

**Boehringer
Ingelheim**

Br. 2

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

Boehringer Ingelheim
Pharmaceuticals Inc.

USNRC Materials License No. 06-19183-01

03017101

September 14, 2006

Dear Mr. Thompson,

Dr. Mike Cerreta, our RSO, resigned as an employee of Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) on August 15, 2006. Since that time, we have been negotiating with Radiation Safety Academy (Gaithersburg, MD) to contract for a temporary qualified RSO until a permanent qualified BIPI employee can be hired. BIPI has now finalized an agreement with Radiation Safety Academy for Mr. Sean Austin to serve as our RSO. Mr. Austin's CV is attached. Our search for a permanent BIPI employee to serve in this position is continuing with high priority. We will, of course, contact you as soon as a suitable candidate is identified and hired.

Karl D. Hargrave, Ph.D.

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ingelheim.com900 Ridgebury Rd/P.O. Box 368
Ridgefield, CT 06877-0368

Please note that BIPI has continued to have a full-time Radiation Safety Specialist (Ms. Sarah Stewart). This BIPI employee assisted Dr. Cerreta prior to his resignation and has continued to handle the day-to-day radiation safety issues. Our plans are for Mr. Austin to spend one day every other week at BIPI unless more frequent visits are needed, and he is available for phone consultation at any time.

We request that our USNRC Materials License No. 06-19183-01 be amended to designate Mr. Sean Austin 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

attachment

139373

NMSS/RGN MATERIALS-002

SEAN M. AUSTIN
Certified Health Physicist

[REDACTED]
[REDACTED]
[REDACTED]
Fax - (707) 988-7334
E-mail - [REDACTED]

Education

1986, B.S. Health Physics, Georgia Institute of Technology, Atlanta, GA, 30332

1993, M.S. Radiation Science, Georgetown University, Washington, DC, 20057

Experience and Qualifications

1997 Certified Health Physicist, American Board of Health Physics, Comprehensive Certification, Re-certified through 2009.

2001-Present Senior Health Physicist, Radiation Safety Academy, Inc., 481 N. Frederick Avenue, Suite 302, Gaithersburg, MD 20877, 301-990-6006

Training course instructor, including 40-hour Radiation Safety Officer, Department of Transportation Shipping, Advanced Radiation Safety Officer, Low-level Waste Management, CHP Certification Review, Site Characterization, Decommissioning, and Decontamination, and other courses. Provides health physics/radiation safety consulting services to clients. Conducts radiation safety program audits. Prepares license applications and amendments, sealed source and device registration applications, and prepares decommissioning plans. Serves as a backup supervisor on federal contract providing oversight of staff operations, performing quality assurance surveys, calibration of radiation measurement instruments, preparation of samples for radioanalysis, and emergency response services.

1999-2001 Private Consultant

Provide health physics/radiation safety consulting services to clients. This includes the presentation of training courses in shipping radioactive and other hazardous materials, developing work procedures, preparation of regulatory documents such as licenses and license amendments, and performing audits and surveys of work areas.

1994-2001 Chief, Radioactive Materials Control Section, Radiation Safety Branch, National Institutes of Health, Bethesda, MD 20892 (GS 1306-14), Supervisor, Robert A. Zoon, Ph=301-496-2254.

Responsible for overseeing the NIH program to manage the acquisition, inventory, and disposal of radioactive materials for approximately 3000 research laboratories. Supervised 5 government and 20-22 contract employees involved in these activities. Supervised staff involved in shipping and receiving radioactive materials. This involves preparation and review of reports summarizing activities related to the radioactive waste and radioactive materials acquisition, processing and delivery programs and ensures that these reports are technically correct and well documented. Oversees the radioactive waste portion of a comprehensive laboratory waste contract which exceeded \$4 million during 1995 and the radioactive materials acquisition program which is approximately \$5 million per year. Served as instructor for courses teaching NIH employees about DOT requirements for shipping radioactive materials.

