

Hill, Carol

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SEP 12 2014

From: Cook, Justin <jcook@montana.edu>
Sent: Friday, September 12, 2014 12:26 PM
To: Murnahan, Colleen; Hill, Carol
Cc: Torres, RobertoJ
Subject: Amendment Request to Broad Scope Type A License 25-00326-06 and RSO Delegation of Authority
Attachments: Amendment to Broad Scope Type A License 25-00326-06 - 12 September 2014.pdf

DNMS

Hi Colleen, Carol,

As previously reported on 18 August 2014, MSU was forced to remove the previous Radiation Safety Officer (RSO), Mr. Curtis Hofer, from his position and placed Ms. Kay Altenhofen from the University of Montana, as the interim RSO until an RSO search could be completed. MSU has reviewed internal candidates for this position and has selected the Biosafety Officer (BSO) Kirk Lubick to take the responsibility as the RSO, relieving Ms. Kay Altenhofen of this interim responsibility, which I have detailed in the attached expedited license amendment request and RSO delegation of authority.

Please let me know if you have any questions and have a great weekend. Take care,

Justin

Justin Cook
Director, Office of Research Compliance
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PUBLIC
☐ Immediate Release
☒ Normal Release
NON-PUBLIC
☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other: _____
Reviewer: MP Date: 9/16/14

12 September 2014

TO: U.S. Nuclear Regulatory Commission, Region IV
1600 East Lamar Boulevard
Arlington, TX 76011-4511

FROM: Justin Cook
Director, Office of Research Compliance
Montana State University

SUBJECT: Request Amendment to Broad Scope Type A License 25-00326-06

To Whom It May Concern,

Montana State University (MSU) requests **an expedited review** for our request to amend MSU's Broad Scope Type A License 25-00326-06 to change the Radiation Safety Officer (RSO).

As previously reported on 18 August 2014, MSU was forced to remove the previous Radiation Safety Officer (RSO), Mr. Curtis Hofer, from his position and placed Ms. Kay Altenhofen from the University of Montana, as the interim RSO until an RSO search could be completed.

MSU has reviewed internal candidates for this position and has selected the Biosafety Officer (BSO) Kirk Lubick to take the responsibility as the RSO, relieving Ms. Kay Altenhofen of this interim responsibility. Although Kirk Lubick does not currently have the RSO credentials, MSU provides the following plan to send Mr. Lubick to the required training, provide a suitable RSO mentor, and provide a lab technician to support the Radiation Safety Program.

Mr. Lubick plans to attend a RSO Course offered by Dade Moeller, Inc. from 13-17 October, which will include the HAZMAT Certification option. In addition, MSU will provide Mr. Lubick a lab technician that will support the day to day tasks, such as picking up waste, surveying labs, decommissioning labs, surveying and delivering radiation packages, and performing sealed source leak tests. Mr. Lubick will also have access to an RSO mentor, which will be formally documented and RSOs from University of Wyoming and Emory University are being considered for this role. Finally, MSU will continue to hire a contractor to dispose of radiation waste, including the disposal of legacy sealed sources.

**Office of Research
Compliance**

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The following is a summary of Mr. Kirk Lubick's experience:

Professional Experience:

2013-Present – Biosafety Program Manager and Biosafety Officer (BSO) in the Office of Research Compliance (ORC) at Montana State University

- Identified all biological research activities conducted at Montana State University and ensured Principal Investigators are in compliance with all applicable Federal and State guidelines
- Developed a Campus Site Map that includes contact information (Principal Investigator and Lab Manager), list of agents, and a summary of these agents, for all biological laboratories on campus
- Started Inventory Inspections of all Biological Freezers on campus with approximately 30 % of all freezers inspected
- Instituted an annual Laboratory Inspection program of all biological laboratories
- Developed a Biosafety training course for laboratory workers and Biosafety training course for non-laboratory workers
- Started a Biosafety Newsletter covering topics ranging from agent hazards to laboratory work practices
- Implemented the following Biosafety policies: biological waste disposal program, bio hazardous spill cleanup procedures, working with sharps plan, and transportation of biological materials on campus
- Developed a new Institutional Biosafety protocol form that is in compliance with the NIH guidelines for research involving recombinant or synthetic nucleic acid molecules
- Transitioned the Institutional Biosafety protocol data base system from paper to an electronic filing system
- Supervised the Radiation Safety Officer from February 2014 until August 2014

2009-2013 – Microbiologist at National Institute of Health (NIH) National Institution of Allergies and Infectious Diseases (NIAID) Rocky Mountain Laboratory (RML)-Hamilton, MT

- Facilitated Flavivirus BSL-4 work (making virus stocks, virus titrations, helped IIP unit BSL-4 experimental completion, maintained BSL-4 Flavivirus select agent records, and wrote SOPs)
- Mentored lab members to acquire BSL-4 solo entry certification
- Stood up and operated Flavivirus BSL-3 lab
- Trained staff members' initial entries into BSL-3 (Donning/Doffing, Working in BSC, Autoclaving, etc.)
- Trained new lab staff in BSL-2 training and procedures

- Responsible for inventory records, maintaining, and working with rare human patient material
- Primary supervisor of students including training in RML lab maintenance and safety compliance (ordering media, waste disposal, glassware, etc)
- Aided IIP members in experimental completion for journal submission

2003-2009 Research Associate in the Department of Veterinary Molecular Biology at Montana State University

- Supported Coxiella burnettii BSL-3 program at Montana State University
- Examined the use of innate immune adjuvants to treat phase I C. burnettii infection in mice
- Wrote/amended SOPs for work in the BSL-3 facility
- Supervised students with the day to day tasks of the lab
- Performed statistical analyses on experimental data sets and prepared figures for grants, patents, posters, and publications in peer-reviewed journals

Education:

2003 Montana State University, M.S., Veterinary Molecular Biology

2001 Montana State University, B.A., Biotechnology

Other Experience/Professional Memberships:

2010 BSL-4 Solo entry certification

2010 BSL-4 Received vaccine for Tick Born Encephalitis Virus, Hamilton, MT

2010 BSL-4 Training initial BSL-4, Hamilton, MT

2006-2013 Annual BSL-3 refresher and Select Agent training

2010 Shipping and Receiving Select Agents

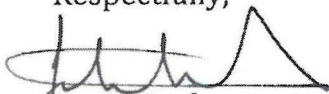
2005 BSL-3 Training- Received vaccine for Coxiella burnettii, Australia, 2005

The following delineates the interim RSO's duties and responsibilities:

The RSO serves as the highest-level campus subject matter expert and responsible officer concerning MSU's radiation safety program and ensures implementation of quality control procedures and safety according to all regulations, specifically those mandated by the NRC. The RSO is responsible for assuring that all campus use of ionizing radiation and radiation material conforms to MSU Broad Scope Type A license, selected industry standards, and applicable government regulations. The RSO is responsible to ensure that radiation exposures to both on-campus and off-campus personnel and members of the general population are As Low As Reasonably Achievable (ALARA).

Please let me know if you have any questions or concerns. My contact information is 406-994-4171 or jcook@montana.edu.

Respectfully,



Justin Cook

Director

Office of Research Compliance
Montana State University