

May 12, 2015

United States Nuclear Regulatory Commission
Region I
Nuclear Material Section B
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

Br. 2

Docket No. 030-09049 and Docket No. 030-19445
License No. 08-00216- License No. 08-00216-23
22

Dear Sir or Madam:

We would like to amend each of our material licenses, referenced above, as follows:

Item 11 Vinod Jyothikumar, PhD, is designated as our new Radiation Safety Officer.
Enclosed is his current CV.

Our current Radiation Safety Officer, Gregory D. Smith, is now designated as the
Assistant Radiation Safety Officer

Please contact me on 202-994-6255 if there are any questions or if you need any additional
information.

Sincerely,



Sheila Rose Garrity, JD, MPH, MBA
Associate Vice President, Research Integrity

Enclosure

NMSS/RGNI MATERIALS-002

586972 / 586973

Vinod Jyothikumar

➤ Subject Matter Expertise

- Biosafety & Risk Assessment
- Radiation Safety
- LASER Safety
- Hazardous Waste Management
- Risk Assessment and Hazard Identification: Infectious Agents, rDNA & Occupational Health Issues. Regulatory Aspects Pertinent to Risk Assessment: NIH Guidelines, Select Agents & Animal Biosafety
- Inspecting for standard room markings, use of warning signs and labels
- Reviewing contamination surveys conducted by the radioactive material users for frequency, recording data, analysis of wipe test samples and response to contamination (if found)
- High Containment Lab Designing, Teaching Lab design
- Reviewing records of radiation safety training
- Inspecting for compliance with security procedures (security of radioactive material) Review PI Radiation Program authorizations for adequate training and experience
- Reviewing the authorized rooms (comparing rooms used with those listed as authorized for use)

➤ Professional Experience

Director, Office of Laboratory Safety George Washington University

The major direct functional responsibilities include oversight and operations of:

- Oversight of Biosafety program –Biosafety Officer for GW
- Worked closely with RSO in maintaining radiation protection program at GW.
- Biosafety and Radiation safety consultant for Human research Program at the GW Campus
- Research uses of Controlled Substances program in accordance with the US-DEA regulations
- Biosafety and Radiation safety consultant for Export Control regulations pertaining to the research enterprise.
- Served on GW Radiation Safety Committee

Advance Imaging Scientist & Biosafety Management

University of Virginia

With my expertise in Microbiology & Biological Safety, I implement, and monitor compliance of center biosafety regulations, systems, procedures, and training, serving as a Biosafety associate ensuring the safe use of center bio-agents and biohazards. Further, as the Imaging scientist of the Keck-Imaging facility, I have expertise in Multiplex imaging, sample preparations and advance microscopy techniques available at the Keck Center for Cellular Imaging.

Consultant: Compliance, Regulatory and Safety

Frost & Sullivan

As a part of my work, I was involved in the development of Market Engineering research services, Regulatory product profiling and Strategic Analysis reports that track the Pharmaceuticals & Biotechnology products; Clinical Diagnostics; Medical Imaging, clinical diagnostic sector and Pharmaceutical and Biotechnology. Demonstrated knowledge and experience in pharm or biotech domain, with particular focus at the product/tools level and deliver high impact projects by effectively employing a range of rigorous research methodologies.

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Postdoctoral Research Fellow
Microbiological safety

University of Guelph

Worked with p32 assay for ProU protein, spectroscopy

Research Assistant

University of Strathclyde

The technology, developed in conjunction with Strathclyde University & Blaze Venture Technologies (Fixed Phage Ltd), using naturally occurring bacterial phages that act as a sensor to detect for the superbug-MRSA. Assisted in Screening the MRSA strains and in prototype of the bacterial Phage detecting systems.

Doctoral Fellow

University of Strathclyde

The major responsibilities include oversight and operations of:

Assay development for antimicrobials, handling of pathogens, culture techniques, isolation & identification of microbes; media preparation, replica plating, Handling of bacteriophage, preparation of competent cells. Knowledge of rDNA, infectious agents, and/or synthetic biology technologies. Knowledge of Equipment, Biological Safety Cabinets, Bioaerosols.

Doctoral Fellow

University of Strathclyde

The major responsibilities include oversight and operations of:

Established molecular biology techniques like PCR, DNA cloning, DNA extraction/preparation, gel electrophoresis, labelling, DNA sequence analysis, DNA-DNA hybridization, Molecular cloning, clone analysis (restriction, Southern blot), site-directed mutagenesis, bacterial transformation techniques in Gve- Bacteria; Conjugation in Gve+ bacteria; PCR mediated mutagenesis, handling of DNA modifying enzymes, RT-PCR. Laboratory culture maintenance, review and develop protocols. Knowledge of Laboratory safety guidelines, MSDS and first aid. Maintaining project grants and preparing manuscripts for journals.

Doctoral Fellow

University of Strathclyde

The major responsibilities include oversight and operations of:

Developed the use of time-lapse microscopy in molecular genetic analysis of cardiolipin synthase homologue SCO1389 in *Streptomyces coelicolor*: Protein production and expression analysis (Tricine SDS-PAGE, SDS-PAGE, Western Blot, iBLOT.), extraction/purification and analysis. Fluorescent microscopy; Time-lapse microscopy; live imaging of bacterial cells; localization of eGFP proteins; fluorescent probes application. Cell culture, fluorescence staining techniques. Optimized and monitored Disinfection, Decontamination, and Sterilization.

Research associate

Indian Institute of Technology

Project: Improvement in Bioreactor Productivities Using Free Radicals. Induced reactive oxygen species (ROS) can be used to improve productivities of bioreactor cultures.

