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May 26, 2004

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Dr. Thomas Thompson  
Division of Nuclear Materials Safety  
U.S. Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406

45-25425-01  
03034650

Dear Dr. Thompson:

This letter is to inform the Nuclear Regulatory Commission that there has again been a change in the status of the Radiation Safety Officer (RSO) at the ATCC due to Dr. Judith Kantor leaving ATCC as of May 27, 2005. We have appointed Essala Lowe, ATCC's Environmental Health and Safety Officer, as interim RSO until we have reassessed our program.

Ms. Lowe has experience in handling radioisotopes, and has been trained as a Radiation Safety Officer. Enclosed is a copy of her curriculum vitae. A new Chief Scientific and Technical Officer will be joining ATCC in June with overall responsibility for our science programs. We have not revised our program to include new activities involving work with radioisotopes, and the current activities are limited to use of the sealed source. When the new directions for our scientific programs are in place, we will review our need to use radioisotopes and revise our program, including reassigning the Radiation Safety Officer position to a senior scientist.

Any questions or concerns about this change should be addressed to my attention.

Sincerely,



Frank P. Simione, V.P.  
Management and Compliance Services

137144  
NMSS/RGNI MATERIALS-002

## **Essala D. Lowe**

212.327.8324/8340 (office/fax)

### *PROFESSIONAL AND RESEARCH EXPERIENCE:*

#### **BIOLOGICAL SAFETY OFFICER/BSL3 MANAGER**, Laboratory Safety and Environmental Health, The Rockefeller University

November 2000- present

Management and execution of the University biosafety program with particular emphasis on research activities involving recombinant DNA molecules, laboratory animals and biohazardous agents. Participation in the activities of the recombinant DNA (IBC), BL3, Hospital Infection Control (ICC), and Animal Care and Use (IACUC) committees, the laboratory safety audit program and medical surveillance program and employee biosafety training. Consultative services to researchers on biosafety and biological procedures/protocols and techniques, and provision of training. Oversight and management of the medical waste program and support to chemical, radiation (site inspection, receipt/delivery of isotopes, dosimetry and exposure monitoring), IH and general industry components of the University's integrated safety program . Oversight/management of the University exposure plan and compliance with the OSHA Blood borne pathogen standard and employee/research training and accident/exposure investigation and resolution. Management of the university biosafety cabinet program and vendor contracting. Environmental sampling work including organism identification, recommendations for initial and corrective action. Consultative services provided to University services such as purchasing on advisement of laboratory equipment for requisitioning by RU community. Oversight of the University shipping of hazardous materials programs, chemical/radioactive/biological. Contact and service coordinator of all BSL3 users, support personnel, equipment, and maintenance needs. Oversight of use of all 3 BSL3 facilities. Management and performance of training and certification for all BSL3 users and support staff. Responsible for Select agent (BL3) inventory and maintenance. Responsible Facility official on CDC select agent licensure. Oversight of budget development and management. Facility SOP development and implementation (BL3). Risk assessment of newly proposed work in BSL3 facilities. Consultation and coordination oversight and liaison of university commissioning of all new BSL3 construction/ renovation. Interim supervisor of the University Media and Glassware Resource Center (MGRC).

#### **STAFF MICROBIOLOGIST**, Research and Development/Quality Control, Vijn Laboratories, St. Louis, Missouri

January, 2000- September 2000

Responsible for all microbiological laboratory start up and equipment purchasing, creation of standard operating procedures and method development protocols for raw material, in process, and product sample testing. Provided personnel training on

biological safety and OSHA laboratory standards. Responsible for contract vendors' microbial testing compliance with company standards and GMP standards. Responsible for development and interpretation of water testing standards according to GMP and GLP standards for OTC pharmaceuticals.

**QC MICROBIOLOGIST**, Quality control Department, Steris Corporation, St. Louis, Missouri.

June 1998-December 1999

Analytical and bioburden testing of in process samples, raw materials, and finished goods, responsible for product testing method qualification and validation processes, environmental sampling and testing, methodology of testing, evaluation, calculation, and recording and reporting of results. Writing and reviewing SOP's and protocols, performed GLP and GMP qualifying work in a pharmaceutical laboratory. Experience and working knowledge of FDA regulations, ISO guidelines, and USP standards for laboratory procedures and processes. Training of personnel for media/solution preparation for all testing and validation experiments.

**RESEARCH TECHNICIAN**, Research and Quality control Laboratory, American Water Works Company, Belleville, IL

January 1998- June 1998

Maintenance of microbial colonies (propagation and harvesting) of *Cryptosporidium* and *Giardia Lambdia*, solution and sample preparation, microscopy (light and DIC), data reporting and interpretation of results, sterilization equipment management.

