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NRC FORM 313
(06-2016)
10 CFR 30, 32, 33, 34
35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3160-0120

EXPIRES: 06/30/2019



APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to InfoCollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1566 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1566/>. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

03029266

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

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

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

- A. NEW LICENSE
- B. AMENDMENT TO LICENSE NUMBER 06-27843-02
- C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Mary C. Hart
Bristol-Myers Squibb Co.
5 Research Parkway/PO Box 5100
Wallingford, CT 06492

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Bristol-Myers Squibb Co
5 Research Parkway
Wallingford, CT 06492

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Mary C. Hart

BUSINESS TELEPHONE NUMBER
(203) 677-6071

BUSINESS CELLULAR TELEPHONE NUMBER
(860) 558-1958

BUSINESS EMAIL ADDRESS
mary.hart@bms.com

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

- a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

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

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

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

10. RADIATION SAFETY PROGRAM.

9. FACILITIES AND EQUIPMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*)
(See 10 CFR 170 and Section 170.31)
*Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.

FEE CATEGORY

AMOUNT ENCLOSED \$

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

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

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

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Mary C. Hart, Associate Director EHS

SIGNATURE

Mary C. Hart

DATE

12/15/16

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

REC'D IN LAT. 12/16/16

592604
NUCLEAR MATERIALS-002



Bristol-Myers Squibb

Research & Development
5 Research Parkway
Wallingford, CT. 06492

December 15, 2016

U.S. Nuclear Regulatory Commission
Region 1
Suite 100
2100 Renaissance Boulevard
King of Prussia, PA 19406

Re: Bristol-Myers Squibb License No. 06-27843-02 Amendment

I am requesting an amendment to License No. 06-27843-02, Bristol-Myers Squibb, 5 Research Parkway, Wallingford, Ct. 06492. I am requesting changes to the BMS site license as described below.

- Designate Mary Hart as the Radiation Safety Officer for the site. Mary has worked in the EHS department for 23 years. Mary's work experience and education are attached.
- Remove the following supervisors: Donna Barten, Mark Krystal, Daniel Tenney and Remesh Padmanabha as they are no longer working at this site.

If you have any questions or concerns please call me at 203-677-6071, e-mail at mary.hart@bms.com or write to the above address.

Sincerely,

Mary Hart
Associate Director
Environment, Health & Safety
Bristol-Myers Squibb Company
5 Research Parkway
Wallingford, CT. 06492
mary.hart@bms.com
203-677-6071

Carl Grant
Site Director
Bristol-Myers Squibb Company
5 Research Parkway
Wallingford, CT. 06492
carl.grant@bms.com
203-677-7637

Work Experience and Education
Mary C. Hart
Associate Director, Environment, Health & Safety
203-677-6071 (Work)
Email: mary.hart@bms.com

Experience: 23 years of experience in EHS, Radiation Safety and Biosafety

Functions/Responsibilities:

- Provides leadership, training and operational support to all levels of the organization and across all functional groups. Provides day-to-day program management and compliance with site, corporate and regulatory standards and requirements. Serves as an expert, and provides resources that will ensure the environmental, health, and safety programs and performance for these sites.
- Establishes programs, ensures staff involvement, and participates in EHS risk assessment, self-assessment, audit and inspection processes.
- Leads, maintains, and assigns responsibility for industrial hygiene programs.
- Provides safety, health, and environmental guidance to others.
- Establishes, facilitates, and participates in various site committees and teams.
- Provides oversight and assistance in monitoring the efforts of consultants, service providers and contractors participating in site activities with safety, health and environmental impacts.
- Support the design of training program content and ensures the deliverance of effective EHS-related training.
- Fosters and maintain liaisons with Facilities, Engineering, and R&D departments to facilitate design and implementation of EHS related projects; evaluate and recommend proposed design facilities & equipment for laboratory operations.
- Utilize record management to maintain all safety records and exposure monitoring and generate reports as required.
- Manages, supports, and conducts incident investigations and appropriate notifications, as required.
- Compiles, analyzes, and interprets data, including data for incident management and reporting. Leads the development of, and participates in, the sites emergency response, including preparedness and business continuity programs.

