

# Bristol-Myers Squibb Pharmaceutical Research Institute

Richard L. Gelb Center for Pharmaceutical Research and Development

June 21, 2005

5 Research Parkway P.O. Box 5100 Wallingford, CT 06492-7660

Licensing Assistant Section  
Nuclear Materials Safety Branch  
U.S. Nuclear Regulatory Commission, Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

Re: License #06-27843-02 Amendment **03029266**  
Bristol-Myers Squibb  
Wallingford, CT

RECEIVED  
GENERAL  
2005 JUN 24 PM 1:19

Dear Sirs,

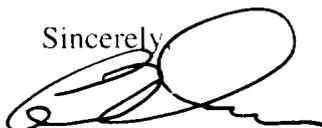
I am submitting this packet of material to update License #06-27843-02. Attached are the sections of the Radiation Safety Manual for which I am requesting two changes. One, I am requesting a change from twice per year calibration of survey meters to once per year. Bristol-Myers Squibb's New Jersey license allows once per year. We have check sources to use to investigate any malfunction or lack of proper response and would take appropriate actions – repair, removal from use, return to manufacture for service and recalibration. The second change is to reduce the number of required radiation safety committee meeting from 4 times per year to 2 times per year. There are not a lot of issues and four meeting per year are not of much value. I would call an additional meeting if any issues arose that required the committee's input.

I want to update the list of principle investigators that are identified in past submittals and on the site's license. John Russel, John Starett, John Torrente, Laura Zawadzke, Robert Myers, Glenn Warr, Frank Yocca, Kevin Burris and Danielle Beaulieu either no longer work for Bristol-Myers Squibb or their duties have change and no longer work with radioactive materials. The following names are the principle investigators currently working with radioactive materials and/or overseeing the safe use of isotopes. Their education and experience is attached. Richard Burrell, Douglas Dischino, Steve Dworetzky, Margi Goldstein, John Herbst, Dan Tenney, Hsu-Tso Ho, Donna Barten, Mark Krystal and Ken Santone.

I am also requesting the addition of a 200 micro curie Cesium-137 sealed source to the license (if required) to be used for a dose calibrator.

If you have any questions or concerns please contact me at 203 677-6342 or the above address.  
Thank you.

Sincerely,



Carl Noonan  
Associate Director  
Environment, Health & Safety

# PHARMACEUTICAL RESEARCH INSTITUTE

BRISTOL-MYERS SQUIBB COMPANY

Wallingford, CT

RADIATION SAFETY MANUAL	PROCEDURE:	§ 4
	DATE	June 1, 2005
	SUPERSEDES	May 14, 1996

## SECTION 4 - PROGRAM SUPERVISION

### RADIATION SAFETY OFFICER

The Radiation Safety Officer is a person who, by virtue of education and experience, is capable of implementing the policies of the Radiation Safety Advisory Committee.

The Radiation Safety Officer shall:

1. Consider the advice of the Radiation Safety Advisory Committee on policy decisions and ensure compliance with the provisions of this Manual.
2. Maintain all records and correspondence necessary to ensure compliance with applicable Regulations and Codes of the NRC.
3. Provide adequate information and training to employees engaged in Company activities utilizing sources of ionizing radiation.
4. Establish and maintain a personnel and environmental monitoring program according to 10 CFR 20.1101. This shall include the maintenance of internal and external dosimetry records as necessary based on the potential to received 10% of their yearly allotted dose (internal and external),

notification to individuals and their supervisors of doses approaching the maximum permissible amounts and recommendations for remedial action consistent with the ALARA Principle.

5. Establish procedures for the purchase, receipt distribution and shipment of all radioactive materials entering or leaving the Company.
  
6. Receive and review authorizations from Department Directors desirous of using sources of ionizing radiation. When needed or requested, the Radiation Safety Officer shall consult with applicants and provide guidance necessary for the proper completion of the authorization form.
  
