or transfer to another person unless they have been leak tested within 6 months before the date of use or transfer.

(12. continued) CONDITIONS

9. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.

C. Each sealed source or detector cell containing licensed material, other than hydrogen 3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months.

D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A 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 and Safeguards Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406, describing the equipment involved, the test results, and the corrective action taken.

13. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), of 10 CFR Part 20, 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 without a color requirement.

14. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Centigrade.

15. Detector cells containing scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 325 degrees Centigrade.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 29-00139-02

Docket or Reference number: 030-05222

Amendment No. 74

(Continued) CONDITIONS

16. 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 2 years from the date of each inventory.

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

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

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

20. This license does not authorize the distribution of byproduct material for medical use under general license pursuant to Paragraph 30.31, 10 CFR 30.

21. This license does not authorize the commercial distribution of exempt quantities of licensed material pursuant to Section 30.18, 10 CFR 30, and Section 32.18, 10 CFR 32.

22. The licensee shall maintain, and execute the response measures of his Radiological Contingency Plan submitted to the Commission on June 29, 1981, as revised on December 4, 1981, March 17, 1982, May 27, 1983, April 3, 1985, August 6, 1985, April 1, 1986, June 12, 1986 and June 15, 1987. The licensee shall also maintain implementing procedures for his Radiological Contingency Plan as necessary to implement the Plan. The licensee shall make no change in his Radiological 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 Contingency Plan without prior Commission approval if the changes do not decrease the response effectiveness of the Plan. The licensee shall maintain records of changes that are made to the Plan without prior approval for a period of two years from the date of the change and shall furnish the Chief, Material Licensing Branch, Division of Fuel Cycle and Material Safety, NMSS, U.S. Nuclear Regulatory Commission, Washington, D.C., 20555, and the appropriate NRC Regional office specified in Appendix D of 10 CFR Part 20, a report containing a description of each change within six months after the change is made.

23. The licensee is authorized 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 29-00139-02
Docket or Reference number 030-05222
Amendment No. 74

(Continued) CONDITIONS

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

A. Letter dated June 29, 1981
B. Letter dated December 4, 1981
C. Letter dated March 17, 1982
D. Letter dated June 22, 1982
E. Letter dated December 15, 1982
F. Application dated May 17, 1983
G. Letter dated May 27, 1983
H. Letter dated June 6, 1983
I. Letter dated July 11, 1983
J. Letter dated October 17, 1983
K. Letter dated December 14, 1983
L. Letter dated February 17, 1984
M. Letter dated September 10, 1984
N. Letter dated February 7, 1985
O. Letter dated April 3, 1985
P. Letter dated July 5, 1985
Q. Two letters dated August 5, 1985
R. Letter dated August 6, 1985
S. Letter dated December 4, 1985
T. Letter dated February 24, 1986
U. Letter dated April 1, 1986
V. Letter dated June 12, 1986
W. Letter dated July 29, 1986
X. Letter dated December 1, 1986
Y. Letter dated December 16, 1986
Z. Two letters dated February 16, 1987
AA. Letter dated June 15, 1987
BB. Letter dated January 22, 1988

For the U.S. Nuclear Regulatory Commission

Date 11 MAR 1988

By _____
Nuclear Materials Safety and
Safeguards Branch, Region I
King of Prussia, Pennsylvania 19406

E.R. Squibb & Sons, Inc.

STANDARD OPERATING PROCEDURE FOR GOOD MANUFACTURING PRACTICES

ADDENDUM #III

SO 4083 8/81

DEPARTMENT	SUBJECT			
Radiodiag. Production	Radioactive Waste Disposal			
PROCEDURE NO. RDP-86	NEW PROCEDURE ☐	REVISED PROCEDURE ☑	REPLACES PROCEDURE #111-4 OF 4/30/86	ORIGINATOR C. Forberg
REVIEWED BY	APPROVAL J. Kimmins	H.P. Approval D.L. Balkunow	DATE / /	EFFECTIVE DATE 2/27/87

PURPOSE: To define proper handling, storage and disposal procedures for radioactive waste materials in the decay storage barn.