Education:

University of Connecticut, Storrs, CT

B.S. Concentration: Allied Health/Medical Technology

B.A. Concentration: Biology

University of New Haven, New Haven, CT

M.S. Occupational Safety and Health Management

Harvard University, Cambridge, Ma-Occupational and Environmental Radiation Protection (40 hour course)

Certifications/Professional Affiliations:

ABSA International-Certified Biosafety Professional, Registered Biosafety Professional

U.S. NUCLEAR REGULATORY COMMISSION

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, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. Bristol-Myers Squibb PRI</p> <p>2. 5 Research Parkway Wallingford, Connecticut 06492</p>	<p>In accordance with the letter dated December 15, 2016</p> <p>3. License number 06-27843-02 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date October 31, 2021</p> <hr/> <p>5. Docket No. 030-29266 Reference No.</p>
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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. Hydrogen 3	A. Any	A. 6 curies
B. Carbon 14	B. Any	B. 5 curies
C. Fluorine 18	C. Any	C. 600 millicuries
D. Phosphorus 32	D. Any	D. 750 millicuries
E. Phosphorus 33	E. Any	E. 500 millicuries
F. Sulfur 35	F. Any	F. 5 curies
G. Calcium 45	G. Any	G. 100 millicuries
H. Copper 64	H. Any	H. 30 millicuries
I. Gallium 68	I. Any	I. 3 millicuries
J. Germanium 68	J. Any	J. 3 millicuries
K. Zirconium 89	K. Any	K. 20 millicuries
L. Iodine 125	L. Any	L. 1 curie
M. Cesium 137	M. Sealed Source (North American Scientific Model MED3550)	M. 300 microcuries

9. Authorized use:

A. through L. Research and development as defined in 10 CFR 30.4; animal studies.

M. Calibration of the licensee's instruments.

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030-29266

Amendment No. 21

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 5 Research Parkway, Wallingford, Connecticut.
11.
 - A. Licensed material shall be used by, or under the supervision of Richard Burrell.
 - B. Licensed material in items 6.A. through 6.J., 6.L., and 6.M., may also be used by, or under the supervision of Richard Burrell, David Harden, John J. Herbst, Fiona McPhee or Kenneth Santone.
12. The Radiation Safety Officer for this license is Mary Hart.
13. The licensee shall not use licensed material in or on human beings.
14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
15. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
16.
 - A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
 - B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
 - C. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
 - D. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred 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 shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
 - E. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of

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radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

- F. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- G. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
17. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, 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 and shall include the radionuclides, quantities, manufacturers name and model numbers, and the date of the inventory.
18. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
19. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
 - B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
 - C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
20. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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21. 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 U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated June 21, 2011 [ML111741043]
- B. Letter September 27, 2011 [ML112710359]

For the U.S. Nuclear Regulatory Commission

Date April 8, 2015By *Original signed by Dennis R. Lawyer*

Dennis R. Lawyer
Commercial, Industrial, R&D and Academic Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee Carl Grant Director of Wallingford Facilities Bristol-Myers Squibb PRI 5 Research Parkway Wallingford, Connecticut 06492	Date December 22, 2016
	License Number(s) 06-27843-02
	Mail Control Number(s) 592604
	Licensing and/or Technical Reviewer or Branch Jim Cassata

This is to acknowledge receipt of your: Letter and/or Application Dated: 12/15/2016

The initial processing, which included an administrative review, has been performed.
 Amendment Termination New License Renewal

There were no administrative omissions identified during our initial review.

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

Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
 Follow the instructions on the form for submission.

The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
 U. S. Nuclear Regulatory Commission
 Division of Nuclear Materials Safety
 2100 Renaissance Boulevard, Suite 100
 King of Prussia, PA 19406-2713
 (610) 337-5260, (610) 337-5313,
 (610) 337-5398, (610) 337-5239