NRC FORM 374
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 82

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

Licensee	
1. E. R. Squibb and Sons, Inc. 2. P. O. Box 191 New Brunswick, New Jersey 08903	In accordance with letter dated November 25, 1991, 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 per radionuclide and 1000 curies total
B. Iodine 131	B. Any	B. 150 curies
C. Molybdenum 99/ Technetium 99m	C. Any	C. 500 curies
D. Any byproduct material with Atomic Nos. 1-83 inclusive, except Strontium 90	D. Any	D. 200 millicuries per radionuclide and 5 curies total
E. Hydrogen 3	E. Any	E. 4 curies
F. Carbon 14	F. Any	F. 4 curies
G. Phosphorus 32	G. Any	G. 750 millicuries
H. Phosphorus 33	H. Any	H. 1 curie
I. Sulfur 35	I. Any	I. 2 curies
J. Nickel 63	J. Plated sources in detector cells	J. Not to exceed 15 millicuries per source and 750 millicuries total
K. Any byproduct with Atomic Nos. 1-83 inclusive, except Strontium 90	K. Any	K. 10 millicuries per radionuclide and 1 curie total
L. Hydrogen 3	L. Any	L. 50 millicuries
M. Any byproduct material listed in Schedule B, 10 CFR 30.71	M. Any radioimmunoassay kit	M. Not to exceed limits specified for each radionuclide in Schedule B, 10 CFR 30.71

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 29-00139-02

Docket or Reference number 030-05222

Amendment No. 82

(Continued)

9. Authorized use

A., B., and C. (1) Research and development as defined in Section 30.4 of 10 CFR 30.
(2) For possession use and processing incident to the manufacture of radiochemicals and radiopharmaceuticals.
(3) For storage prior to distribution of manufactured radiochemicals and radiopharmaceuticals.
(4) For packaging and distribution of manufactured radiochemicals and radiopharmaceuticals to persons authorized to receive the licensed material pursuant to the terms and conditions of a specific license issued by the Nuclear Regulatory Commission or an Agreement State.

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

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

CONDITIONS

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

B. Licensed material in Items 6.D., E., F., G., H., I. and J. may only be used at licensee's facilities at Route 206 and Provienceline Road, in Lawrenceville, New Jersey, 675 College Road East, Princeton Forrestal Center, Plainsboro, New Jersey, and at the Convatec facility at 200 Headquarters Drive, Skillman, New Jersey.

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

D. Licensed material in Item 6.L. 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 Daniel K. Balkunow.

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

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
29-00139-02
Docket or Reference number
030-05222
Amendment No. 82

(12. Continued) CONDITIONS

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

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

(i) they contain only hydrogen 3; or

(ii) they contain only a gas; or

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

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

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

F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken.

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

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 29-00139-02

Docket or Reference number: 030-05222

Amendment No. 82

(Continued)

14. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding that specified by the manufacturer.

15. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory.

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

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

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

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

20. 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.

21. The licensee shall maintain and execute the response measure of his Radiological Contingency Plan submitted to the Commission on June 29, 1981 and 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 period of two years from the date of the changes 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.

22. 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.

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
29-00139-02

Docket or Reference number
030-05222

Amendment No. 82

(Continued)

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

A. 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
FF. Letter dated June 16, 1989
GG. Letter dated October 4, 1989
HH. Letter dated July 24, 1990
II. Letter dated May 17, 1990
JJ. Letter dated April 15, 1991
KK. Letter dated November 25, 1991

For the U.S. Nuclear Regulatory Commission

Original Signed By:
By Francis M. Costello

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

Date FEB 20 1992

FEB 20 1992

License No. 29-00139-02
Docket No. 030-05222
Control No. 115844

E. R. Squibb & Sons, Inc.
ATTN: Daniel Balkunow RSO
Squibb Institute for Medical Residence
One Squibb Dr.
P.O. Box 191
New Brunswick, NJ 08903-0191

Dear Mr. Balkunow:

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) 337-5093, so that we can provide appropriate corrections and answers.

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

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

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

OFFICIAL RECORD COPY ML 29-00139-02/LTR - 0001.0.0
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We wish you success in operating a safe and effective licensed program.