RESPONSIBILITY: All supervisory and operating personnel are required to assure compliance with this procedure.

PROCEDURE:

I. General

A. The decay barn will be closed and locked when no one is in attendance.

B. A daily check by the assigned decay barn person will be made to insure that all red blinking lights are on and blinking. If lights are not operating properly, notify your supervisor so that they can be repaired.

C. All materials to be stored in the decay barn must be delivered in appropriate containers and shielded when required. All vials must be stoppered and crimped or tightly capped. Lead container covers must be securely taped or shrink wrapped.

D. All radioactive material delivered to decay barn will be properly identified with isotope, amount and date. If waste is delivered in cans the surface radiation dose rate must be recorded along with operator name.

E. Contained liquid waste shall be kept separate from solid waste to facilitate waste disposal.

F. Manufacturing radioactive waste cans reading over 100mR/Hr, or full radioactive waste cans reading 30mR/Hr and more are to be emptied into Health Physics approved waste decay hoods.

G. Storage and removal of material from decay barn and decay hoods will be in accord with recommended safe practices as detailed by Health Physics.

H. All batch pigs which are moved to the barn for storage must have the cover securely taped to container. Such containers must be placed in a plastic bag which is closed and air tight. All batch bottles or vials must be stoppered and crimped or tightly capped.

E. R. Squibb & Sons, Inc.

STANDARD OPERATING PROCEDURE FOR GOOD MANUFACTURING PRACTICES

SO 4083 8-81

DEPARTMENT Radiodiagnostic Production	SUBJECT Radioactive Waste disposal			
PROCEDURE NO. RDP-36	NEW PROCEDURE ☐	REVISED PROCEDURE ☒	REPLACES PROCEDURE # 111-4 OF 4 / 30 86	ORIGINATOR C. Torbett
REVIEWED BY	QC APPROVAL J. Kimmins	H.P. Approval	DATE 1 / 1	EFFECTIVE DATE 2/20/87

I. Isotopes with half lives of greater than 30 days should be stored in a special area separated from isotopes with half lives of 30 days or less.

J. All drums or cans used in the shipment of radioactive waste must comply with all DOT regulations for radioactive waste containers.

K. Breathing zone monitors must always be worn during all radioactive waste transfer or compacting operations.

II. <u>Receipt, Storage and Packaging of Waste in the Decay Barn</u>

A. Radioactive waste which is brought to the decay barn must be packed separately to distinguish between solid waste and contained liquids.

1. Solid waste in 5 gallon containers should have surface radiation dose readings taken and documented on Radioactive Waste Disposal Records (Attachment #3). If less than 30mR/Hr, the 5 gallon containers should be placed on pallets in the "Hold Area" designated for waste delivery in the new barn. If greater than 30mR/Hr, the 5 gallon container should be emptied into a decay hood.
2. Contained liquids which are not in lead containers should have readings taken and the same criteria as A-1 should be used (i.e., 0-30mR/Hr in "Hold Area", new barn). Contained liquids greater than 30mR/Hr should be emptied into a decay hood.
3. Contained liquids in lead containers should be placed on the appropriate shelf to allow for decay and subsequent lead recovery. The barn person is responsible for controlling the availability of shelf space for waste. Waste in this category should be allowed to decay for approximately 10 half lives prior to lead recovery and subsequent waste disposal (see SOP RDP-38 for Lead Recovery Procedure).

B. The assigned barn person will have 55 gallon drums available for the disposal of waste. These drums will be clearly marked with one of the following descriptions:

1. Solid Waste - Category D
2. Contained Liquid - Category V

E.R. Squibb & Sons, Inc.

