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Bristol-Myers Squibb Company

P.O. Box 191 New Brunswick, NJ 08903-0191 732-2: 7-5000

February 20, 2009

Mr. Dennis Lawyer
Division of Nuclear Material Safety
U. S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

brz

RECEIVED
FEB 25 PM 12:28

Re: **Radioactive Material License Amendment -
License No. 29-00139-02, Docket No. 030-05222**

Dear Mr. Lawyer:

E. R. Squibb & Sons, LLC, a wholly owned subsidiary of Bristol Myers Squibb Company, requests the following amendments to its radioactive material license.

- The current Chair of the Radiation Safety Committee, Craig Woodard, should be replaced with William McGrath, Director, Pharma Quality and EHS. Mr. McGrath's resume is attached for your review.
- The current Radiation Safety Officer, Michael Vala, should be replaced with James Owens, Manager EHS. Mr. Owens's resume is attached for your review. In addition to the training and experience outlined in his resume, Mr. Owens is scheduled to attend Radiation Safety Officer training during the week of February 23, 2009 to further enhance his radiation safety expertise. This 40 hour training course will be provided at the Dade Moeller & Associates - Radiation Safety Academy located in Gaithersburg, Maryland.

A new Delegation of Authority notice and revised organization chart is also include for your information. If you require any additional information concerning this application, please contact michael.vala@bms.com or (732) 227-5096.

Sincerely,

Louis Fedele
Vice President, Facilities

Enclosures (4)

Cc: W. McGrath
J. Owens
M. Vala

William P. McGrath, CSP, CIH

Bldg. 137, Room 316

New Brunswick, NJ 08903

william.mcgrath@bms.com

Tel: C (b)(6) O - (732) 227-7365

EMPLOYMENT:

2008-Present

Group Director – PQ&EHS

Bristol-Myers Squibb Company

Responsible for creating strategic and operational alignment of EHS systems, processes, and training within R&D consistent with regulatory requirements, business needs and corporate strategies. Manage the R&D specific EHS programs including the exposure guideline process, occupational toxicology, Material Safety Data Sheet (MSDS) management, bio-safety, and R&D external partnerships.

2000-2008

Associate Director – CEHS

Bristol-Myers Squibb Company

Acting director (interim, 2006 to present) of the CEHS Product Technology team - Provides strategic leadership of workplace exposure evaluation and control initiatives including:

Management of the New Brunswick AIHA certified laboratory.

Oversight of all potent compound containment capital spending projects.

Management of the Industrial Toxicology and MSDS development teams.

Technical EHS lead for a multi-disciplinary team that develops, implements, and updates guidelines for the design of potent compound handling facilities.

Manages EHS pipeline support for new product development, launch, and technical transfer activities at BMS network and contract manufacturing locations.

Identifies, communicates, and makes recommendations to management regarding emerging EHS issues that may impact the business.

Represents BMS on industry and governmental work teams.

1995 to 2000

Associate Director - Environmental Health and Safety, Worldwide Medicines Group

Bristol-Myers Squibb Company

Provides Environmental, Health and Safety support for the Europe,

Asia, and Latin America operating facilities of the Worldwide Medicines Group including 45 manufacturing and distribution locations. Advises location management regarding current and emerging EHS initiatives. Responsible for the design and implementation of group wide EHS programs including process safety, industrial hygiene, drug manufacturing safety, emergency response and loss prevention. Provided internal consulting services in the areas of occupational hygiene, safety, and environmental protection.

1990 to 1995

Manager - Health and Safety, Pharmaceutical Group
Bristol-Myers Squibb Company

Provided guidance and leadership to Health and safety professional staff at 30 international Group operating locations. Designs and facilitates the implementation of, health and safety programs for the Group. Made personnel development, staffing, and organizational reporting recommendations for approximately 40 indirect EHS staff members worldwide.

1987 to 1990

Department Head - Worldwide Occupational/Environmental Safety Department
Squibb Corporation

Responsible for the management of the Safety and Loss Prevention sections of the department. The department served as a resource to all Squibb Corporation locations on a worldwide basis, providing expert advice in the areas of fire protection, loss prevention, emergency response, safety engineering and workers' compensation. Implemented the first companywide EHS Management Awareness training program, resulting in improved reporting and a significant reduction in accidents.