Sincerely,

Original Signed By:
Francis M. Costello

Francis M. Costello, Chief
Research, Development &
Decommissioning Section
Division of Radiation Safety
and Safeguards

Enclosures:
1. Amendment No. 82
2. Requirements for Materials Licensees

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Bristol-Myers Squibb Company
Pharmaceutical Group Technical Operations
One Squibb Drive PO Box 191 New Brunswick, NJ 08903-0191 201 519 2000

030-05222

November 25, 1991

Ms. Betsy Ullrich
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Rec: 1
Log
140798
1230
3A
AMD
12/26/91
SF

RE: LICENSE AMENDMENT,
LICENSE #29-00139-02

Dear Ms. Ullrich:

This is a request to amend the byproduct materials license (#29-00139-02) of E. R. Squibb & Sons, Inc., a wholly-owned subsidiary of the Bristol-Myers Squibb Company to reflect the following changes:

1. Changes in committee membership are as follows:

   - Mr. Ralph del Campo has become a new member
   - Dr. Fred Yost has become a new member
   - Ms. Susan Voigt replaces Dr. E. Nickoloff as Chairperson of the Radiation Safety Committee
   - Dr. E. Nickoloff is no longer a member of the committee

2. Changes in site possession limits for the listed facilities:

   A. Location: Route 206 and Provinceline Road, Lawrenceville, NJ

      - Increase the possession limit of Phosphorous^{32} (^{32}P) to 750 millicuries.

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- Increase the possession limit of Phosphorous ^{33} (^{33}P) to 1 Curie. This radionuclide provides similar results as Sulfur^{35} and subsequently will be of significant benefit for storage and decay.

- Increase the possession limit of Tritium (^{3}H) to 4 Curies.

B. Location: 200 Headquarters Drive, Skillman, NJ

- Increase the possession limit of Phosphorous ^{33} (^{33}P) to 100 millicuries.

C. Location: 905 Herrontown Road, Princeton, NJ

- Increase the possession limit of Tritium (^{3}H) to 50 millicuries.

D. Location: 675 College Road East, Plainsboro, NJ

- Increase the possession of Phosphorous^{33} (^{33}P) to 200 millicuries.

All radionuclides will be ordered in any form and used exclusively in non-human research and development studies.

Attached are copies of resumes for Mr. del Campo and Dr. Yost and a check for $230.00 to cover the cost of processing the amendment.

Sincerely,

Larry Gaines
Health Physics Department

LG:bl

Attachments (3)

NAME: Ralph del Campo

WORK HISTORY:

Dates	Company	Title
1989 - Present	Bristol-Myers Squibb	Vice President, Facilities Administration
1986 - 1989	Bristol-Myers Squibb	Maintenance & Engineering Director
1984 - 1986	Bristol-Myers Squibb	Parenterals Operations Director
1982 - 1984	Bristol-Myers Squibb	Parenterals Formulation Manager
1978 - 1982	Bristol-Myers Squibb	Section Head, Parenterals Formulation
1977 - 1978	Bristol Myers Squibb	Section Head, Tablet Manufacturing
1974 - 1977	Schering Corporation	Pharmaceutical Supervisor

EDUCATION:

Dates	School	Degree
(b)(6)	Fairleigh Dickinson University	M.B.A. - Pharmaceutical Marketing
	Newark College of Engineering	B.S. - Chemical Engineering

CURRENT LEVEL:

CURRENT SALARY:

FREDERICK J. YOST JR.
(b)(6)

SUMMARY:

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

EDUCATION

Ph.D Organic Chemistry/Biochemistry June (b)(6)
University of North Carolina, Chapel Hill, N.C.
NSF Fellow, 1969 - 1971

Bachelor of Arts, Chemistry, Hunter College.
(b)(6)

PUBLICATIONS

Seven abstracts
Fifteen papers
One patent

EXPERIENCE
1981 - present

BRISTOL-MYERS SQUIBB
New Brunswick, New Jersey
Group Leader Research & Development and Group Leader Operations.

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

1977 - 1981

GENERAL DIAGNOSTICS DIVISION OF WARNER-LAMBERT
Morris Plains, New Jersey

Senior Scientist.

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

SEARLE DIAGNOSTICS INC.
Des Plaines, Illinois

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

1972 - 1977

DEPARTMENT OF MEDICINE AND BIOCHEMISTRY
Duke University, Durham, North Carolina

Research Fellow and Post Doctoral Fellow.

Discovered a new form of superoxide dismutase.

PERSONAL

Born: (b)(6)
(b)(6)

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BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03211
STATUS CODE: 2
FEE CATEGORY: 3A
EXP. DATE: 19390331
FEE COMMENTS:
DECOM FIN ASSUR REQD: Y

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: E. R. SQUIBB & SONS, INC.
RECEIVED DATE: 911204
DOCKET NO: 3005222
CONTROL NO.: 115844
LICENSE NO.: 29-00139-02
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: #230.00
CHECK NO.: 140778

3. COMMENTS

SIGNED Rebecca J. Brown
DATE 12/12/91

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

1. FEE CATEGORY AND AMOUNT: 3A $221

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

3. OTHER

SIGNED
DATE 12/26/91