7. Coordinate routine radiation and contamination surveys of Company areas where radioactive materials are used, stored or disposed. Survey results shall be sent promptly to researchers and shall clearly indicate radiation or contamination conditions requiring corrective action.
  
8. Respond to emergencies and provide supervision of radiation and contamination control efforts.
  
9. Supervise and coordinate the waste disposal program.
  
10. Perform semi-annual inventory of all sealed sources of radioactive material and maintain the required records.
  
11. Supervise semi-annual leak testing on sealed sources as required.

12. Maintain a record of all portable radiation survey instruments (type, manufacturer, location and calibration date). The Radiation Safety Office shall ensure that such instruments are calibrated annually.
  
13. Establish and maintain an isotope inventory of all radioactive materials (including waste) to ensure compliance with the isotope quantity limits set forth in the license.
  
14. Post appropriate signs at the entrances to rooms, laboratories, indicating the presence of radioactive materials.
  
15. Survey and maintain records of all ionizing radiation-producing equipment.
  
16. Be notified of any proposed change in location, orientation or shielding of electrical equipment producing ionizing radiation.

#### RADIATION SAFETY ADVISORY COMMITTEE

The Radiation Safety Advisory Committee is composed of representatives who, by virtue of responsibility, education and training or experience, are qualified to have direct involvement in providing guidance for the establishment and maintenance of policy germane to the safe use and disposal of sources of ionizing radiation.

The Radiation Safety Advisory Committee shall:

1. Provide guidance for the establishment of policy for the Radiation Safety Program that will provide adequate protection to Bristol-Myers Squibb PRI-Wallingford personnel engaged in work that utilizes sources of ionizing radiation.

2. Provide guidance for the establishment of policy, consistent with Good Laboratory and Production Practices, that will maintain radiation doses to all employees, as well as members of the general public, to levels that are as low as reasonably achievable.
3. Provide guidance and advice to the Radiation Safety Officer on matters concerning radioisotope work in laboratories.
4. Review all applications for the use of sources of ionizing radiation under the jurisdiction of Bristol-Myers Squibb PRI-Wallingford.
5. Review all proposed major changes in established procedures and facilities which may impact the Radiation Safety Program.
6. Review instances of alleged infractions of the safe use of sources of ionizing radiation with the Radiation Safety Officer and the responsible individuals.
7. Recommend appropriate corrective actions to ensure compliance with both the Regulations and Codes of the NRC and the policies of the radiation safety program.
8. Meet at least twice per year and provide Company Management with a written record of Committee activities.

DEPARTMENT DIRECTOR

Each Department Director shall:

1. Receive a copy of this Manual, read it with intent to comply with its provisions.
2. Provide adequate supervision and training of the employees with regard to specific operations in his/her laboratory involving R.A.M.'s or sources.
3. Provide employees with information regarding the radio-toxicity, physical and chemical properties and special handling requirements of radioactive materials found in her/her laboratory.
4. Should examine his/her laboratory monthly to ensure that radioactive materials are properly secured.
5. Provide and maintain, in good working condition, a portable radiation survey instrument capable of detecting the penetrating radiation from sources of ionizing radiation he/she is authorized to possess. Laboratories containing only the radioisotope H-3, are exempt from this provision.
6. Submit a monthly isotope inventory to the Radiation Safety Office.
7. Inform the Radiation Safety Office of any significant proposed changes to be made in operational procedures, quantities, storage areas, disposal procedures, facilities or personnel incident to the use of sources of ionizing radiation.
8. Ensure that Maintenance personnel enter and perform work in the laboratory only in the presence of a member of the laboratory staff cognizant of the radiological conditions existing in the laboratory. The Radiation Safety Office must be notified as soon as possible if work involves removing

contaminated or potentially contaminated laboratory equipment.

9. Promptly notify the Radiation Safety Office of any loss or accidental inhalation, ingestion or injury involving radioactive material and carry out the recommended corrective actions.
  
