ENVIRONMENT, HEALTH & SAFETY

1120 ESTES DRIVE EXTENSION CAMPUS BOX 1650 CHAPEL HILL, NC 27599-1650 T 919.962.5507 F 919.962.0227 ehs.unc.edu

September 2, 2016

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: Development of Improved Containment for Laboratory Mice

This letter constitutes The University of North Carolina at Chapel Hill's follow up to our January 19, 2016 letter to NIH OSP regarding laboratory mice breaching containment. As discussed in that letter, a majority of the University's reported incidents have involved mice breaching primary containment in biological safety cabinets. None of the incidents led to exposures to laboratorians or escapes from the laboratories. The majority of the incidents involved novel strains of inbred mice in a project titled the Collaborative Cross (CC).

Collaborative Cross mice represent a highly genetically diverse model of the human population, and thus are useful for understanding genetic contributions to a variety of diseases, including viral infections. As CC mice are new mouse lines, and due to the fact that their genomes are mosaics from a variety of immunologically, behaviorally and physiologically distinct founder mouse lines, their behaviors, activity levels and responses to anesthetics can vary wildly. As a result, these animals present novel challenges in terms of preventative approaches to safety and corrective action not previously encountered at our University or at those of our colleagues and collaborators. Though the number of escapes is small when compared to the frequency at which these mice are handled, the University has made addressing this issue a top priority.

UNC's approach to preventing further breaches in containment is multi-faceted.

- A. Mouse users undergo extensive training prior to performing experiments with CC mice. After undergoing the standard training required of all UNC animal users, prospective CC mouse users work with personnel from the Systems Genetics Core Facility which developed the CC mice in order to understand the range of behaviors and activity levels that can occur across different mouse strains. This training includes assessments of behavior as well as safe handling and containment techniques. Following the training, individual users practice their handling and containment on uninfected animals to attain proficiency. When users are comfortable in their skillset, they then undergo a variety of assessments of their handling and containment to be approved for work on diverse mouse strains in ABSL-2 and ABSL-3 conditions.
- B. A working group comprised of representatives from the Department of Environment, Health and Safety (EHS), Division of Laboratory Animal Medicine (DLAM) and the research laboratories utilizing CC mice in infectious disease models have focused on reviewing previous incidents as well as the development of safety practices and engineering controls for infectious disease

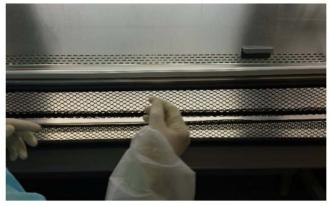
of NORTH CAROLINA at CHAPEL HILL

ENVIRONMENT, HEALTH & SAFETY

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research involving CC mice. Successfully implemented engineering controls include screw top containers for weighing mice, individual housing for mice exhibiting jumpy or aggressive behavior and use of PVC pipes with a single opening in the biological safety cabinet. As escaping mice typically run along the vertical surfaces within the biological safety cabinet while looking for shelter, the PVC pipes take advantage of instinctive animal behavior by providing apparent shelter, which can be easily capped to facilitate recapture within the biological safety cabinet.

The working group is currently evaluating the use of netting at the opening of the biological safety cabinet as a new engineering control to prevent further breaches of containment. The University has partnered with NuAire to develop a removable frame to secure the netting to the biosafety cabinet along with an elastic opening to allow users ease of access and unencumbered range of motion. The prototype has been tested by the most senior CC mouse users and found to be a promising enhancement to existing



containment strategies. The design and construction require minor modifications to accommodate varying cage sizes as well as withstanding repeated autoclaving. NuAire is currently incorporating the University's assessment into the next prototype. We will issue an additional report once the next prototype is tested.

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 Mitch Picker, IACUC Chair Craig Fletcher, Director of DLAM

Hunter, Renee (NIH/OD) [C]

From: Eisenman, Dan <disenman@email.unc.edu>

Sent: Friday, September 2, 2016 9:28 AM

To: Bayha, Ryan (NIH/OD) [E]

Cc: Koza, Mary Beth Christine; Cyr, Douglas M.; Picker, Mitchell J; Fletcher, Craig A; Harris, Kathryn

(NIH/OD) [C]

Subject: UNC Chapel Hill Follow Up Regarding Mouse Containment

Attachments: UNC-CH Follow-up Letter to NIH re CC Mice Containment 9-2-16.pdf

Dear Mr. Bayha,

Please find attached UNC Chapel Hill's follow up regarding our efforts to improve containment for Collaborative Cross mice. This letter is a follow up to the letter we submitted to NIH OSP on 1/19/16.