STANDARD OPERATING PROCEDURE FOR GOOD MANUFACTURING PRACTICES

DEPARTMENT	SUBJECT			
Radiodiag. Production	RADIOACTIVE WASTE DISPOSAL			
PROCEDURE NO. RDP-36	NEW PROCEDURE ☐	REVISED PROCEDURE ☒	REPLACES PROCEDURE # 111-4 OF 4/30/86	ORIGINATOR C. Forberg
REVIEWED BY	APPROVAL J. Rimmins	H.P. Approval	DATE 1/1	EFFECTIVE DATE 2/27/87

C. The assigned barn person will insure that the 55 gallon drums are set up as follows and will complete a "Radioactive Waste Drum Log Sheet" (Attachment #1) for each drum, as well as assure that a copy of the "Radioactive Disposal Record" is attached to each drum (Attachment #2).

1. Solid Waste - Category D - A 55 gallon D.O.T. specification metal container lined with 4mil plastic bag.
   a. Waste from decay hood and 5 gallon cans reading 30mR/Hr or less is transferred into 55 gallon drum.
   b. Attach all Radioactive Waste Disposal Sheets from bags and cans to log sheet.
   c. Compact contents of drum using the radioactive waste compactor.
   d. Additional waste may be added to the drum following Step a and b above, until can is full.
2. Contained Liquid - Category V
   a. D.O.T. specification 55 gallon outer container with approved 30 gallon inner container.
   b. Fill 3 inches of Rad-Lite or equivalent on the bottom of the 55 gallon outer container and 8 inches of Rad-Lite in the bottom of 30 gallon inner container.
   c. Place 30 gallon drum lined with 4mil (minimum) plastic liner into outer drum.
   d. Attach all Radioactive Waste Disposal Sheets from 5 gallon cans to log sheet.
   e. Fill drum with liquid radioactive waste contained in vials. Vial must not contain more than 50mL of radioactive waste. When drum is almost full, add at least 1 inch of Rad-Lite, secure plastic bag with tape.
   f. Seal inner drum and fill outer drum with Rad-Lite insuring that all sides and top of 30 gallon drum are surrounded with Rad-Lite.

E.R. Squibb & Sons, Inc.

STANDARD OPERATING PROCEDURE
FOR
GOOD MANUFACTURING PRACTICES

SQ 4063 861

DEPARTMENT		SUBJECT			
Radiodiag. Production		RADIOACTIVE WASTE DISPOSAL			
PROCEDURE NO. RDP-36	NEW PROCEDURE ☐	REVISED PROCEDURE ☒	REPLACES PROCEDURE #111-4 OF 4/30/86		ORIGINATOR C. Forberg
REVIEWED BY	APPROVAL J. Kimmins	H.P. Approval D. Barkhorn	DATE / /		EFFECTIVE DATE 2/27/87

III. Shipment of Waste

A. When 55 gallon containers are full, the plastic bag should be sealed and the cover placed on container. The assigned barn person must take the surface radiation dose reading on each drum. If surface reading of container is greater than 200mR/Hr or 1 meter reading is greater than 10mR/Hr, it should be placed in the "high radiation" cubicle to allow it to decay to less than 200mR/Hr. If surface reading is less than 200mR/Hr and 1 meter reading is less than 10mR/Hr, this container can be shipped.

B. A radioactive waste drum log sheet is completed on each drum to be shipped. This, along with radioactive disposal records, are brought to the supervisor for the preparation of the shipping manifest.

C. Place the appropriate completed DOT labels (2) on the drum and record highest T.I. Type of labels are selected by the following criteria:

	White I (mR/Hr)	Yellow II (mR/Hr)	Yellow III (mR/Hr)
Surface Reading	< 0.5	< 50	< 200
1 meter Reading (R.I.)	-	< 1	< 10

D. Make sure cover gasket is in good condition. Secure cover to drum with a bolt and security seal.

E. The drum must be marked with drum number from "Radioactive Waste Disposal Record" (Attachment #2) and "This Side Up" label.

F. Weigh container. If gross weight is greater than 110 lbs. (50KG) the container must have gross weight marked plainly and durably on the outside of the container. Maximum permissable gross weight cannot exceed 480 lbs. (218KG) for 55 gallon drum, 260 lbs. (118KG) for 30 gallon drums.