10. Promptly notify the Radiation Safety Office of any loss or accidental release of radioactive material and carry out the recommended corrective actions.
  
11. The Department Director may delegate any or all of the above duties to the principal investigator assigned to using the ionizing radiation.

BRISTOL-MYERS SQUIBB  
PHARMACEUTICAL RESEARCH INSTITUTE – WALLINGFORD

NAME: Richard Burrell

DATE: 6/2/05

JOB TITLE: Radiochemist

DEPARTMENT NAME: Chemical Synthesis

**A. TRAINING IN USE OF RADIOACTIVE MATERIALS:**

Please provide the names and dates of the college(s) or university you attended where you receive formal training in the use of radioactive materials.

I did not receive formal training to handle radioactive material in school.

**Formal Course Work:**

Describe the formal course work you have had in the following areas:

1. Principles and practices of Radiation Protection

I have not taken any formal classes on principles and practices of radiation protection.

2. Radioactivity measurements, standardization, monitoring techniques and instruments.

I have not taken any formal classes on radioactivity measurements, standardization, monitoring techniques or instruments.

3. Mathematics and calculations basic to the use and measurement of radioactivity

I have not taken any formal classes on mathematics and calculations basic to the use and measurement of radioactivity.

4. Biological effects of radiation

I have not taken any formal classes on biological effects of radiation.

## **B. ON-THE-JOB TRAINING**

Please provide a brief description of the on-the-job training you have received.

From January 2003 to February 2004 I worked as a radiochemist at the BMS site in New Brunswick, NJ. During this time I worked closely with my mentor Samuel Bonacorsi Jr and other senior radiochemists to learn the skills necessary to handle radioactive materials safely. These skills include limiting exposure to radioactive materials, methods of personal protection, methods for monitoring for radioactive materials, mathematics and calculations used in radioactivity measurement, and the rules and regulations imposed by BMS, local, state and federal agencies for handling radioactive materials. I also completed all of the training classes mandated by the BMS radiation safety and environmental health and safety departments.

From February 2003 to the present I worked as a radiochemist at the BMS site in Wallingford, CT. During this time I continued to work closely with senior radiochemists in NJ and the Wallingford radiation safety department to develop safe practices for handling radioactive materials. Safety and continued training is a focus for all members of the radiochemistry group. This emphasis is particularly visible at our monthly group meeting where safety and training are discussed by group members and speakers from other departments.



BRISTOL-MYERS SQUIBB  
PHARMACEUTICAL RESEARCH INSTITUTE – WALLINGFORD

NAME: \_\_Doug Dischino\_\_\_\_\_      DATE: June 8, 2005

JOB TITLE: Sr. Principle Scientist

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DEPARTMENT NAME: Chemical Synthesis

**A. TRAINING IN USE OF RADIOACTIVE MATERIALS:**

Please provide the names and dates of the college(s) or university you attended where you receive formal training in the use of radioactive materials.

Washington University in St. Louis

1978-1983, M.A. 1980, Ph.D. 1983

Ph.D. Thesis-Synthesis and Biological Studies of Positron-Emitting Radiopharmaceuticals

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**Formal Course Work:**

Describe the formal course work you have had in the following areas:

1. Principles and practices of Radiation Protection  
               Introduction to Radiochemistry (lecture and lab course)  
               Sept 1978  

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2. Radioactivity measurements, standardization, monitoring techniques and instruments.  
               same as above  

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3. Mathematics and calculations basic to the use and measurement of radioactivity

\_\_\_\_\_ same as above

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4. Biological effects of radiation

\_\_\_\_\_ same as above

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### **B. ON-THE-JOB TRAINING**

Please provide a brief description of the on-the-job training you have received.

