

## MATERIALS LICENSE

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, 38, 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.

<p>Licensee</p> <p>1. E. R. Squibb &amp; Sons, Inc.</p> <p>2. One Squibb Drive P. O. Box 191 New Brunswick, New Jersey 08903-0191</p>	<p>In accordance with the application dated May 26, 1999,</p> <p>3. License number 29-00139-02 is amended in its entirety to read as follows:</p> <p>4. Expiration date September 30, 2008</p> <p>5. Docket No. 030-05222 Reference No.</p>
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with Atomic Nos. 1-83 except Strontium 90</p> <p>B. Iodine 131</p> <p>C. Hydrogen 3</p> <p>D. Carbon 14</p> <p>E. Sulfur 35</p> <p>F. Strontium 90</p> <p>G. Any byproduct material with Atomic Nos. 84-103</p> <p>H. Nickel 63</p> <p>I. Any byproduct material with Atomic Nos. 1-83 except Strontium 90</p> <p>J. Hydrogen 3</p> <p>K. Carbon 14</p>	<p>Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Any</p> <p>G. Any</p> <p>H. Plated sources in detector cells</p> <p>I. Any</p> <p>J. Any</p> <p>K. Any</p> <p>7. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 5 curies per radionuclide and 1000 curies total</p> <p>B. 150 curies</p> <p>C. 20 curies</p> <p>D. 20 curies</p> <p>E. 10 curies</p> <p>F. 2 millicuries</p> <p>G. 1 millicurie</p> <p>H. Not to exceed 15 millicuries per source and 750 millicuries total</p> <p>I. 200 millicuries per radionuclide and 6 curies total</p> <p>J. 7 curies</p> <p>K. 5 curies</p>

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Exemptions 6  
FOIAPA 201-8063

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

29-00139-02

Docket or Reference Number

030-05222

Amendment No. 96

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

L. Phosphorus 33

L. Any

L. 1 curie

M. Sulfur 35

M. Any

M. 10 curies

N. Molybdenum 99/Technetium 99m

N. Any

N. 50 curies

O. Iodine 125

O. Any

O. 500 millicuries

P. Iodine 131

P. Any

P. 500 millicuries

Q. Technetium 99

Q. Any

Q. 200 millicuries

R. Nickel 63

R. Plated sources in detector cells

R. Not to exceed 15 millicuries per source and 750 millicuries total

S. Any byproduct with Atomic Nos. 1-83 except Strontium 90

S. Any

S. Not to exceed 200 millicuries per radionuclide and 6 curies total

T. Nickel 63

T. Plated sources in detector cells

T. Not to exceed 15 millicuries per source and 750 millicuries total

U. Any byproduct material with Atomic Nos. 1 through 83 except Strontium 90

U. Any

U. Not to exceed 10 millicuries per radionuclide and 1 curie total

V. Hydrogen 3

V. Any

V. 100 millicuries

W. Carbon 14

W. Any

W. 100 millicuries

X. Sulfur 35

X. Any

X. 300 millicuries

Y. Phosphorous 32

Y. Any

Y. 100 millicuries

Z. Phosphorous 33

Z. Any

Z. 200 millicuries

AA. Iodine 125

AA. Any

AA. 50 millicuries

BB. Nickel 63

BB. Plated sources in detector cells

BB. Not to exceed 15 millicuries per source and 750 millicuries total

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**9. Authorized use:**

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

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

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13. The licensee shall not use licensed material in or on human beings.
14. The licensee shall not use licensed material in field applications where activity is released.
15. Experimental animals administered licensed materials or their products shall not be used for human consumption.
16. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources and detector cells need not be leak tested if:
- (I) they contain only hydrogen-3; or
  - (II) they contain only a radioactive gas; or
  - (III) the half-life of the isotope is 30 days or less; or
  - (IV) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
  - (V) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

