



U. S. Nuclear Regulatory Commission
Region 1 Nuclear Materials Branch 2
Division of Nuclear Materials Safety
475 Allendale Road
King of Prussia, PA 19406

GlaxoSmithKline
1250 South Collegeville Road
PO Box 5089
Collegeville, PA
19426-0989
Tel. 610 917 7000
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www.gsk.com

License Numbers: 37-00²⁸²~~280~~-04, 37-00282-05
03-05986
03029439

Subject: License Amendment for the Appointment of new Radiation Safety Officer

Dear Sir or Madam,

SmithKline Beecham Pharmaceutical d/b/a/ GlaxoSmithKline wishes to amend its byproduct material and irradiator Nuclear Regulatory Commission Licenses to reflect the appointment of Leo P. Foley as the Radiation Safety Officer replacing Richard Rebar current Interim Radiation Safety Officer.

Leo P Foley has twenty three years of experience in Environment Health & Safety, with an expertise in Radiation Protection, including Regulatory Compliance, Training, Environmental Monitoring, Public Interfacing and Emergency Preparedness. He has been with the GlaxoSmithKline for twelve years in a number of positions of increasing responsibility. His work as the Radiation Safety Coordinator from 1997-2003 and his continued involvement in the development of Radiation Safety Processes for GSK has provided the experience needed to perform the duties of the Radiation Safety Officer.

Attached please find the resume of Leo P. Foley as well as the signed Delegation of Authority. The current Radiation Safety Staff remains intact. Mr. Foley will report to Richard B Kehler, Occupational Exposure Control Manager, Environment, Health & Safety.

Should you have any questions, please call me at (610) 270-6071, or Eileen Hotte, Director, Environment, Health & Safety, at (610) 917-6352.

Sincerely,

Eliot H. Ohlstein, Ph.D.
SVP, Cardiovascular and Urogenital Diseases
Center of Excellence for Drug Discovery
GlaxoSmithKline, R&D
709 Swedeland Road
Mail Code UW 2523
King of Prussia, PA 19406

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REGION 1

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NMSS/RGN1 MATERIALS-002



Delegation of Authority
Radiation Safety Officer

GlaxoSmithKline
1250 South Collegeville Road
PO Box 5089
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Memorandum: To: File
From: Eliot Ohlstein
Subject: Delegation of Authority for Radiation Safety Officer

Leo P. Foley has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of byproduct 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 regulations for the use of byproduct 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 byproduct material in which health and safety may be compromised or may result in the non-compliance with NRC requirements.

Eliot Ohlstein
SVP Cardiovascular and Urogenital Diseases Centre of Excellence for Drug Discovery
GlaxoSmithKline, R&D

LEO P. FOLEY, JR.



QUALIFICATION HIGHLIGHTS

Twenty-three years of experience in Environment Health & Safety (EH&S), with an expertise in Radiation Protection, Regulatory Compliance, Training, Environmental Monitoring, Public Interfacing, Emergency Preparedness, Procedure Writing, Task Analysis, Lesson Plan Development, Classroom Instruction and Database and Website Management.

PROFESSIONAL EXPERIENCE

GLAXOSMITHKLINE, Research and Development

1997-Present

EH&S Radiation Safety Manager (1/2007-Present)

- ◆ Direct management of all aspects of the R&D Radiation Safety Program for Environment Health & Safety at the Upper Merion and Upper Providence R&D sites which includes 360 radiation users under GSKs Broad Scope License.
- ◆ Develop and manage cross-site programs in ionizing and non-ionizing radiation use and safety in alignment with R&D business needs, R&D Corporate goals and standards, and US NRC and PADEP License requirements.
- ◆ Establish and take the lead for R&D's Radiation Safety Committee which addresses site needs and regulatory requirements.