\_\_\_\_\_ I have conducted research at Medi-Physics in Emeryville, CA in the synthesis and biological studies of C-11 labeled compounds. My Ph. D. thesis was dedicated to positron-emitting labeled compounds. I passed numerous exams in both practical and theoretical radiochemistry in qualifying exams for my degree. I attended a 3 day workshop at the National Tritium Labeling Facility. I have attended annual BMS radiation refresher courses and outside speakers presenting seminars on safety with positron emitting radiolabeled compounds. I have designed and supervised the construction of three devices (patent pending) to reduce personal radiation exposure.

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BRISTOL-MYERS SQUIBB  
PHARMACEUTICAL RESEARCH INSTITUTE – WALLINGFORD

NAME: Steven Dworetzky                      DATE: 5-31-2005

JOB TITLE: Senior Principal Scientist

DEPARTMENT NAME: Neuroscience

**A. TRAINING IN USE OF RADIOACTIVE MATERIALS:**

Please provide the names and dates of the college(s) or university you attended where you receive formal training in the use of radioactive materials.

University of Florida 1981-1988

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**Formal Course Work:**

Describe the formal course work you have had in the following areas:

1. Principles and practices of Radiation Protection  
Molecular Biology classes in graduate school  
\_\_\_\_\_  
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\_\_\_\_\_
  
2. Radioactivity measurements, standardization, monitoring techniques and instruments.  
same as above  
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\_\_\_\_\_  
\_\_\_\_\_
  
3. Mathematics and calculations basic to the use and measurement of radioactivity  
no formal coursework  
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4. Biological effects of radiation  
no formal coursework

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**B. ON-THE-JOB TRAINING**

Please provide a brief description of the on-the-job training you have received.

- Graduate Student on the job training for 125I and 35S labeling of proteins
- Post-Doctoral training in 32P for labeling of DNA probes
- Radiation Safety training class and refresher classes at Bristol-Myers Squibb

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BRISTOL-MYERS SQUIBB  
PHARMACEUTICAL RESEARCH INSTITUTE – WALLINGFORD

NAME: Margi Goldstein

DATE: June 14, 2005

JOB TITLE: Senior Research Investigator II

DEPARTMENT NAME: Neuroscience

**A. TRAINING IN USE OF RADIOACTIVE MATERIALS:**

Please provide the names and dates of the college(s) or university you attended where you receive formal training in the use of radioactive materials.

University of Rochester Medical Center

University of Pennsylvania

National Institutes of Health

\_\_\_\_\_

**Formal Course Work:**

Describe the formal course work you have had in the following areas:

1. Principles and practices of Radiation Protection  
Full two day classroom courses with exams  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
  
2. Radioactivity measurements, standardization, monitoring techniques and instruments.  
Full two day classroom courses with exams  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
  
3. Mathematics and calculations basic to the use and measurement of radioactivity  
Full two day classroom courses with exams  
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4. Biological effects of radiation

Full two day classroom courses with exams

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**B. ON-THE-JOB TRAINING**

Please provide a brief description of the on-the-job training you have received.

Individual training in the laboratory when performing a method for the first time,  
and yearly radiation safety training

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BRISTOL-MYERS SQUIBB  
PHARMACEUTICAL RESEARCH INSTITUTE – WALLINGFORD

NAME: John J. Herbst Ph.D

DATE: 6-16-05

JOB TITLE: Sr. Research Investigator

DEPARTMENT NAME: Lead Discovery And Profiling

**A. TRAINING IN USE OF RADIOACTIVE MATERIALS:**

**Please provide the names and dates of the college(s) or university you attended where you receive formal training in the use of radioactive materials.**

University of Utah Medical Center 1985-1992

Pfizer Inc 1992-1994

Dartmouth Medical Center Department of Biochemistry 1994-1997

Bristol Myers Squibb Co. 1997-Present

**Formal Course Work:**

Describe the formal course work you have had in the following areas:

- 1. Principles and practices of Radiation Protection**  
Received formal training as part of various courses during Ph.D. Training. These courses included principles of biochemical investigation , exzymology, experimental pathology, experimental immunology, etc. Additionally I was trained by the University Radiation Safety Offices at the University of Utah and Dartmouth College as well as the Radiation Safety Departments at Pfizer and Bristol Myers Squibb.
- 2. Radioactivity measurements, standardization, monitoring techniques and instruments.**  
These principals were covered as methods of investigative techniques covered during formal course work in classes in experimental pathology, enzymoogy, cell biology, biochemistry etc. Additional instruction was provided during directed study under the supervision of various professors.
- 3. Mathematics and calculations basic to the use and measurement of radioactivity**  
Covered as part of experimental design and directed study courses and post graduate training.