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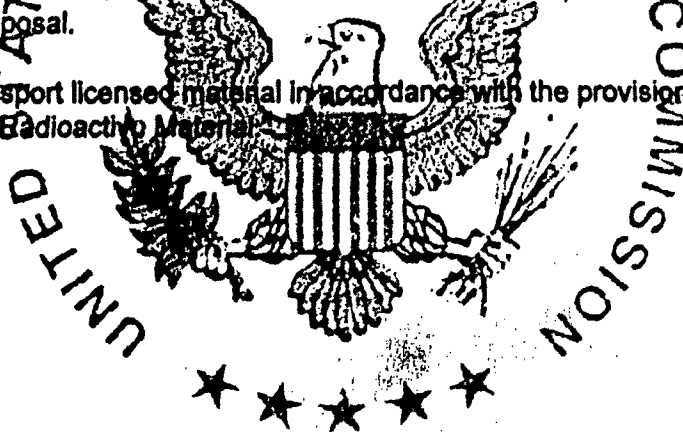
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- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
17. Detector cells containing a titanium triide foil or a scandium triide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding that specified by the manufacturer.
18. The licensee shall conduct a physical inventory every six months, or at other interval approved by NRC, to account for all sealed sources and/or devices received and possessed under the license.
19. The licensee shall not acquire licensed material in a sealed source or in a device that contains a sealed source unless the source or device has been registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.
20. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee. ★ ★ ★ ★ ★
21. The licensee shall maintain and execute the response measure of his Radiological Emergency Contingency Plan submitted to the Commission on February 18, 1997. The licensee shall also maintain procedures as necessary to implement the plan. The licensee shall make no change in his Radiological Emergency Contingency Plan that would decrease the response effectiveness of the plan without prior Commission approval as evidenced by license amendment. The licensee may make changes to his Radiological Emergency Contingency Plan without prior Commission approval if the changes do not decrease the response effectiveness of the plan, and shall maintain records of changes that are made to the plan without prior approval for a period of two years from the date of the changes and shall furnish the Chief, Nuclear Materials Safety Branch, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, a report containing a description of each change within six months after the change is made.

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22. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash, provided:
- A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.
  - B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
  - C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
23. The licensee may transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."



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

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



For the U.S. Nuclear Regulatory Commission

Date June 7, 1999

By

*Original signed by Francis M. Costello*

Francis M. Costello, Acting Chief  
Nuclear Materials Safety Branch 2  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406

June 7, 1999

Docket No. 030-05222

License No. 29-00139-02

Control No. 126887

Thomas M. Primm  
Vice President, US Manufacturing  
E. R. Squibb & Sons, Inc.  
One Squibb Drive  
P. O. Box 191  
New Brunswick, NJ 08903-0191

Dear Mr. Primm:


This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

*Original signed by John R. McGrath*

 Francis M. Costello, Acting Chief  
Nuclear Materials Safety Branch 2  
Division of Nuclear Materials Safety

Enclosure:  
Amendment No. 96

cc:  
Susan Voigt, Chair of the Radiation Safety Committee  
Senior Director, WWMG EH&S  
Michael J. Vala, CHP, Radiation Safety Officer

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T. Primm  
E. R. Squibb & Sons, Inc.

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DOCUMENT NAME: B:\DNMS Documents\Lic Cover Letter\L29-00139-02.wpd

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To receive a copy of this document, indicate in the box: "C" = Copy w/o attachmend "E" = Copy w/ attachmend "N" = No copy

OFFICE	DNMS/RI	<input checked="" type="checkbox"/> N	DNMS/RI	<input checked="" type="checkbox"/> N				
NAME	JBondick <i>JB</i>	<input checked="" type="checkbox"/>	FCostello <i>JM</i>					
DATE	06/07/99	<input checked="" type="checkbox"/>	06/8/99		06/ /99		06/ /99	

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This is to acknowledge the receipt of your letter/application dated

05-26-99, and to inform you that the initial processing which includes an administrative review has been performed.

☒ **AMEND** 29-00139-02  
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number **126887**  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.

DMC FORM 532 (01)  
10-98

Sincerely,  
Licensing Assistance Team Leader



# Bristol-Myers Squibb Company

Pharmaceutical Group Technical Operations

One Squibb Drive P.O. Box 191 New Brunswick, NJ 08903-0191  
908 519-2000

May 26, 1999

Dr. John Kinneman  
US Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19404

RE: **RADIOACTIVE MATERIAL LICENSE NUMBER 29-00139-02**

Dear Dr. Kinneman:

E.R. Squibb & Sons, Inc., a wholly owned subsidiary of Bristol-Myers Squibb Company, wishes to amend its current radioactive license (#29-00139-02) to reflect the following:

- ♦ Replace Mr. Daniel K. Balkunow, the current Radiation Safety Officer, with Michael J. Vala, CHP, effective on or about June 14, 1999.

Mr Vala's résumé, which outlines his experience and qualifications, is enclosed for your review. A check for \$530.00 is also enclosed to cover the cost of this amendment. If you have any questions regarding this matter, please contact Mr. Vala at (732) 519-2987.