Served as the radioactive waste manager for the NIH Radiation Safety Branch since 1989. Currently acting as Assistant Project Officer for the Comprehensive Management Program for Chemical, Radioactive and Mixed Wastes contract. Assures NIH compliance with radioactive and mixed waste disposal regulations and policies, and maintain USNRC required radioactive waste disposal records for NIH. Reviews radioactive and mixed waste manifests and inspects shipments of radioactive and mixed wastes to and from NIH. Developed the technical requirements for the chemical, radioactive and mixed waste service contract. Oversees the establishment of radioactive waste minimization programs. Coordinates the development of NIH's computer database for all radioactive waste and radioactive materials management. Reviews contractor invoices for radioactive waste services and audits contractor activities. Provides contract technical review for NIH Contracting Office. Conducts health and safety evaluations of new, proposed methods for processing radioactive waste to assure compliance with NRC license conditions.

**PERSONAL INFORMATION WAS REMOVED
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WAS RETAINED BY THE NRC.**

Other duties and special projects included developing, implementing and overseeing the work to decommission a building at the NIH which formerly housed three medical waste incinerators. This work was performed in 1997 and the decommissioning plan was prepared in accordance with NRC NUREG CR-5849. Future decommissioning projects will be planned and carried out in accordance with MARSSIM guidance documents. In addition, I was responsible for developing and implementing a program to conduct an annual inventory of radioactive materials at the NIH. This was a new program and required extensive research to plan the activities of government staff, contract auditors and the computer programming specialists to create a method and procedure for conducting site visits and updating existing databases to reflect the actual radioactive items stored.

1987-1994 Health Physicist, Radiation Safety Branch, National Institutes of Health, Bethesda, MD 20892 (GS 1306-7-13). Supervisor, Robert A. Zoon, Ph=301-496-2254.

Managed the NIH radioactive and mixed waste management operations for the Radiation Safety Branch (1989-1994). Provided health physics consultation and oversight for radioactive materials use in approximately 350 research laboratories. This required conducting surveys and safety evaluations of current and proposed uses of radiation and radioactive materials in biomedical research. Conducted evaluations of discharges of radioactive materials to the environment from activities such as waste incineration, sewer discharges, and releases due to routine operations. Served as the health physicist for the NIH cyclotron facility from 1988-1991. All work involved investigating internal and external radiation exposures to NIH and contractor personnel. Provided radiation safety training and consultation to researchers and routinely lecture in NIH radiation safety training courses. Reviewed protocols to use large amounts of radioactive materials in laboratories and in studies involving humans and animals. Performed inventories and leak tests of sealed sources and irradiators. Conducted surveys and inspections of NIH laboratories and radiation producing equipment. Reviewed researcher application to order and use radioactive materials. Assisted in patient treatment involving the use of radioactive materials.

Other Activities

- Past-President of the RSO Section of the Health Physics Society.
- Assistant Executive Producer for Radiation Safety Branch Refresher Training video for 1992.
- Presented Professional Enrichment Program course, "Biomedical Radioactive Waste Management", at 1992 and 1993 National Health Physics Society annual meetings.
- Presented Professional Enrichment Program course, "Transportation of Radioactive Material", at 2001 and 2002 (invited) National Health Physics Society annual meetings.
- Associate Editor, "Operational Radiation Safety", a supplement to "Health Physics", August 2000 to present.
- Member, State of Maryland Radiation Control Advisory Board, November 2003-present.