E. R. Squibb & Sons, Inc.

STANDARD OPERATING PROCEDURE FOR GOOD MANUFACTURING PRACTICES

SO 4063 8/81

DEPARTMENT		SUBJECT		
Radiodiag. Production		RADIOACTIVE WASTE DISPOSAL		
PROCEDURE NO. RDP-36	NEW PROCEDURE ☐	REVISED PROCEDURE ☑	REPLACES PROCEDURE #111-4 OF 4/30/86	ORIGINATOR C. Forbes
REVIEWED BY	QA APPROVAL J. Kimmins	H.P. APPROVAL D.A. Baldwin	DATE / /	EFFECTIVE DATE 2/27/87

G. A Test Request for a contamination survey shall be submitted to Health Physics. Health Physics shall perform a wipe test on each drum. If the drum is satisfactory, Health Physics will label the drum/s "Free of Contamination". If unsatisfactory, Manufacturing will clean the outside until Health Physics finds the drum/s satisfactory. A copy of the satisfactory Test Request is attached to the log sheet.

H. The drum/s are then moved to the yard area on the scheduled date of waste pick up.

I. An NDL manifest will be completed (Attachment #4). This manifest includes date, container number, container volume, waste category, container weight, physical form, waste description, solidification or absorbent media (if any), principal chemical form, stable/nonstable waste class radionuclide, activity, A1/A2, SNM/source, radiation level (surface & T.I.) and D.O.T. label used. A copy of the manifest shall be maintained with the log sheet in the office files.

J. An M.S.O. (Miscellaneous Shipping Order) must be prepared to document the number and category of drums to be picked up.

RADIOACTIVE WASTE DRUM LOG SHEET — Attachment #1

Drum # _____ (Use Registry # from Waste Disposal Record)

	OPERATOR	DATE
I. Complete Section 1, 2, 3 or 4		
1. Solid Waste Category D		
A. 55 gallon D.O.T. approved drum lined with 4mil (minimum) plastic bag.		
B. Attach all Radioactive Waste Disposal Sheets from 5 gallon cans to Log Sheet.		
2. Contained Liquid Category V		
A. D.O.T. specification 55 gallon outer container with approved 30 gallon inner container.		
B. Fill 3 inches of Rad-Lite or equivalent on the bottom of the 55 gallon outer container and 9 inches of Rad-Lite in the bottom of 30 gallon inner container.		
C. Place 30 gallon drum lined with 4mil (minimum) plastic liner into outer drum.		
D. Attach all Radioactive Waste Disposal Sheets from 5 gallon cans to Log Sheet.		
E. Fill drum with liquid radioactive waste contained in vials. Vial must not contain more than 50ml of radioactive waste. When drum is full, the plastic bag must be secured by tape or equivalent.		
F. Seal inner drum and fill outer drum with Rad-Lite insuring that all sides around drum and top are filled with Rad-Lite.		
3. Absorbed Liquid Category L		
A. 30 gallon drum filled with approximately 9" of Rad-Lite or equivalent.		
B. 30 gallon drum placed inside of 55 gallon drum in which the 30 gallon drum is surrounded with Rad-Lite or equivalent.		

4/82

	OPERATOR	DATE
3. C. As liquid is put into 30 gallon inner drum insure that Absorbed Liquid Log is completed. Total volume allowed in 30 gallon drum is 37,850ml or approximately 10 gallons of liquid. NOTE: THE pH OF ALL LIQUIDS MUST BE BETWEEN 6 AND 9 AND DOCUMENTED ON ABSORBED LIQUID LOGS.		
4. Filters - Category "L"		
A. D.O.T. specification 55 gallon outer container with approved 30 gallon inner container.		
B. Fill 3 inches of Rad-Lite or equivalent on the bottom of 55 gallon outer container and 5 inches of Rad-Lite or equivalent in the bottom of 30 gallon inner container.		
C. Place 30 gallon drum lined with 4mil (minimum) plastic liner into outer drum.		
D. Attach all Radioactive Waste Disposal Sheets from 5 gallon cans to Log Sheets.		
E. Fill drum with filters contained in plastic bags in layers. Place one layer of filters into drum; then cover these filters with a layer of Rad-Lite or equivalent. Continue to fill drum in layers until 5 inches from top of 30 gallon drum and then fill with Rad-Lite or equivalent.		
F. Seal inner 30 gallon drum and fill outer drum with Rad-Lite or equivalent insuring that all sides around drum and top are completely filled.		
II. Drum Sealing and Contamination Survey		
1. When the drum is full the cover should be placed on the drum. Mark drum with drum # and "This Side Up". Drum should be marked plainly and durably on the outside of the container.		
2. Weigh container and mark gross weight plainly and durably on outside of container if in excess of 110 lbs. (50.0kg). Gross weight must not exceed 480 lbs. (218kg) for 55 gallon drums or 260 lbs. (118kg) for 30 gallon drums. Gross Weight		