Thanks, Dan

Daniel Eisenman, PhD, RBP, SM(NRCM), CBSP Biological Safety Officer / Alternate Responsible Official Environment, Health & Safety University of North Carolina at Chapel Hill

1120 Estes Drive Ext. Campus Box 1650 Chapel Hill, NC 27599-1650

Office: 919-962-5722 Fax: 919-962-0227

Hunter, Renee (NIH/OD) [C]

From: Eisenman, Dan <disenman@email.unc.edu>

Sent: Tuesday, January 19, 2016 10:54 AM

To: Bayha, Ryan (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]

Cc: Koza, Mary Beth Christine; Cyr, Douglas M.; Picker, Mitchell J; Fletcher, Craig A

Subject: UNC Follow Up Report - 8/27/15 Incident

Attachments: UNC Incident Report to NIH - Incident Date 8-27-15.pdf

Dear Mr. Bayha,

Please find attached UNC Chapel Hill's follow up report associated with the 8/27/15 incident.

Please let me know if you require any more information.

Thanks, Dan

Daniel Eisenman, PhD, RBP, SM(NRCM), CBSP Biological Safety Officer / Alternate Responsible Official Environment, Health & Safety University of North Carolina at Chapel Hill

1120 Estes Drive Ext. Campus Box 1650 Chapel Hill, NC 27599-1650

Office: 919-962-5722 Fax: 919-962-0227

Email: eisenman@ehs.unc.edu

From: Eisenman, Dan

Sent: Thursday, August 27, 2015 4:34 PM

To: bayhar@od.nih.gov

Cc: Koza, Mary Beth Christine <MBKoza@ehs.unc.edu>; Chaplinski, Nick <njchaplinski@ehs.unc.edu>

Subject: Initial Report

Dear Mr. Bayha,

This is an initial report of a loss of containment from a biosafety cabinet involving a collaborative cross mouse 24 days post infection with a recombinant clone derived mouse adapted SARS coronavirus. The incident occurred about an hour ago. The mouse was promptly captured in the BSL-3 lab and the area was disinfected. I will follow up with a full report.

Thanks,

Dan

Daniel Eisenman, PhD, RBP, SM(NRCM), CBSP Biological Safety Officer / Alternate Responsible Official Environment, Health & Safety University of North Carolina at Chapel Hill

1120 Estes Drive Ext. Campus Box 1650 Chapel Hill, NC 27599-1650

Office: 919-962-5722 Fax: 919-962-0227

Hunter, Renee (NIH/OD) [C]

From: Eisenman, Dan <eisenman@ehs.unc.edu>

Sent: Friday, August 28, 2015 12:08 PM

To: Bayha, Ryan (NIH/OD) [E]

Cc: Koza, Mary Beth Christine; Chaplinski, Nick; Harris, Kathryn (NIH/OD) [C]

Subject: RE: Initial Report

Hi Ryan,

We are available on Monday at 1:15 PM. Please call 919-962-2723 to join the conference call.

Thanks,

Dan

Daniel Eisenman, PhD, RBP, SM(NRCM), CBSP Biological Safety Officer / Alternate Responsible Official Environment, Health & Safety University of North Carolina at Chapel Hill

1120 Estes Drive Ext. Campus Box 1650 Chapel Hill, NC 27599-1650

Office: 919-962-5722 Fax: 919-962-0227

Email: eisenman@ehs.unc.edu

From: Bayha, Ryan (NIH/OD) [E] [mailto:bayhar@od.nih.gov]

Sent: Friday, August 28, 2015 10:56 AM **To:** Eisenman, Dan <eisenman@ehs.unc.edu>

Cc: Koza, Mary Beth Christine <MBKoza@ehs.unc.edu>; Chaplinski, Nick <njchaplinski@ehs.unc.edu>; Harris, Kathryn

(NIH/OD) [C] <HarrisKath@mail.nih.gov>

Subject: RE: Initial Report

Dan,

Can we set up a phone call to discuss these events? This afternoon and Monday look good for us.