Specialized Training Courses Presented

2001-present Radiation Safety Academy Training courses, Gaithersburg, MD:

- Radiation Safety Officer, 40-hour,
- Advanced Radiation Safety Officer,
- Radiation Safety Program Management,
- DOT & NRC Requirements for Radioactive Material Shipping and Receiving,
- Basic Radiation Safety,
- Low Level Radioactive & Mixed Waste Management,
- Radiation Safety Technician,
- CHP Exam Prep,
- NRRPT Exam Prep,
- Radiation Regulations, Licensing, Inspections and Compliance.
- Medical Radiation Safety

1999 - "Transportation of Radioactive Materials", Washington Hospital Center, Washington, DC

1999 - "Transportation of Radioactive Materials-Limited Quantities", BioTraces, Inc., Herndon, VA

1995-99 - "Radioactive Waste Management" - NIH Authorized Users course

1995-98 - "Transportation of Radioactive Materials", NIH Department of Transportation training

1993 - "Biomedical Radioactive Waste Management", 38th Health Physics Society annual meeting, Atlanta, GA

1992 - "Biomedical Radioactive Waste Management", 37th Health Physics Society annual meeting, Columbus, OH

Specialized Training Courses Attended

- 1987 - NIH "Radiation Safety in the Laboratory", 8 hr.
- 1988 - NIH "Radiation Safety for Authorized Users", 40 hr.
- 1988 - Health Physics Society Summer School, "Beta Dosimetry", New Haven, CT.
- 1989 - DHHS "Basic Project Officer".
- 1992 - "Transportation and Packaging of Radioactive Materials".
- 1993 - Hazardous Waste Confined Space Entry.
- 1993 - Hazardous Waste Worker Refresher training (8 hour).
- 1993 - ASME "Management of Mixed Radioactive and Hazardous Waste".
- 1994 - NIH "Managing Relationships Toward Greater Productivity".
- 1995 - DHHS "Writing Statements of Work, Supplies and Services".
- 1995 - Baltimore-Washington Chapter HPS Certification Review Course.
- 1996 - Mediation Training, DHHS, Bethesda, MD.
- 1997 - RESRAD-BUILD Workshop, NRC, Rockville, MD.
- 1997 - RESRAD Workshop, NRC, Rockville, MD.
- 1997 - "Radiological Surveys in Support of Decommissioning" Workshop, NRC, Rockville, MD.

Professional Affiliations

Plenary Member Health Physics Society.
Member American Academy of Health Physics.
Member Baltimore-Washington Chapter of the Health Physics Society.

Publications

Goldstein, D.S., Chang, P.C., Smith, C.B., Herscovitch, P., Austin, S.M., Eisenhofer, G., and Kopin, I.J., "Dosimetric Estimates for Clinical Positron Emission Tomographic Scanning After Injection of [¹⁸F]-6-Fluorodopamine", J Nucl Med 32:102-110; 1991.

Holcomb, W.H., Zoon, R.A., Austin, S.M., and Newman, N.E., "Radiation Safety Program at the National Institutes of Health", RSO Magazine, 4(4):17-28; 1999.

Rau, E. H., Alaimo, R.J., Ashbrook, P.C., Austin, S.M., Borenstein, N., Evans, M.R., Gilpin, R.W., Hummel, S.J., Jacobsohn, A.P., Lee, C., Merkle, S., Radzinski, T., Sloane, R., Wagner, K.D., and Weaner, L.E., "Minimization and Management of Wastes from Biomedical Research", Environ Health Perspect 108(suppl 6):953-977 (2000).

Austin, S.M, Zoon, R. A., Ribaud, C. A., "Decommissioning a Medical Waste Incinerator", In: Decommissioning and Environmental Restoration. Proceedings of the 35th Midyear Topical Meeting of the Health Physics Society, Orlando, FL, February, 2002.

Austin, S.M., Rau, E.H., Holcomb, W.F., Zoon, R.A., "Reduction in Radioactive Material Use and Waste Generation at the National Institutes of Health", Health Phys. 83 (Supplement 5):S85-S95; 2002.

Austin, S.M., "A Study of the Volatilization of Iodine-125 During Flash Point Testing of Biomedical Mixed Waste Using Setaflash Closed-Cup Apparatus", thesis submitted to the Georgetown University Graduate School in partial fulfillment of the requirements for the degree of Master of Science, 1993.