EH&S Manager Business Planning & Process (2005-2006)

- ◆ Developed and implemented plans for effective management of the administrative processes for GSK's Radiation Safety Program, which includes streamlining radiation user and radioactive material usage registration processes.
- ◆ Implemented new Radiation Management system (RAMS) which allows Principal Radiation users to electronically manage their radiation inventory and also allows Radiation Safety to register and track radiation users and usage.
- ◆ Manage all EH&S policies, procedures and required documentation in accordance with GSK Standards and regulatory requirements.
- ◆ Work with customer groups to ensure clear understanding of user requirements to develop/build efficient solutions ensuring appropriate levels of quality and documentation are built into all EH&S processes.
- ◆ Provide information and recommendations to EH&S management on IT applications that deliver cost effective process improvement.
- ◆ Evaluate, recommend and implement current technologies for EH&S Process Improvement.
- ◆ Participate in EH&S management team contributing to development of EH&S business initiatives.
- ◆ R&D Enhance Expert for EH&S department. R&D Enhance is a change management program that uses 'Accelerated Change Management and Lean Sigma philosophies' to improve efficiency.
- ◆ Served as Team Lead for R&D Enhance project on the Radiation Program which resulted in numerous improvements and efficiencies for the Radiation Safety program.

**PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.**

EH&S Training & Operations Manager (2003-2005)

- ◆ Evaluated and made recommendations for the selection of a new radiation dosimeter supplier contract
- ◆ Managed the maintenance of R&D Radiation Safety exposure records, employee training records and radioisotope purchase records.
- ◆ Responsible for the management of all EH&S Training, deployment and records.
- ◆ Managed all EH&S computer based training programs.
- ◆ Managed the operation of both R&D, EH&S Offices.
- ◆ Provided support to all EH&S disciplines based on R&D needs.
- ◆ Implemented and maintained the GSK Global Learning Management System.
- ◆ Responsible for communicating employee information to all UM & UP R&D.

EH&S Radiation Coordinator (1997-2002)

- ◆ Responsible for the R&D radioisotope inventory system. This includes overseeing and approving radioisotope purchases for all US R&D to ensure strict adherence to US NRC regulations and GSK nuclear materials license.
- ◆ Managed the radiation dosimeter program for the Upper Merion and Upper Providence R&D sites.
- ◆ Maintained R&D Radiation Safety databases and files which included radiation dosimeter records, employee training records and radioisotope purchase, use, disposal and accountability records.
- ◆ Participated in the development and management of the Safety intranet web site for to provide another vehicle for disseminating safety information and training to the R&D community.
- ◆ Member of the Corporate Safety Awareness Team, acting as a liaison between R&D and the Corporate Staff, providing R&D input to safety awareness initiatives.

SMITHKLINE BEECHAM, Research and Development

1995-1997

Environmental Coordinator, EH&S .

- ◆ Managed and Processed Hazardous and Radioactive Materials for Disposal.
- ◆ Performed Radiological Material Receipt Surveys while maintaining Inventory Control.
- ◆ Performed Laboratory and Equipment Release Surveys.
- ◆ Responsible for Waste Water Sampling and Analysis.

PECO ENERGY COMPANY, Limerick Generating Station

1984 - 1995

Health Physics Supervisor

Responsible for Ensuring Plant Procedures, Technical Specifications and NRC Regulatory Guidelines were adhered to during normal and abnormal station operations. Developed and supervised the implementation of Health Physics Support Activities.

Health Physics Technician

Responsible for maintaining Radiation Protection Guidelines to ensure Public Health and Safety, as well as, maintain Exposure Levels *As Low As Reasonably Achievable*.

EDUCATION and TRAINING

West Chester University

BS, Political Science. Minor Study: Public Administration.

1983

ANSI Certification for Radiation Protection

1986

Certified Evaluator for On-the-Job Training

1987

Health Physics Classroom Instructor

1987

HAZMAT Training

1995

Radiation Safety Officer Certification

RSO Associates

2001

Radiation Safety Officer Certification

Oak Ridge Associates University

2007

This is to acknowledge the receipt of your letter/application dated undated
RECEIVED 10/26/2007, and to inform you that the initial processing which
includes an administrative review has been performed.

AMEND. 37-00282-04 ← 37-00282-05
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** 141242 / 141243
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.