Thanks

Ryan

From: Eisenman, Dan [mailto:eisenman@ehs.unc.edu]

Sent: Thursday, August 27, 2015 4:34 PM

To: Bayha, Ryan (NIH/OD) [E] < bayhar@od.nih.gov>

Cc: Koza, Mary Beth Christine < MBKoza@ehs.unc.edu>; Chaplinski, Nick < njchaplinski@ehs.unc.edu>

Subject: Initial Report

Dear Mr. Bayha,

This is an initial report of a loss of containment from a biosafety cabinet involving a collaborative cross mouse 24 days post infection with a recombinant clone derived mouse adapted SARS coronavirus. The incident occurred about an hour ago. The mouse was promptly captured in the BSL-3 lab and the area was disinfected. I will follow up with a full report.

Thanks, Dan

Daniel Eisenman, PhD, RBP, SM(NRCM), CBSP Biological Safety Officer / Alternate Responsible Official Environment, Health & Safety University of North Carolina at Chapel Hill

1120 Estes Drive Ext. Campus Box 1650 Chapel Hill, NC 27599-1650

Office: 919-962-5722 Fax: 919-962-0227

Hunter, Renee (NIH/OD) [C]

From: Bayha, Ryan (NIH/OD) [E]

Sent: Friday, August 28, 2015 10:38 AM **To:** Harris, Kathryn (NIH/OD) [C]

Subject: FW: Initial Report

FYI

From: Eisenman, Dan [mailto:eisenman@ehs.unc.edu]

Sent: Thursday, August 27, 2015 4:34 PM

To: Bayha, Ryan (NIH/OD) [E] <bayhar@od.nih.gov>

Cc: Koza, Mary Beth Christine <MBKoza@ehs.unc.edu>; Chaplinski, Nick <njchaplinski@ehs.unc.edu>

Subject: Initial Report

Dear Mr. Bayha,

This is an initial report of a loss of containment from a biosafety cabinet involving a collaborative cross mouse 24 days post infection with a recombinant clone derived mouse adapted SARS coronavirus. The incident occurred about an hour ago. The mouse was promptly captured in the BSL-3 lab and the area was disinfected. I will follow up with a full report.

Thanks, Dan

Daniel Eisenman, PhD, RBP, SM(NRCM), CBSP Biological Safety Officer / Alternate Responsible Official Environment, Health & Safety University of North Carolina at Chapel Hill

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Office: 919-962-5722 Fax: 919-962-0227

Hunter, Renee (NIH/OD) [C]

From: Bayha, Ryan (NIH/OD) [E]

Sent: Friday, August 28, 2015 10:56 AM

To: Eisenman, Dan

Cc: Koza, Mary Beth Christine; Chaplinski, Nick; Harris, Kathryn (NIH/OD) [C]

Subject: RE: Initial Report

Dan,

Can we set up a phone call to discuss these events? This afternoon and Monday look good for us.

Thanks Ryan

From: Eisenman, Dan [mailto:eisenman@ehs.unc.edu]

Sent: Thursday, August 27, 2015 4:34 PM

To: Bayha, Ryan (NIH/OD) [E] <bayhar@od.nih.gov>

Cc: Koza, Mary Beth Christine <MBKoza@ehs.unc.edu>; Chaplinski, Nick <njchaplinski@ehs.unc.edu>

Subject: Initial Report

Dear Mr. Bayha,

This is an initial report of a loss of containment from a biosafety cabinet involving a collaborative cross mouse 24 days post infection with a recombinant clone derived mouse adapted SARS coronavirus. The incident occurred about an hour ago. The mouse was promptly captured in the BSL-3 lab and the area was disinfected. I will follow up with a full report.

Thanks, Dan

Daniel Eisenman, PhD, RBP, SM(NRCM), CBSP Biological Safety Officer / Alternate Responsible Official Environment, Health & Safety University of North Carolina at Chapel Hill

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January 19, 2016

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: Loss of Containment Involving a Mouse Infected with Mouse Adapted SARS

As required by Appendix G-II-C-2-q of *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, on August 27, 2015, the University of North Carolina at Chapel Hill ("UNC") submitted an initial report of a loss of containment involving a mouse 24 days post infection with mouse adapted SARS derived from a recombinant infectious clone. The incident was immediately reported to Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy at the National Institutes of Health. At the request of NIH OBA, a conference call was held on August 31, 2015 to discuss the incident. NIH OBA granted UNC additional time to address the root cause and submit a follow up report. This letter constitutes UNC's follow up report describing the incident and the steps taken to mitigate the risk of recurrence.