**4. Biological effects of radiation**

Covered as part of experimental design, directed study, toxicology, immunology and pathology courses as well as in radiation safety courses..

**B. ON-THE-JOB TRAINING**

**Please provide a brief description of the on-the-job training you have received.**

Received extensive NRC sanctioned training in safe handling, disposal and use of radioactive materials from the Univ. Of Utah, Dartmouth College, Pfizer and Bristol Myers Squibb.

Isotopes Handled	Maximum Quantities Handled	Where Experience Was Gained	Duration of Activities	Type of Use
125I	50mCi	Univ of Utah, Dartmouth, Pfizer and BMS	1985-Present	Iodination, Ligand binding studies, enzymological studies, etc.
131I	10mCi	Univ of Utah, Dartmouth, Pfizer and BMS	1985-Present	Iodination, Ligand binding studies, enzymological studies, etc.
35S	20mCi	Univ of Utah, Dartmouth, Pfizer and BMS	1985-Present	Metabolic labelling studies
14C	50mCi	Univ of Utah, Dartmouth, Pfizer and BMS	1985-Present	Metabolic labelling studies
32/33P	50mCi	Univ of Utah, Dartmouth, Pfizer and BMS	1985-Present	Kinase phosphatase, phospholipid enzymatic studies
3H	30mCi	Univ of Utah, Dartmouth, Pfizer and BMS	1985-Present	Binding and uptake studies

BRISTOL-MYERS SQUIBB  
PHARMACEUTICAL RESEARCH INSTITUTE – WALLINGFORD

NAME: Daniel J. Tenney DATE: June 6, 2005

JOB TITLE: Group Leader

DEPARTMENT NAME: Virology

**A. TRAINING IN USE OF RADIOACTIVE MATERIALS:**

Please provide the names and dates of the college(s) or university you attended where you receive formal training in the use of radioactive materials.  
The Medical College of Pennsylvania, Philadelphia,  
PA \_\_\_\_\_

**Formal Course Work:**

Describe the formal course work you have had in the following areas:

1. Principles and practices of Radiation Protection  
Advanced Laboratory  
Techniques \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
2. Radioactivity measurements, standardization, monitoring techniques and  
instruments.  
Advanced Laboratory Techniques  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
3. Mathematics and calculations basic to the use and measurement of  
radioactivity  
Advanced Laboratory Techniques  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
4. Biological effects of radiation  
Advanced Laboratory Techniques  
\_\_\_\_\_

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**B. ON-THE-JOB TRAINING**

Please provide a brief description of the on-the-job training you have received.

DuPont De Nemours, Inc. Experimental Station Radiation  
Training\_\_\_\_\_

Bristol-Myers Squibb Pharmaceutical Research Institute Radiation  
Training\_\_\_\_\_

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Isotopes Handled	Maximum Quantities Handled	Where Experience Was Gained	Duration of Activities	Type of Use
32P	1 mCi	Med Coll Of PA, DuPont, BMS		
33P	5 mCi	DuPont, BMS		
35S	25 mCi	DuPont, BMS		
14C	1 mCi	DuPont, BMS		
89Sr	5 mCi	Med Coll Of PA		
55Fe	1 mCi	Med Coll Of PA		
3H	50 mCi	DuPont, BMS		
125I	5 mCi	Med Coll Of PA, DuPont, BMS		
51Cr	1 mCi	Med Coll Of PA		

BRISTOL-MYERS SQUIBB  
PHARMACEUTICAL RESEARCH INSTITUTE – WALLINGFORD

NAME: Hsu-Tso Ho DATE: June 1, 2005

JOB TITLE: Principle Scientist

DEPARTMENT NAME: Virology

**A. TRAINING IN USE OF RADIOACTIVE MATERIALS:**

Please provide the names and dates of the college(s) or university you attended where you receive formal training in the use of radioactive materials.