	OPERATOR	DATE
3. If Category D, V or "L" filters, check to assure that plastic bag is secured with tape or equivalent.		
4. Supervisory check to assure that the contents are as stated on the drum (i.e., contained liquids, absorbed liquids, solid waste or filters). Supervisor_____		
5. Check to assure that the drum cover has a proper gasket and is in good condition. Secure cover to the drum with a bolt. Seal drum with Dept. Lead Seal and attach a copy of Waste Disposal Record to this log sheet.		
6. Read and record surface readings around drum. Make (X) mark on drum surface with highest reading. Take 3 ft. reading around drum and insure that the highest surface reading on drum is monitored closely at 3 ft. mark. NOTE: DOSE RATE MUST NOT EXCEED 200mR/hr AT SURFACE OR 10mR/hr AT 3 FT. A. Highest surface reading_____mR/hr B. Highest T.I. reading_____mR/hr		
7. Submit a Test Request to Health Physics to perform a wipe test of the entire drum to insure that there is no significant removable contamination. NOTE: ATTACH SATISFACTORY TEST REQUEST RESULTS TO LOG SHEET.		
8. A. The isotopes on the Radioactive Disposal Record are consolidated and decayed to a common date by the supervisor. The isotopes, quantities and dates are recorded on the Radioactive Disposal Record by the Supervisor. B. Place (2) appropriate completed D.O.T. labels on drum and record T.I. from Step 2B on label. C. The completed Radioactive Disposal Record is taped onto the drum.		
SUPERVISOR CHECK_____		

(Attachment #2)

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 .....

Date Received .....

Weight .....

Container Size:

55 gal. ☐

30 gal. ☐

5 gal. ☐

Other .....

E 483

(Attachment #3)

MEDOTOPE MANUFACTURING

RADIOACTIVE WASTE DISPOSAL RECORD

DEPT. 20-460

☐ CONTAINED LIQUID* ☐ SOLID* ☐ FILTERS*

☐ DRY WASTE FOR COMPACTION

*CHEMICAL FORM REQUIRED

SO 4748 11/80

ISOTOPE	CHEMICAL FORM	APPROX. AMT. (mCi)	DATE

MR/HR AT SURFACE _____ DATE _____

DELIVERED TO WASTE HOLDING AREA BY _____

Attachment 14

Radioactive Waste License Nos.:
NRC 31-12000-2
NYS 1226-1422

the NDL Organization, inc.

post office box 791 (914) 737-7330 peekskill, new york 10566

Manifest No.: 32654 page 1 of

Customer-Generator _____ Customer No. _____ Date: _____

Address _____ Telephone No. _____

Dept./Div./Lab _____

RADIOACTIVE MANIFEST and DISPOSAL RECEIPT

Shipper: The NDL Organization Inc. Address: Peekskill, N.Y. Via: The NDL Organization Inc. Vehicle No.