**HOSPITAL SERVICES TECHNICIAN**, Blood Services Department, American Red Cross/MO-IL

St. Louis, Missouri

September 1997- January 1998

Coordination of blood and blood products to hospital for daily inventory needs, shipping and receiving blood/blood products inventory for on site inventory and incoming resources, coordination of transportation for hospital inventory delivery for accounts in Missouri and Illinois, customer service to hospital blood banks, performance of quality control procedures and protocols for blood and blood products according to FDA and cGMP standards and guidelines.

**RESEARCH ASSISTANT**, Physiology Department, Old Dominion University, Norfolk, Virginia

August 1996 – May 1997

Maintenance of laboratory animals (AALAS certification) (Norwegian White rabbits), data integration and record keeping, administration of medicines to laboratory research subjects, administration of serological and cytological tests on animals in research study, participation in small animal surgery and anesthetic procedures.

**LIBRARY TECHNICIAN I**, Library, Eastern Virginia Medical School, Norfolk, Virginia

May 1995 – July 1996

Customer services to library patrons, general clerical and office administrative duties, assistance of patrons with Medline software and audiovisual equipment, article searches for laboratories, physicians, other patrons for reference use

**RESEARCH AND LABORATORY ASSISTANT**, Biology Department, Virginia State University, Petersburg, Virginia

May 1994 – May 1995

Maintenance of microbial colonies for harvesting and propagation for research studies, media and solution preparation of classes and research studies, spectrophotometry and turbidity testing, performance of various analytical and microbiological testing including DNA mapping, RNA extraction, recombinant DNA techniques.

*EDUCATION:*

*Fall 1991 –1995*, Virginia State University, Petersburg VA- Biology (premedical concentration major), *Fall1999*, University of Missouri- St. Louis, St. Louis, Missouri  
*2002- present*: Currently pursuing **B.S. in Psychology/Biology, minor in Environmental Management**, (*2<sup>nd</sup> semester junior status*) University of Maryland University College, Adelphi, Maryland  
*Expected Graduation Date: December 2004*

*PROFESSIONAL ENRICHMENT:*

Radiation Safety Officer Training, 40-hour course  
The Rockefeller University, December 2000

OSHA 10-Hour Construction Safety  
Niagara Community College, Division of Lifelong Learning, at the Rockefeller University, March 14-15,2001.

Design and Construction of BSL3 Facilities  
Eagleson Institute and American Biological Safety Association, Colorado State University, May 7-8,2001

Select Agents: Existing, New and Pending Regulations  
Eagelson Institute, University Of Pennsylvania, Philadelphia, PA, May 6-9 2002

Control of Biohazards  
BioControl, Inc, Baltimore Maryland, September 9-14,2002

49 CFR/IATA Hazardous Shipping Trainer Recertification  
Dangerous Goods Advisory Council, Orlando, Florida, April 16-19,2002

Radiation Safety Officer Refresher Training, 10 hour Course, May 2003

*PROFESSIONAL ACTIVITIES:*

American Biological Safety Association (#3241), Member, 2000-  
American Society of Microbiology (#55387385), Member, 1998-  
Association of Analytical Chemistry (#81481), 1999-  
American Public Health Association (#9783715), Member, 2001-  
Association of Professionals in Infection Control (#98754), 2001-  
The Rockefeller University Hospital Infection Control Committee, Member, 2000-  
The Rockefeller University Institutional Animal Care and Use Committee, Member,  
2001-  
The Rockefeller University BSL 3 Users Committee, Chairperson, 2001-  
The Rockefeller University Institutional Biosafety Committee, Chairperson, 2001-  
American Biological Safety Association Finance Committee, Member, 2002-

*CONSULTATIVE SERVICES:*

Vivoquest, Inc, Valley Cottage, NY September 2003 - present

*AWARDS AND CERTIFICATIONS:*

General Laboratory Practices Certification (GLP), 2000  
CGMP Certification, 1997  
ISO 9000 training and certification, 1999  
Certified 49 CFR/DOT/IATA Hazardous Shipping Trainer  
Beta Beta Beta Biological Honor Society, Member, 1994

*MEETINGS AND CONFERENCES:*

Seventh Annual National Symposium on Biosafety, "Managing Risk in Animal Care and Use", Atlanta, GA, January 26-30,2002, sponsored by CDC/ABSA/USDA/NIH

IBCs in a Changing Research Landscape: A Policy Conference, Bethesda Maryland, December 7-8,2001, sponsored by NIH/Office of Biotechnology Activities

First Annual U.S. Bioseminar on the Transportation of Infectious and Diagnostic Substances, Miami Beach, FL, April 20-24, 2001, sponsored by World Courier, Inc and IATA (International Air Transport Association)

American Biological Safety Association National Conference, San Francisco, California September 20- 24, 2002, sponsored by ABSA

Dangerous Goods By Air 2003 Conference, Miami Beach, Florida, April 29- May 1,2003  
Sponsored by IATA (International Air Transport Association)

American Biological Safety Association National Conference, Philadelphia, Pennsylvania October 12- 15, 2003, sponsored by ABSA