Key Opinion Leadership

Science and Engineering Hall-Biosafety Level 3 Lab Design

The George Washington University

The major direct functional responsibilities include oversight and systematic review of all safety features and processes associated with the laboratory (engineering controls, personal protective equipment, building and system integrity, standard operating procedures (SOPs) and administrative controls such as documentation and record retention systems). All the risks associated with laboratory operations and the use of biohazardous materials was evaluated and that demonstrates the use of SOPs that protect human and animal occupants, the environment and the research integrity.

Nano-fabrication & Imaging Labs

The George Washington University

The major direct functional responsibilities include oversight and operations of:

Work Activities, Heating, Ventilating, And Air-Conditioning, Chemical safety Hygiene plan, Nano-hazard waste management, Medical Surveillance.

Global Threat Reduction Initiative (GTRI)

The George Washington University

NNSA established the Global Threat Reduction Initiative (GTRI) in the Office of Defense Nuclear Nonproliferation to, as quickly as possible, identify, secure, remove and/or facilitate the disposition of high risk vulnerable nuclear and radiological materials around the world that pose a threat to the United States and the international community. I headed the project completion, validating, training and testing with GWPD, PNL and DC-MPD

Biosafety and Biosecurity Training Workshop

AgNovos Healthcare

AgNovos Healthcare is a privately held medical device company focused on bone health, a crucial quality-of-life issue facing the aging population.

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➤ Board Membership

Committee	Role	
Radiation Safety Committee [RSC]	Director, office of Lab Safety, RSC member, Radiation Protection Planner	The George Washington University
Institutional Biosafety Committee [IBC]	Biosafety Officer, IBC member, Biosafety Protection Planner	The George Washington University
Institutional Animal Care and Use Committee [IACUC]	Biosafety Officer, IACUC member, Animal Biosafety Protection Planner, Animal virology studies reviewer	The George Washington University
Institutional review board [IRB]	Biosafety Officer, Biosafety Protection Planner, X Ray Radiation Safety recommendation,	The George Washington University
Product Innovation and Safety	Scientific & Safety Advisor	Quantum Technology Group

➤ Education

University of Strathclyde	PhD-Molecular Microbiology	
University of Madras	Msc-Biotechnology	
University of Madras	Bsc-Biochemistry	

➤ Training and Certifications

Dade Moeller Training Academy	Radioactive Waste Management and Disposal	
Harvard University	Radiation Safety Officer Training (42hrs)	
Radiation Safety Training	The George Washington University	
Irradiator Safety Training	The George Washington University	
LASER Safety Training	The George Washington University	
British Safety Council	Health and Safety for Directors and Senior Managers	
National Environmental Health Association	CDC1201-SCDC-Control of RMSF: Vectors and Environmental Health- The importance of Pest Control Programs	
Occupational Safety Health Academy	48 hrs. Occupational Safety and Health Manager	
FBI	Biosecurity Engagement Workshop	
The American Biological Safety Association (ABSA)	ABSA Advanced Biosafety Training Series: Module 1 -7	
USDA-ARS	ARS-07: Bioterrorism Awareness for the Animal Health Community	

➤ Awards & Honors

- Biophysical Society Education Travel Grant-2013
- Overseas Research Students Awards Scheme (ORAS) - Secretary of State for Education and Science- The United Kingdom: October 2005.
- University of Strathclyde Research Scholarships: October 2005
- Awarded IC & SR fellowship from in Dept. of Biotechnology, IIT-Madras, Chennai, India, June 2004
- N. George Memorial Best Outgoing Student Award, June 2002

➤ Teaching Online e-Learning Modules & short courses

- Irradiator Training for end users at George Washington University
- Laser Safety Training: University of Virginia
- MLS 6244 Research Ethics and Scientific Integrity: The George Washington University, (2015). ONLINE MODULE.
- Understanding Biosafety and Laser Safety in Advanced Optoelectronics and Microscopy Core Facilities: ABSA-57th American Biological Safety Association, (2014).
- Use of Nano-particle in Research. A Self Paced e-learning module: Asia Pacific Biosafety Association [A-PBA], (2013). ONLINE MODULE.

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- Research Scholar teaching University of Virginia, Charlottesville. My teaching duties include Fundamental Microbiology, Basic cell culture, Sample preparation, Bio-safety guideline and Skills Development-BIO5070 class, (2012-2014).

➤ Professional Leadership and Service

- General Secretary -Alpha Arts & Science College, [REDACTED]
- Student Ambassador- Alpha Arts & Science College [REDACTED]
- Graduate Resident Manager: University of Strathclyde [REDACTED]
- Resident Manager: University of Virginia, Family Housing [REDACTED]
- Organizing and Program Committee-University of Virginia, FRET Workshop on Advance Microscopy Imaging, 2012
- Virginia Department of Health- Thomas Jefferson Medical Reserve Corps (TJMRC) [REDACTED]
- Emergency Clinical Volunteer-University of Virginia Health System [REDACTED]

➤ Affiliations To Professional Organization

- Laser Institute of America [LIA]
- District of Columbia : Radiation Safety Officers [DC RSO]
- The National Association of Safety Professionals [NASP]
- American Biological Safety Association (ABSA)
- The Chesapeake Area Biological Safety Association (ChABSA)
- Society of Risk Analysis [SRA]
- American Industrial Hygiene Association [AIHA]
- Semiconductor Environment Health & Safety Association
- National Environmental Health Association [NEHA]

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

05/12/2015, and to inform you that the initial processing which includes an administrative review has been performed.

88-00216-22
88-00216-33 } (Amendment)
☒ 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 586972/586973
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.