This incident occurred as a researcher was removing a collaborative cross mouse that was 24 days post-infection with a mouse adapted SARS Urbani from one of the Buxco (plethysmograph) chambers inside a biological safety cabinet in an ABSL-3 facility. When attempting to remove the mouse the researcher thought she had a successful grip on the mouse's tail and fully removed the lid from the plethysmograph chamber. As this was happening the mouse twisted in the researcher's hand and got free. The mouse immediately turned towards the researcher's arm, ran out of the biosafety cabinet, onto the researchers tyvek apron and onto the floor. The mouse was promptly caught within the laboratory and returned to the cage. Both of the researchers who were in the laboratory at the time decontaminated their PPE and the floor with 70% ethanol. The researchers were wearing tyvek suits, tyvek aprons, tyvek booties, PAPR and double gloves. Neither of the researchers involved experienced a breach in PPE or respiratory protection.

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 and any signs or symptoms of infection over the following ten days. The medical surveillance period passed without incident.

The actual risk posed to the laboratorians in the August 27, 2015 incident was likely low as mice infected with mouse adapted SARS have cleared the virus by day 10 post infection. As the mouse was at day 24 post infection, it had most likely cleared the infection and was kept primarily to study the ensuing adaptive immune responses.

UNC's approach to preventing further breaches in containment is multi-faceted.

A. Mouse users undergo extensive training prior to performing experiments with CC mice. After undergoing the standard training required of all UNC animal users, prospective CC mouse users work with personnel from the Systems Genetics Core Facility which developed the CC mice in order to understand the range of behaviors and activity levels that can occur across different mouse strains. This training includes assessments of behavior as well as safe handling and containment techniques. Following the training, individual users practice their handling and containment on uninfected animals to attain proficiency. When users are comfortable in their skillset, they then

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

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undergo a variety of assessments of their handling and containment to be approved for work on diverse mouse strains in ABSL-2 and ABSL-3 conditions.

B. A working group comprised of representatives from EHS, Division of Laboratory Animal Medicine (DLAM) and the research laboratories utilizing CC mice in infectious disease models have focused on reviewing previous incidents as well as the development of safety practices and engineering controls for infectious disease research involving CC mice. Successfully implemented engineering controls include screw top containers for weighing mice, individual housing for mice exhibiting jumpy or aggressive behavior and use of PVC pipes with a single opening in the biological safety cabinet. As escaping mice typically run along the vertical surfaces within the biological safety cabinet while looking for shelter, the PVC pipes take advantage of instinctive animal behavior by providing apparent shelter, which can be easily capped to facilitate recapture within the biological safety cabinet. Unfortunately, the 8/27/15 incident involved a mouse that ran directly towards the opening of the biological safety cabinet rather than the vertical surfaces.

The working group is currently evaluating the use of netting at the opening of the biological safety cabinet as a new engineering control designed to prevent further breaches of containment. The netting is attached to either the sash or the exterior of the hood and weighted down to provide contact with the work surface. Researchers are able to access the work surface by sliding their arms under the netting. We are currently working with NuAire to develop a removable frame to secure the netting to the biosafety cabinet along with an elastic opening to allow users greater ease of access and range of motion. Our ultimate goal is the creation of a professionally crafted engineering control to successfully mitigate the risk of future breaches of containment while avoiding any adverse effect on containment or impeding scientific research.

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

Daniel 45

Cc: Doug Cyr, IBC Chair

Mary Beth Koza, Director of EHS Mitch Picker, IACUC Chair

Craig Fletcher, Director of DLAM

From: Eisenman, Dan <disenman@email.unc.edu>

Sent: Wednesday, December 16, 2015 4:23 PM

To: Bayha, Ryan (NIH/OD) [E]

Cc: Harris, Kathryn (NIH/OD) [C]; Koza, Mary Beth Christine; Cyr, Douglas M.

Subject: Follow Up Correspondence - 10-14-15 Incident - UNC Chapel Hill

Attachments: 10-14-15 Incident - Response to Correspondence from NIH.pdf; 10-14-15 Incident -

NIH Response.pdf

Dear Mr. Bayha,

Please find attached UNC Chapel Hill's response to your correspondence regarding the 10-14-15 incident involving a SARS virus plaque assay that fell from a biosafety cabinet in a BSL-3 facility.

Please let me know if you require any more information.