Department of Chemistry, Ohio State University, 1983

**Formal Course Work:**

Describe the formal course work you have had in the following areas:

*Received as part of my graduate research requirement to conduct thesis projects.*

1. Principles and practices of Radiation Protection
  - Minimal level and time of exposure as necessary
  - Wear protective garment, gloves, shoes, safety glasses.
  - Work at designated radioactive usage bench area.
  - Protect work area with protective/absorbing covering material.
  - Clean up and dispose radioactive waste routinely.
  - Proper maintenance of record for radioactive material use/disposal.
  - Report accidents, spills and clean up to safety officer
  
2. Radioactivity measurements, standardization, monitoring techniques and instruments.
  - Scintillation counting using high flash point scintillation cocktails and scintillation counter.
  - Bench top detection using Geiger counters
  - Swipe test work area and instruments for radioactive contamination
  
3. Mathematics and calculations basic to the use and measurement of radioactivity  
See "Terrance G Cooper, *The Tools of Biochemistry, Chapter 3 Radiochemistry*. John Wiley & sons, New York, 1977".
  
4. Biological effects of radiation  
Minimize unnecessary radiation exposure to avoid potential harmful effects.

## **B. ON-THE-JOB TRAINING**

Please provide a brief description of the on-the-job training you have received.

Yearly refresher training on handling and safe use of radioactive material for bench top research. Experimental protocol evaluation/approval prior to conducting experiments. Evaluation of availability of equivalent, non-radioactive assays. Standard protocols for radioactive wastes disposal. Procedure for accidental radioactive material spill clean up. Procedure for handling and reporting accidental radiation exposure. Routine exposure monitoring and record keeping.



BRISTOL-MYERS SQUIBB  
PHARMACEUTICAL RESEARCH INSTITUTE – WALLINGFORD

NAME: Donna M. Barten DATE: 6-1-05

JOB TITLE: Principal Scientist

DEPARTMENT NAME: Neuroscience Drug Discovery

**A. TRAINING IN USE OF RADIOACTIVE MATERIALS:**

Please provide the names and dates of the college(s) or university you attended where you receive formal training in the use of radioactive materials.

State College of NY at Syracuse Radiation Chemistry Course (500 level), Spring 1983

University of Minnesota standard training on the use of Radio-isotopes in the lab, with supervised use in the lab, including through one pregnancy, with all of the extra pre-cautions involved (1983-88)

Yale University standard training on the use of Radio-isotopes in the lab, including 3 separate Gamma cell Irradiator training sessions, supervised use in the lab, including through one pregnancy, with all of the extra pre-cautions involved (1988-94)

**Formal Course Work:**

Describe the formal course work you have had in the following areas:

1. Principles and practices of Radiation Protection  
Radiation Chemistry Course, SUNY NY, 1983  
\_\_\_\_\_
2. Radioactivity measurements, standardization, monitoring techniques and instruments.  
Radiation Chemistry Course, SUNY NY, 1983  
\_\_\_\_\_
3. Mathematics and calculations basic to the use and measurement of radioactivity  
Radiation Chemistry Course, SUNY NY, 1983  
\_\_\_\_\_
4. Biological effects of radiation  
Radiation Chemistry Course, SUNY NY, 1983  
Toxicology Class, University of Minnesota 1985  
\_\_\_\_\_

## **B. ON-THE-JOB TRAINING**

Please provide a brief description of the on-the-job training you have received.