6/85 to 7/87

Section Head - Safety Administration
Colgate-Palmolive Company

Responsible for all safety, industrial hygiene, and environmental control activities for the Research and Development division. Initiated the first formal accident investigation program. Began facility compliance audits at three N.J. locations. Responsible for all aspects of Right-To-Know compliance. Initiated computer based chemical inventory system and conducted training for 700 laboratory and production employees. Initiated a program of measurement and documentation of employee workplace exposures. Managed the hazardous waste disposal program.

3/80 to 6/85

Safety Supervisor

Allied Corporation

Responsible for management of site safety department at corporate headquarters/research facility. Directed safety and industrial hygiene programs for full time and contract employees. Lead 25 member industrial fire brigade. Responsible for all aspects of site fire protection program. Conducted accident investigation and workers' compensation claims processing. Directed site safety training activities.

9/77 to 3/80

Safety Engineer

Allied Corporation

Responsible for administration of site technology safety program. Work site included laboratory, pilot plant and manufacturing facilities. Initiated respiratory protection program. Established hazardous waste disposal program and the low level radioactive waste disposal program.

EDUCATION:

Master of Science, New Jersey Institute of Technology (Health and Safety) (b)(6)

Bachelor of Science, University of Connecticut (b)(6)

PROFESSIONAL CERTIFI

MEMBERSHIPS:

Certified Safety Professional. Comprehensive Practice.

Certified Industrial Hygienist. Comprehensive Practice.

Chair, PhRMA Health and Safety Expert Team

NIOSH Hazardous Drug Work Group

American Society of Safety Engineers, past chairman Legislative Committee, New Jersey Chapter.

Member, State of New Jersey Low Level Radioactive Waste Disposal Facility Siting Commission. (1988-2000)

Director, Inter-American Safety Council. 1993-2003

JAMES RUSSELL OWENS

(b)(6)

SUMMARY OF QUALIFICATIONS

- Manager of radiation safety, hazardous waste, emergency response, fire safety, and confined space entry programs.
- Ensure compliance with federal, state and local regulations concerning areas of responsibility.
- Superior ability to manage within an environment which supports safety, quality, and reliability, while rewarding people based upon performance.

PROFESSIONAL EXPERIENCE

8/02 – Present

Bristol-Myers Squibb Company
Pennington, NJ

Manager. Radiation Safety Operations

- Responsible for managing three union employees in the day-to-day operations of the Health Physics program at multiple sites.
- Conducted training courses for research and support personnel.
- Conducted safety audits in laboratories and non-laboratory areas
- Participated in local, State and Federal regulatory agency inspections
- Manage Emergency Response Team
- Manage Hazardous Waste program
- Manage Fire Safety program
- Manage Confined Space Entry program

1/00 – 8/02

Bristol Myers Squibb Co.
Pennington, NJ
Environmental Engineer

- Manage Emergency Response Team HazMat Technicians and EMT's.
- Manage Hazardous Waste program.
- Manage Fire Safety program.
- Manage Confined Space Entry program.
- Perform additional EHS tasks, as required.

4/92 - 1/00

Bristol Myers Squibb Company
Lawrenceville, NJ
Health Physics Supervisor/Scientist

- Approve purchase requisitions for radioactive material use.
- Perform radiation safety and general safety audits at three research sites to ensure compliance with federal, and state regulatory agencies.
- Provide training to research personnel and outside contractors on the safe handling of radioactive material.
- Manage personnel exposure program for 600+ researchers.
- Interact with federal and state regulatory agencies.
- Manage database for radionuclide and sealed source inventory.
- Manage radioactive waste disposal procedures to comply with DOT, NJDEP, and NRC regulations.
- Manage Laser Safety program.

10/85 - 7/91

MEDI-PHYSICS, INC., Subsidiary of HOFFMAN-LaROCHE
South Plainfield, NJ
Production Manager

- Coordinate production planning, raw material inventories, and operations/supply purchasing in the manufacture of diagnostic pharmaceuticals in an aseptic filling environment.
- Interact with federal and state regulatory agencies including the Food and Drug Administration.
- Prepare and control department expense budget to effectively contain operating costs.
- Interact with support departments to coordinate manufacturing schedules.