Sincerely,

Susan Voigt, Chair of the Radiation Safety Committee  
Senior Director, WWMG EH&S

Enclosures (2)

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MAY 28 1999

**Michael J. Vala, Jr., CHP**  
**Bristol-Myers Squibb Company**  
**One Squibb Drive, P.O. Box 191**  
**New Brunswick, New Jersey 08903**  
**(732) 519-2987**

## **EDUCATION**

**Masters of Technology Management, May (b)(6)**  
**Stevens Institute of Technology, Hoboken, NJ**  
**Major: Technology Management**

**Masters of Science, May (b)(6)**  
**Rutgers University, New Brunswick, NJ**  
**Major: Radiation Science**

**Bachelor of Engineering, May (b)(6)**  
**Stevens Institute of Technology, Hoboken, NJ**  
**Major: Engineering Physics**

## **EXPERIENCE**

**Health Physics Supervisor**  
**Bristol-Myers Squibb, New Brunswick, NJ**

**March 1992 - Present**

- Responsible for regulatory compliance and radiation safety at a nuclear medicine manufacturing and distribution facility
- Provides operational Health Physics support for largest non-utility radioactive material license in New Jersey
- Review of clinical research protocols involving radiolabeled investigational drugs
- Development of strategic goals and objectives for Health Physics Department
- Provide technical expertise and support for Central New Jersey Radiation Safety Committee
- Represents Environmental Health & Safety on the Facilities & Engineering Quality Customer Focus Team
- Represents Bristol-Myers Squibb on the PhRMA low level radioactive waste sub-committee
- Knowledge of applicable DOT, EPA, FDA, NRC, OSHA and NJ DEP regulations regarding radioactive material use
- Conducting facility compliance audits
- Develops and provides radiation safety training for research, manufacturing, and support personnel
- Personnel monitoring/bioassay techniques and dose calculations
- Approved by the NJ DEP as a Qualified Individual for the performance of radiation surveys for diagnostic x-ray equipment in accordance to NJAC 7:28-15.

EXPERIENCE (continued)

- Projects completed:
  - ◊ Championed the preparation of the application for renewal of the Central New Jersey radioactive material license
  - ◊ Identified and assessed new dosimetry contractor for Bristol-Myers Squibb
  - ◊ Development of a Decommissioning Funding Plan for five licensed sites including a Radiopharmaceutical manufacturing facility and R&D areas for submission to the NRC
  - ◊ Developed radioactive waste labeling, sorting and packaging program for PRI personnel in preparation of interim waste storage period.

Health Physicist  
Teledyne Isotopes, Westwood, NJ

March 1987 - March 1992

- Managed radioactive waste brokerage service
  - ◊ Regulatory compliance
  - ◊ Non-routine waste disposal
  - ◊ Facility decontamination and disposal
  - ◊ Supervised environmental and facility characterizations, remediations, and decontaminations
  - ◊ Radiation safety audits and evaluations for consulting clients

CERTIFICATION

American Board of Health Physics -  
Comprehensive Certification in Health Physics, November 1993, Re-certified 1997

PROFESSIONAL SOCIETIES

- New Jersey Health Physics Society (President 1995)
- National Health Physics Society
- American Academy of Health Physics

PRESENTATIONS & PUBLISHED ABSTRACTS

- *Regulatory Requirements for an Interim Waste Storage Facility at a Pharmaceutical R&D Facility*, Midyear Topical Meeting of the Health Physics Society, Albany, NY, February, 1994
- *Waste Segregation Program for R&D Personnel*, Annual Meeting of the Health Physics Society, San Francisco, CA, June, 1994

BETWEEN: 6.3.

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: 20080930  
Fee Comments: -----  
Decom Fin Assur Req'd: Y  
.....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: E. R. SQUIBB & SONS, INC.  
Received Date: 19990528  
Docket No: 3005222  
Control No.: 126887  
License No.: 29-00139-02  
Action Type: Amendment

2. FEE ATTACHED

Amount: \$530.00  
Check No.: 01262217

3. COMMENTS

Signed  
Date

R. J. Brown  
5/28/99

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /L/)

1. Fee Category and Amount: 3A \$530

2. Correct Fee Paid. Application may be processed for:

Amendment -----  
Renewal -----  
License -----

3. OTHER -----  
-----

Signed  
Date

Log  
Folio  
Check No. 01262217  
Amount \$530  
Fee Category 3A  
Type of Fee Amend  
Cross Check Rec'd 6/7/99  
Cross Completed  
By: [Signature]

EXPEDITE