\_\_\_\_\_Annual Radiation Safety training for 10 years at BMS. Emphasis on the safe use and handling of radio-isotopes, emphasizing ALARA. Calculation skills, record keeping and measurement of radio-isotopes also covered in depth

Additional training on the use of a Gamma Cell irradiator on site in 1995

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Donna Barten				6/1/2005
Isotopes Handled	Maximum Quantities Handled	Where Experience Was Gained	Duration of Activities	Type of Use
3H	1 mCi or less	University of Minnesota, Yale School of Medicine, BMS	Several years	Labelling cellular metabolites, 3H-Thymidine proliferation assays, Compd distribution studies
45Ca	1 mCi or less	University of Minnesota	~ 1 yr	45Ca- uptake studies
35S	1 mCi or less	Yale School of Medicine, BMS	~3 yrs, then ~1 yr	DNA sequencing studies, protein sythesis studies
33P	1 mCi or less	Yale School of Medicine	~ 6 months	In situ hybridization
32P	1 mCi or less	University of Minnesota, Yale School of Medicine	~ 6 months, ~ 3years	Metabolite labelling, Northern, Southern Probes
125I (not free)	1 mCi or less	University of Minnestoat, Yale School of Medicine, BMS	~1 yr, ~ 1 yr, ~ 6 months	Photoaffinity labelling of proteins, Western blot analysis
14C	1 mCi or less	BMS	~ 1yr	Compd labelling and distribution studies
137Cs (in irradiator)	3500 Ci	Yale School of Medicine, BMS	~ 3 years, ~ 1 year intermittently	Irradiation of cells to prevent division

BRISTOL-MYERS SQUIBB  
PHARMACEUTICAL RESEARCH INSTITUTE – WALLINGFORD

NAME: Mark Krystal DATE: June 8, 2005

JOB TITLE: Director

DEPARTMENT NAME: Virology

**A. TRAINING IN USE OF RADIOACTIVE MATERIALS:**

Please provide the names and dates of the college(s) or university you attended where you receive formal training in the use of radioactive materials.

SUNY at Stony Brook 1976-1980

Mt. Sinai School of Medicine 1981-1992

Bristol-Myers Squibb Pharmaceutical Research Institute 1992-present

**Formal Course Work:**

Describe the formal course work you have had in the following areas:

1. Principles and practices of Radiation Protection  
No formal course work at Stony Brook or Mt. Sinai, but informal training by principal investigators at both sites  
Formal course and refresher course each year at BMS 1992-present
2. Radioactivity measurements, standardization, monitoring techniques and instruments.  
Took graduate course which encompassed these techniques ~1977  
Formal course and refresher course each year at BMS 1992-present

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3. Mathematics and calculations basic to the use and measurement of radioactivity  
Took graduate course which encompassed these techniques ~1977  
Formal course and refresher course each year at BMS 1992-present

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4. Biological effects of radiation  
Took graduate course which encompassed this area ~1977  
Formal course and refresher course each year at BMS 1992-present

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**B. ON-THE-JOB TRAINING**

Please provide a brief description of the on-the-job training you have received.

Principal Investigators and/or experienced scientists continually provided on-the job training in the use of radioactive materials. This included training on the needed precautions, potential misuse and procedures for cleaning up spills and disposing of radioactive waste.

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Isotopes Handled	Maximum Quantities Handled	Where Experience Was Gained	Duration of Activities	Type of Use
Iodine 125	5 millicuries	SUNY at Stony Brook	1977-78	Radiolabel RNA for use as probe
Phosphorous 32	5 millicuries	SUNY at Stony Brook Mt. Sinai School of Medicine BMS	1978-92	Radiolabel DNA for use as probe and for DNA sequencing
Sulfur 35	5 millicuries	Mt. Sinai School of Medicine BMS	1981-1994	Radiolabel cellular proteins for expression/immunoprecipitation analyses
Phosphorous 33	1 millicurie	BMS	1992-1996	Radiolabel DNA for use as probe and for DNA sequencing

BRISTOL-MYERS SQUIBB  
PHARMACEUTICAL RESEARCH INSTITUTE – WALLINGFORD

NAME: Kenneth Santone, Ph.D.