Total Quantity Shipped	Proper Shipping Name & Hazard Class (per 49 CFR 172.101)	Identification Number
Containers	Radioactive Material, L.S.A., N.O.S. — Radioactive Material	UN 2912
Containers	Radioactive Material, N.O.S. — Radioactive Material	UN 2982
Containers	Radioactive Material, Special Form, N.O.S. — Radioactive Material	UN 2974
Containers	Radioactive Material, Limited Quantity, N.O.S. — Radioactive Material	UN 2910

X	Container Number	Container Volume gal ☐ ft³ ☐	NDL Waste Category *	Container Weight (Lbs.)	Physical Form	Waste Description	Solidification or Absorbent Media (if any)	Principal Chemical Form (Show % Chelating Agent if any)	Stable/ Nonstable	Waste Class	Radionuclide	Activity (mCi)	A_1/A_2	SNM/ Source (gms)	Radiation Level mR/hr. Surface	Radiation Level mR/hr. 1M (Th)	D. O. T. Label Used
																	Radioactive -
																	Radioactive -
																	Radioactive -
																	Radioactive -
																	Radioactive -
																	Radioactive -
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																	Radioactive -
																	Radioactive -
																	Radioactive -
																	Radioactive -
																	Radioactive -

The above containers have been checked for removable contamination; Results: Alpha _____ dpm/cm² Beta-gamma _____ dpm/cm²

* See Other Side

I, _____ (please print), as an authorized agent for above customer-generator, hereby transfer title and/or ownership of the above-named materials to The NDL ORGANIZATION and disclaim all rights to recover said materials. I certify that the above-named materials are packaged and category labelled according to The NDL ORGANIZATIONS' 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.

I, _____ (please print), 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: _____

Attachment #5

ABSORBED LIQUID - LOG

Drum #__________(Use Registry #)

NOTE: MAXIMUM VOLUME ALLOWED PER 30 GALLON DRUM IS 37,850ml

DATE	ISOTOPE	AMOUNT (mCi)	VOLUME	TOTAL VOLUME	pH	OPERATOR

ROBERT·WOOD·JOHNSON
UNIVERSITY HOSPITAL

July 3, 1987

Earl H. Eaton, M.D.
Associate Corporate Medical Director
E.R. Squibb & Sons
P.O. Box 191
New Brunswick, N.J. 08903

Dear Dr. Eaton:

The Hospital's Radiation Safety Committee met on 6/27/87 and your request for this institution to provide treatment and care for your employees involved in radiological accidents within your facility was reviewed. I am delighted to inform you that this institution will be happy to continue to provide treatment and care for your employees as previously described.

Please feel free to contact me at your convenience if you have any questions regarding this matter. I can be reached at (201) 937-8613.

Once again, I would like to thank you for your continued support of this institution as your health care provider

Sincerely yours,

Sinecio González, R.T.
Technical Director,
Radiology / Nuclear Medicine

SG/pt
cc: J. L. Nosher, M.D.
T. Stahl, M.D.
R. Russo, M.D.
K. McTernan
D. Rao

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

AUG 3 1988

Docket No. 03005222

TO: C. James Holloway, License Fee Management Branch, ARM

SUBJECT: MATERIALS LICENSE AMENDMENT CLASSIFICATION

APPLICANT: E. R. Squibb & Sons, Inc.

License No: 29-00139-02 Fee Category: 3A

Application Dated: 7/12/88 Received: 8/2/88

The changes to the licensee's Radiological Contingency Plan transmitted by the subject application (check appropriate box):

☑ Do not decrease the effectiveness of the plan (fee not required)

☐ Decrease the effectiveness of the plan (fee required)

Signature: John F. Glenn

Date: 11/30/88

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03211
STATUS CODE: 0
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: 880719
DOCKET NO: 3005222
CONTROL NO.: 109258
LICENSE NO.: 29-00139-02
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: 0
CHECK NO.: ---

3. COMMENTS Contingency Plan Update

SIGNED [signature]
DATE 7/27/88

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED / LTS)

1. FEE CATEGORY AND AMOUNT: 3A ~~FEE NOT REQUIRED~~

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR: Sue J. Ellis 11/30/88
AMENDMENT ✓
RENEWAL ---
LICENSE ---

3. OTHER ---

SIGNED [signature]
DATE 12/12/88