



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

ENVIRONMENT, HEALTH & SAFETY

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October 26, 2015

Allan C. Shipp, M.H.A.
National Institutes of Health
Program on Biosecurity and Biosafety Policy
Office of the Director
National Institutes of Health
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892-7985

RE: Loss of Containment for Mouse Adapted

As required by Appendix G-II-C-2-q of *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, on October 14, 2015, the University of North Carolina at Chapel Hill ("UNC") submitted an initial report of a dropped plaque assay containing mouse adapted in a BSL-3 facility to Ryan Bayha, Senior Analyst for Science Policy Outreach at the National Institutes of Health. This letter constitutes UNC's follow up report describing the incident.

A plate containing a plaque assay fell from within the biological safety cabinet onto the lab floor causing a small amount of agarose to spill onto the floor. The plate was being sealed with tape and the tape stuck to the researcher's glove as the arm was withdrawn from the hood.

The spill was cleaned as per the lab SOP. All personnel in the area were notified of the incident and vacated the area. Aerosols were allowed to settle for 30 minutes prior to decontaminating with 70% ethanol for 20 minutes. The spill was cleaned with paper towels which were placed in a biohazard bag and autoclaved. The PI, Biological Safety Officer, Responsible Official and the Director of the University Employee Occupational Health Clinic were immediately notified. The incident was deemed as a potential exposure and personnel were placed on medical surveillance, reporting baseline temperatures as well as morning and evening temperatures over the following ten days. The medical surveillance period ended on Saturday 10/24/15 without incident.

The three personnel in the facility wore the following PPE: scrubs, tyvek suits, tyvek boots, tyvek apron, double gloves and PAPR. There were no failures involving PPE or the facility.

Please contact me at (919) 962-5722 or eisenman@ehs.unc.edu if you have any questions.

Sincerely,

Daniel Eisenman, PhD, CBSP
Biological Safety Officer
Environment, Health and Safety

Cc: Doug Cyr, IBC Chair
Mary Beth Koza, Director of EHS



National Institutes of Health

U.S. Public Health Service
Bethesda, Maryland 20892

Office of Science Policy
National Institutes of Health
6705 Rockledge Drive
Suite 750, MSC 7985
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(301) 496-9838 (Phone)
(301) 496-9839 (Fax)
<http://osp.od.nih.gov>

December 4, 2015

Daniel Eisenman, Ph.D., RBP, SM(NRCM), CBSP
Biological Safety Officer
Environmental Health and Safety
University of North Carolina at Chapel Hill
1120 Estes Drive Ext.
Campus Box 1650
Chapel Hill, NC 27599-1650

Dear Dr. Eisenman:

Thank you for your October 14, 2015, email and October 26, 2015, follow-up report to the National Institutes of Health (NIH) Office of Science Policy (OSP) regarding an October 14, 2015, incident in which there was a loss of containment while working with a mouse adapted strain of

From your report, we understand that a plate containing a plaque assay of mouse adapted fell out of the biological safety cabinet (BSC) in a biosafety level 3 laboratory at the University of North Carolina (UNC). At the time of the incident, a researcher was sealing the plate with tape. As the researcher withdrew his hand from the BSC, the tape stuck to his glove, causing the plate to fall to the floor. There were three researchers in the laboratory at the time of the spill and all were wearing appropriate personal protective equipment including powered air purifying respirators.

In response to this incident, all personnel in the area vacated the laboratory. Aerosols were allowed to settle for 30 minutes prior to decontaminating the spill with 70% ethanol. The principal investigator, biological safety officer, and the director of the University Occupational Health Clinic were notified and deemed the incident a potential exposure. The three researchers were placed on medical surveillance for 10 days. No symptoms were reported during the surveillance period.

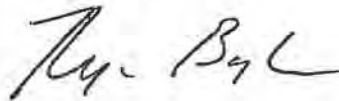
Staff from the biological safety office have discussed with the researchers some possible strategies to prevent a reoccurrence of this incident, including sealing the plates with parafilm instead of tape. We understand that there was concern about using parafilm because of the need to cut the film, and the researchers want to avoid the use of sharps in the laboratory. As we recommended in

Daniel Eisenman, Ph.D., RBP, SM(NRCM), CBSP
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an October 26, 2015, email, if there is concern about using sharps to cut the parafilm in the BL3 laboratory, the parafilm could be pre-cut to the desired size to seal the plates outside of the BL3. The pre-cut film could then be brought into the lab to have on hand.

Please revise the procedure for sealing the plates to reduce the possibility that such an incident will occur again. No further information is required regarding this incident. Please contact NIH staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Ryan Bayha". The signature is fluid and cursive, with the first name "Ryan" and last name "Bayha" clearly distinguishable.

Ryan Bayha
Senior Analyst for Biosecurity and Biosafety Policy
Office of Biotechnology Activities

cc: Mary Beth Koza, Director of Environmental Health and Safety, UNC
Douglas Cyr, Ph.D., IBC Chair, UNC
Carrie Wolinetz, Ph.D., Associate Director for Science Policy, NIH
Lyric Jorgenson, Ph.D., Acting Director, OBA, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), OBA,
NIH



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December 16, 2015

Ryan T. Bayha
Senior Analyst for Biosecurity and Biosafety Policy
National Institutes of Health
Office of Science Policy
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

RE: October 14, 2015 Incident

Dear Mr. Bayha,

Thank you for your correspondence regarding the October 14, 2015 incident in which a plate containing a plaque assay fell from a biosafety cabinet. As previously reported, the cause of the incident was the tape used to seal the plate adhered to the researchers glove and fell from the biosafety cabinet as the researcher retracted his arms from the hood. The use of parafilm was considered as a substitute for tape, but eschewed due to concerns over unnecessary use of sharps in the BSL-3 facility. In the correspondence received from NIH OBA dated December 4, 2015, a suggested corrective action was the use of parafilm, pre-cut in the BSL-1 setting, to seal plates in the BSL-3 facility. After discussing the matter with the lab, it has been decided that the lab will forgo the use of tape or parafilm and simply transport the plates from the biosafety cabinet to the incubator in secondary containment.

Please contact me at (919) 962-5722 or eisenman@ehs.unc.edu if you have any questions.

Sincerely,

Daniel Eisenman, PhD, CBSP
Biological Safety Officer
Environment, Health and Safety

Cc: Doug Cyr, IBC Chair
Mary Beth Koza, Director of EHS