DATE: 6-6-2005

JOB TITLE: Associate Director

DEPARTMENT NAME: Pharmaceutical Candidate Optimization, Metabolism and Pharmacokinetics

**A. TRAINING IN USE OF RADIOACTIVE MATERIALS:**

Please provide the names and dates of the college(s) or university you attended where you receive formal training in the use of radioactive materials.

Univ. of Connecticut (UConn), 1974-78

The Univ. of Texas at Austin (UTexas), 1978-83

Mayo Clinic Graduate School of Medicine (MCGSM), 1984-87

**Formal Course Work:**

Describe the formal course work you have had in the following areas:

1. Principles and practices of Radiation Protection

UConn 1977: Lectures on handling and use of radioisotopes

UTexas 1978: Lectures and practical training in use of radioisotopes

2. Radioactivity measurements, standardization, monitoring techniques and instruments.

UTexas 1978: Laboratory course in radioactivity measurements and detection instrumentation

3. Mathematics and calculations basic to the use and measurement of radioactivity

UConn 1977: Formal lectures in calculations connected with radioactive materials.

UTexas 1978: Supervised practical experience in calculations involved in experiments utilizing radioactivity.

4. Biological effects of radiation

MCGSM 1894: Post-graduate course in radiobiology and radiation health physics.

## **B. ON-THE-JOB TRAINING**

Please provide a brief description of the on-the-job training you have received.

MCGSM 1984: Use and disposal of radioactivity

The Upjohn Co. 1988: Initial new-user radiation safety training

The Upjohn Co. 1989: NRC approved radiation safety training course

Bristol-Myers 1989: Initial new-user radiation safety training

Bristol-Myers Squibb 1990-2002: Yearly radiation safety training certification for experienced users.

Isotopes Handled	Maximum Quantities Handled	Where Experience Was Gained	Duration of Activities	Type of Use
Ca-45	1 mCi	Univ. of Texas at Austin	1978-84	In Vitro binding and uptake studies
C-14	1 mCi	Univ. of Texas at Austin	1978-84	In Vitro metabolism studies
C-14	1 mCi	Mayo Clinic School of Medicine	1984-87	In Vitro metabolism studies
H-3	1 mCi	Mayo Clinic School of Medicine	1984-87	In Vitro metabolism studies
C-14	5 mCi	The Upjohn Company	1987-89	In Vitro and In Vivo metabolism studies
H-3	5 mCi	The Upjohn Company	1987-89	In Vitro and In Vivo metabolism studies
C-14	5 mCi	Bristol-Myers Squibb	1989-2002	In Vitro and In Vivo metabolism studies
H-3	5 mCi	Bristol-Myers Squibb	1989-2002	In Vitro and In Vivo metabolism studies

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

6/21/2005, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 06-27843-02 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

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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** 137276.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.

(FOR LFMS USE)  
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

: Program Code: 03620  
: Status Code: 0  
: Fee Category: 3M  
: Exp. Date: 20120229  
: Fee Comments:  
: Decom Fin Assur Req'd: Y  
: .....

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: BRISTOL-MYERS SQUIBB PRI  
Received Date: 20050624  
Docket No: 3029266  
Control No.: 137276  
License No.: 06-27843-02  
Action Type: Amendment

2. FEE ATTACHED

Amount:           /            
Check No.:           /          

3. COMMENTS

Signed Rebecca J. Ford  
Date 7/16/05

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

1. Fee Category and Amount: \_\_\_\_\_

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

Amendment \_\_\_\_\_  
Renewal \_\_\_\_\_  
License \_\_\_\_\_

3. OTHER \_\_\_\_\_  
\_\_\_\_\_

Signed \_\_\_\_\_  
Date \_\_\_\_\_