6/79 - 10/85

MEDI-PHYSICS, INC., Subsidiary of HOFFMAN-LaROCHE
South Plainfield, NJ
Production Supervisor

- Organized and supervised the daily manufacturing of diagnostic pharmaceuticals including aerosols, capsules and sterile dosage forms.
- Directed shift operations and insured technical accuracy of all production processes and procedures.
- Maximized productivity while insuring proper adherence to cGMP.
- Designed, modified and built processing systems.

8/76 – 6/79

MEDI-PHYSICS, INC., Subsidiary of HOFFMAN-LaROCHE
South Plainfield, NJ
Production Lead Technician

- Supervised daily manufacturing operations in the absence of a supervisor.

8/75 – 8/76

MEDI-PHYSICS, INC., Subsidiary of HOFFMAN-LaROCHE
South Plainfield, NJ
Production Technician

- Processed raw materials into final drug form.

EDUCATION

UNIVERSITY OF FLORIDA, Gainesville, FL
B.S. Laboratory Animal Science

LICENSE AND CERTIFICATIONS

- NJ Certified Fire Safety Inspector – December 2004
- Certified Hazardous Material Manager (CHMM) – June 2003
- NJ Certified Emergency Medical Technician (EMT) – December 2001

CONTINUING EDUCATION

- Management Communication Skills
- Managing in an Equal Opportunity Environment
- Time Management
- Interaction Management
- Managing in a Non-Union Environment
- Managing in a Union Environment
- Targeted Selection
- Managing Performance
- Hazardous Waste Management
- Occupational & Environmental Radiation Protection
- Laser Safety Hazards, Inspections & Controls
- Fundamentals of Industrial Hygiene
- OSHA Mandates and Compliance Managing the Workplace

ACTIVITIES

(b)(6)

REFERENCES

Available on request

Radiation Safety Officer Delegation of Authority

James R. Owens is the Radiation Safety Officer for the Lawrenceville, New Brunswick and Pennington facilities and is responsible for ensuring the safe use of radioactive material. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulation for the use of radioactive material. The Radiation Safety Officer is hereby delegated the authority necessary to meet these responsibilities.

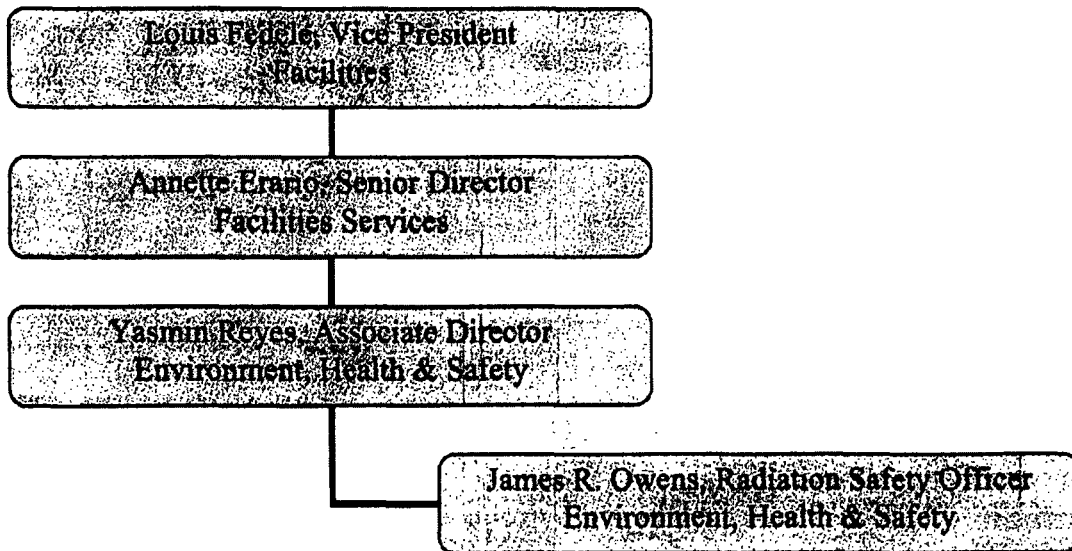
The Radiation Safety Officer has the authority to immediately stop any operations involving the use of radioactive material in which health and safety may be compromised or may result in non-compliance with NRC, NJ DEP, or radioactive material license requirements.

Approved by:

A handwritten signature in black ink, appearing to read 'Louis Fedele', written over a horizontal line.

Louis Fedele, Vice President
Facilities

Facilities Organizational Chart



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

2/26/2009, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Answer 29-0039-02 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 143448.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader