



NMS82

Boehringer Ingelheim
Pharmaceuticals Inc.

United States Nuclear Regulatory Commission
Region I
Attention: Mr. Thomas K. Thompson
475 Allendale Road
King of Prussia, PA 19406-1415

03017101

March 9, 2007

NRC Materials License No. 06-19183-01

Dear Mr. Thompson,

We are appointing Mr. William Galdenzi as our temporary Radiation Safety Officer effective March 9, 2007. Mr. Galdenzi joined Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) on February 12, 2007 as a regular employee. In his previous position, he was RSO and Superintendent of Laboratory Safety at Bayer Corporation, Pharmaceutical Division, West Haven, CT. In addition, he is a Certified Safety Professional (CSP) and Certified Industrial Hygienist (CIH). A copy of the Radiation Safety Officer Delegation of Authority memo, his resume and additional supporting information are attached.

Karl D. Hargrave, Ph.D.
Tel: 203-798-5136
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karl.hargrave@rdg.boehringer-
ingelheim.com
900 Ridgebury Rd/P.O. Box 368
Ridgefield, CT 06877-0368

If approved by the NRC, Mr. Galdenzi will permanently replace Mr. Sean Austin as our RSO. Since Mr. Austin is a contract worker residing in Maryland, our goal has been to retain Mr. Austin until we could hire a regular BIPI employee as RSO who will be on site full time.

We request that our NRC Materials License No. 06-19183-01 be amended to designate Mr. William Galdenzi as our RSO.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

Karl D. Hargrave, Ph.D.
Chairman, Radiation Safety Committee

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REGION 1

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attachments

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NMSS/RGN1 MATERIALS-002

Memo



To: R&D Department Heads

Paul C. Anderson, Ph.D.
Sr. Vice President, Research
Peter R. Farina, Ph.D.
Sr. Vice President, Development

March 09, 2007

Delegation of Authority for Radiation Safety Officer

Boehringer Ingelheim
Pharmaceuticals Inc.

Dear Colleagues,

Mr. William Galdenzi 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 non-compliance with NRC requirements.

Sincerely,

Handwritten signature of Paul C. Anderson in black ink.

Paul C. Anderson, Ph. D.
Senior Vice President, Research

Handwritten signature of Peter R. Farina in black ink.

Peter R. Farina, Ph. D.
Senior Vice President, Development

cc: Mr. William Galdenzi
Dr. Karl Hargrave, Chairman, Radiation Safety Committee
Ms. Mary McConnell-Meachen, Exec. Dir., Environ. Affairs & Safety
Ms. Sarah Stewart, Radiation Safety Specialist

William L. Galdenzi, CIH, CSP

Home: [REDACTED]

wgaldenz@rdg.boehringer-ingelheim.com

Work: (203) 778-7759

QUALIFICATIONS:

Accomplished, dedicated EHS Manager with significant experience developing, implementing and leading Health, Environment and Safety teams. Impressive history of providing high quality, sound, and risk-based technical support and superior customer service and guidance. Strong ability promoting change through clear communication, motivational leadership and thorough problem analysis. Trusted to advise senior management on all aspects of corporate safety and health compliance and promotion of corporate environmental, health and safety image. Current Certified Safety Professional (CSP) since 1993 and Certified Industrial Hygienist (CIH) with Indoor Environmental Quality sub-specialty since 1995. Additional areas of expertise include:

- ◆ Radiation Safety
- ◆ Budget Management
- ◆ Change Leadership
- ◆ Public Speaking
- ◆ Laboratory Safety
- ◆ Educational Programs
- ◆ Personnel Development
- ◆ Incident Investigation
- ◆ Regulatory Compliance

HONORS AND AWARDS:

- *Earned*, 2002 Pinnacle Award, the highest recognition at *Bayer*, for creating a state-of-the-art radioactive material protocol, order, inventory, and tracking program to manage over 1.2 million in annual radioactive material orders. The program substantially reduced cost and time and increased Bayer's regulatory compliance.
- *Recognized*, together with the *Bayer*, with the Ron Brown Award for Corporate Leadership in 2000, for Bayer's industry leading ergonomics program. West Haven site was first Bayer site to be in full compliance with Bayer's Structured Ergonomic Process.
- *Elected*, President of the Connecticut River Valley, American Industrial Hygiene Association (2000).
- *Served*, National American Industrial Hygiene Association Workplace Environmental Exposure Level Committee from 1997 to 2003.

CAREER ACCOMPLISHMENTS:

- Lead Team that developed and implemented Bayer's Environmental, Safety and Health Management System. This structured EH&S program improved Bayer's safety performance to one of the best-in-class.
- Train 600+ laboratory and manufacturing employees on environmental, safety, and health regulations.
- Monitor and communicate emerging environmental, safety, and health and legislative issues to the organization.
- Developed and implemented a monthly environmental, safety, and health Points to Consider document to consistently deliver regulatory required EHS training and information to laboratory groups.
- Served as a member of the corporate audit team, tasked with performing comprehensive environmental and safety compliance audits of various sites including GMP/GLP areas.

PROFESSIONAL EXPERIENCE:

Boehringer Ingelheim, Pharmaceuticals, Ridgefield, CT

2/07- present

Manager of Laboratory Safety

- Manage several major regulatory programs including Radiation Safety, Chemical Hygiene, Biological Safety, and Laser Safety.
- Manage 1 Radiation Safety Technician.

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

Bayer Corporation, Pharmaceutical Division, West Haven, CT
Superintendent of Laboratory Safety/Radiation Safety Officer

1/97 – 2/07

- Manage several major regulatory programs including serving the following regulatory functions for the site: Chemical Hygiene Officer, Radiation Safety Officer, Biological Safety Officer, and Laser Safety Officer. Chair the site's Ergonomic, Reproductive Health, Scientific Safety, Biological Safety, and Institutional Animal Use and Care Committees.
- Manage 5 radiation/lab safety professionals and an annual budget of almost \$1.2 million
- Investigate on-site and field incidents, determine root causes, and develop recommendations to prevent reoccurrences. Work closely with Occupational Medicine. Extensive experience in OSHA recordkeeping and workers' compensation.
- Develop and implement risk-based programs that are compliant, efficient, and cost effective.
- Coordinate the site's respiratory health, PPE, industrial hygiene/IAQ, Fleet Safety, MSDSs, emerging issues, performance metric/statistics, and lead and asbestos programs.
- Serve as Site's Senior Incident Commander, Hazmat Team and First Aid Team Member.

Sikorsky Aircraft, Stratford, CT
Safety & Industrial Hygiene Engineer

8/96 – 1/97

- Coordinated all elements of United Technologies/Sikorsky Aircraft's safety and health program for Sikorsky's largest unit, the Machine and Transmission Center.
- Participated in Corporate UTC Assurance Reviews as well as prepare Sikorsky-Stratford for their Assurance Review.
- Served as Sikorsky's Laser Safety Officer.

Aetna Life and Casualty, Windsor, CT
Certified Industrial Hygienist

4/93 – 7/96

- Provided technical safety and health oversight and resources to national field locations and clients.
- Managed West Coast Territory and 4 Industrial Hygiene Specialists.
- Provided on-going safety and industrial hygiene service to covered clients. Service included industrial hygiene monitoring, compliance audits, employee training, ergonomic surveys, laser and radiation evaluation and monitoring.

Aetna Life and Casualty, Stratford, CT
Loss Control Engineer

11/89 – 4/93

- Managed local territory performing and coordinating safety and industrial hygiene audits/inspections of all prospective and covered clients to ensure compliance with regulatory and insurance requirements. Clients represent a broad base of industries including, but not limited to, research institutions, biotechnology, heavy industrial, construction, micro-electronics, and aerospace.
- Provided on-going safety and industrial hygiene service to covered clients. Service included, but was not limited to, industrial hygiene monitoring, compliance audits, employee training, fire surveys, fire equipment testing, fire code/life safety code reviews, ergonomic surveys, laser and radiation evaluation and monitoring, and construction loss control surveys.

UpJohn, Fine Chemical Division, North Haven, CT
Industrial Hygienist

5/88-11/88

- Performed safety and industrial hygiene audits/inspections for regulatory and corporate compliance.
- Established a proactive industrial hygiene-monitoring program.
- Trained and monitored workers in confined-space entry and personal protective equipment use and care.