Honors

NIH Office of Research Services Service Excellence for Teamwork Special Recognition Award, "Special Recognition for the exceptional use of teamwork to produce an award-winning radiation safety training video", 1999.

NIH Office of Research Services Special Achievement Certificate, 1996.

NIH Merit Award, 1993: "In recognition of exceptional contributions to the support of the National Institutes of Health research mission through expert management of radioactive and mixed waste".

NIH Division of Safety Special Achievement Certificate, 1993.

NIH Merit Award, 1988: "For dedicated efforts in applying technical skills to a study of radioactive contamination in NIH Medical Pathological Waste".

Lectures Presented

ACURI Association 3rd Annual Meeting, "Low-Level Radioactive Waste Management and Disposal" Workshop, Harrisburg, Pennsylvania, September 1992.

11th Annual Radioactive Exchange Low-Level Radioactive Waste Management Decisionmakers' Forum, "Are We Ready to 'Leap' Back to the Future, or Go Forward with Another Scenario", Amelia Island, Florida, June 1995.

12th Annual Radioactive Exchange Low-Level Radioactive Waste Management Decisionmakers' Forum, "Perspectives on Low-Level Waste Management", Park City, Utah, June 1996.

ACURI Association 7th Annual Meeting, "Research Techniques and Management", Harrisburg, Pennsylvania, August 1996.

13th Annual Radioactive Exchange Low-Level Radioactive Waste Management Decisionmakers' Forum, "Is the Medical Community Ready to Back the Compact Approach", Amelia Island, Florida, June 1997.

42nd Annual Meeting of the Health Physics Society, "Radioactive Materials Inventory and Accountability at the National Institutes of Health", San Antonio, Texas, July, 1997.

ACURI Association 8th Annual Meeting, "Regulator and Generator" Panel Discussion, Harrisburg, Pennsylvania, August 1997.

44th Annual Meeting of the Health Physics Society, "Radioactive Medical Waste Monitoring and Management at the National Institutes of Health", Philadelphia, PA, June, 1999.

Appalachian States Compact LLRW Minimization and Volume Reduction Workshop, "Minimization of Mixed Wastes at the National Institutes of Health", Aberdeen, MD, August, 1999.

National Association of Physicians for the Environment Leadership Conference: Biomedical Research and the Environment, "Radioactive Waste Management" presented at the Natcher Conference Center, National Institutes of Health, November 2, 1999.

45th Annual Meeting of the Health Physics Society, "Radiation Safety Surveys at the National Institutes of Health", Denver, CO, June, 2000.

Medical Waste Institute's 2000 Compliance Conference, "Strategies for Managing Mixed Waste Efficiently: What Your Employees Need to Know", Alexandria, VA, October, 2000.

Maryland Department of the Environment, Low-Level Radioactive Waste Pollution Prevention Seminar, "Alternatives to Use of Radioisotopes in Biomedical Research", Germantown, MD, October, 2000.

35th MidYear Topical Meeting of the Health Physics Society, "Decommissioning a Medical Waste Incinerator", Orlando, FL, February, 2002.

NELRAD Annual Meeting, "Reduction in Radioactive Material Use and Waste Generation at the National Institutes of Health", Weston, MA, April, 2003.

PROFESSIONAL, POLITICAL, AND CIVIC ORGANIZATIONS

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| 2000-Present | Member, Montgomery County Solid Waste Advisory Committee. The Committee reviews and makes recommendations on the collection, transportation, and storage of solid wastes and evaluates the County's solid waste management plan. Vice-Chair, 2002-2005. |
| 1997-1999 | Board Member, Waters Landing Homeowners Association, Germantown, MD, 1995-1997, Served as President, 1997. |
| 2003-Present | Board Member, Seneca Brooke Homeowners Association, Laytonsville, MD, Served as President, 2003-2004. |

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

9/14/2006, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 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 139396.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.