EDUCATION:

UNIVERSITY OF NEW HAVEN, West Haven, CT
Masters of Science in Cell & Molecular Biology, Research Project remaining.

UNIVERSITY OF NEW HAVEN, West Haven, CT
Masters of Science in Industrial Hygiene.

CENTRAL CONNECTICUT STATE UNIVERSITY, New Britain, CT
Bachelor of Science in Chemistry.

CSI RADIATION SAFETY
Radiation Safety Officer (40-hour) Sept. 2000

BAYER PHARMACEUTICALS, West Haven, Connecticut
Manager Development Leadership Program.

BOEHRINGER INGELHEIM PHARMACEUTICALS, Ridgefield, Connecticut
J.L. Shepherd Mark I Irradiator Training. February 2007

March 9, 2007

William L. Galdenzi, CIH, CSP

1. Almost 19 years of progressive safety and health experience. Current Certified Safety Professional (CSP) and Certified Industrial Hygienist (CIH).

2. 40-hour RSO training in 2000 by CSI, Radiation Safety Academy. Topics included:

- Radiation and Radioactivity, Radioactive Decay, Radiation Units, Sources of Radiation, Interaction with Matter
- Health Effects
- Radiation Protection Standards, 10 CFR Part 19 and 20, Essential Highlights of 10 CFR Part 2, 30, 31, 33.
- External Radiation Protection and Shielding, Internal Radiation Protection,
- Sealed Sources & Industrial Gauges
- Math Review & Radiation Safety Problem Solving,
- Radiation Survey Instruments, Instruments Lab, Applications & Troubleshooting,
- Emergency Response
- Radiation Safety Surveys
- Effective Communications for the Radiation Safety Officer as a Manager and Instructor Hands-on Laboratory Survey and PPE Exercise
- Interpreting Radiation Measurements and Quality Assurance
- Transportation of Radioactive Materials and Package Receiving
- Practical Record-keeping for RSOs
- Radioactive Waste Management, Mixed Wastes, Waste Manifests
- Legal Implications: Radiation Litigation
- Radiation Protection Program Management,
- Preparing for Regulatory Inspections

3. RSO and Superintendent of Laboratory Safety at Bayer. Bayer license included the following:

By-product, source, and/or special nuclear material.	Chemical and/or physical form.	Maximum amount that may be possessed at any one time.
Any By-product material with atomic numbers 1 through 83 with a physical half-life less than or equal to 120 days.	Any	Not to exceed 100 millicuries per radionuclide and 1 curie total.
Hydrogen 3 (³ H)	Any	5 curies
Carbon 14 (¹⁴ C)	Any	5 curies
Phosphorus 32 (³² P)	Any	10 curies
Phosphorus 33 (³³ P)	Any	10 curies
Sulfur 35 (³⁵ S)	Any	10 curies
Chlorine 36 (³⁶ Cl)	Any	10 millicuries
Calcium 45 (⁴⁵ Ca)	Any	350 millicuries
Iron 55 (⁵⁵ Fe)	Any	100 millicuries
Iodine 125 (¹²⁵ I)	Any	1 curie
Iodine 131 (¹³¹ I)	Any	1 curie
Gadolinium 153 (¹⁵³ Ga)	Any	10 millicuries
Nickel 63 (⁶³ Ni)	Sealed	500 millicuries

4. Responsible for radiation safety program that used radioactive materials for pharmaceutical research (biochemical assays,... and animals) and included:

- 100 active radioactive labs,
- Approximately 1.2 million in annual radioactive material orders.

- Approximately 200 users,
 - Dosimeter program including approximately 300 employees (ancillary workers such as Distribution, Maintenance, and Utilities workers included).
5. Responsible for instructor led training of all employees in safe radioactive materials use (approximately 500 employees annually).
 6. Responsible for radiological, biological and chemical emergency response (i.e. HAZMAT and First Aid trained). Member of the Senior Incident Command Team.
 7. Responsible for investigating all lab-related incidents (analyze, determine immediate and root causes, develop recommendation to prevent reoccurrence,...).
 8. Developed, implemented, revised and maintained policies and procedures related to radiation safety and lab safety.

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

3/9/2007, and to inform you that the initial processing which includes an administrative review has been performed.

Amend. 06-19183-01 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 140210.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.