Thanks,

Dan

Daniel Eisenman, PhD, RBP, SM(NRCM), CBSP Biological Safety Officer / Alternate Responsible Official Environment, Health & Safety University of North Carolina at Chapel Hill

1120 Estes Drive Ext. Campus Box 1650 Chapel Hill, NC 27599-1650

Office: 919-962-5722 Fax: 919-962-0227

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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 SARS 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



Office of Science Policy National Institutes of Health 6705 Rockledge Drive Suite 750, MSC 7985 Bethesda, MD 20892-7985 (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 SARS.

From your report, we understand that a plate containing a plaque assay of mouse adapted SARS 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 withdraw 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 December 4, 2015 Page 2

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 precut 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,	
Personal Info	

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

From: Harris, Kathryn (NIH/OD) [C]

Sent: Monday, October 26, 2015 1:06 PM

To: 'disenman@email.unc.edu'

Cc: Bayha, Ryan (NIH/OD) [E]

Subject: Mouse adapted SARS incident

Dear Dr. Eisenman:

Thank you for submitting the report on the loss of containment while working with a mouse adapted strain of SARS. As we discussed on the phone it would be helpful if you could provide additional information on any actions taken to prevent a reoccurrence of the incident. For example, was the need to take extra care while sealing plates discussed?

I understand there had been a discussion the possibility of using parafilm to seal the plates but that was decided against due to the need to avoid the use of sharps in the BL3 to cut the Parafilm. Perhaps it might be possible to precut the Parafilm to the desired size to seal plates outside of the BL3 lab and then bring the precut film into the lab to have on hand?

Regards,

Kathryn Harris

Kathryn Harris Ph.D. RBP (contractor)
Senior Outreach and Education Specialist
NIH Office of Science Policy
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985

Tel: (301) 496-9838 Fax: (301) 496-9839

From:

Bayha, Ryan (NIH/OD) [E]

Sent:

Monday, October 26, 2015 9:41 AM

To:

Harris, Kathryn (NIH/OD) [C]

Subject:

FW: UNC Chapel Hill Incident Report

Attachments:

UNC Incident Report to NIH - Incident Date 10-14-15.pdf

See attached.

From: Eisenman, Dan [mailto:disenman@email.unc.edu]

Sent: Monday, October 26, 2015 8:48 AM

To: Bayha, Ryan (NIH/OD) [E]

Sayhar@od.nih.gov>; Koza, Mary Beth Christine <MBKoza@ehs.unc.edu>

Cc: Cyr, Douglas M. <douglas_cyr@med.unc.edu>

Subject: UNC Chapel Hill Incident Report

Dear Mr. Bayha,

Please find attached UNC Chapel Hill's follow up report regarding the incident that occurred on 10-14-15.

Please let me know if you require any more information.

Thanks,

Dan

Daniel Eisenman, PhD, RBP, SM(NRCM), CBSP Biological Safety Officer / Alternate Responsible Official Environment, Health & Safety University of North Carolina at Chapel Hill

1120 Estes Drive Ext. Campus Box 1650 Chapel Hill, NC 27599-1650

Office: 919-962-5722 Fax: 919-962-0227

Email: eisenman@ehs.unc.edu

-----Original Message-----From: Eisenman, Dan

Sent: Wednesday, October 14, 2015 4:45 PM

To: bayhar@od.nih.gov; Koza, Mary Beth Christine <MBKoza@ehs.unc.edu>

Subject: Initial Report UNC Chapel Hill

Dear Mr. Bayha,

This is an initial report of a loss of primary containment involving a plaque assay involving mouse adapted SARS in a BSL3 facility. Three personnel were present in the lab. PPE including respiratory protection were not compromised. The area was decontaminated as per sop. The occupational health physician was immediately notified and personnel are self monitoring. We will follow up with a full report.

Thanks,

Dan

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 SARS

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 SARS (MA15) 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

From: Bayha, Ryan (NIH/OD) [E]

Sent: Thursday, October 15, 2015 8:18 AM

To: Harris, Kathryn (NIH/OD) [C] **Subject:** FW: Initial Report UNC Chapel Hill

FYI

----Original Message----

From: Eisenman, Dan [mailto:disenman@email.unc.edu]

Sent: Wednesday, October 14, 2015 4:45 PM

To: Bayha, Ryan (NIH/OD) [E] <bayhar@od.nih.gov>; Koza, Mary Beth Christine <MBKoza@ehs.unc.edu>

Subject: Initial Report UNC Chapel Hill

Dear Mr. Bayha,

This is an initial report of a loss of primary containment involving a plaque assay involving mouse adapted SARS in a BSL3 facility. Three personnel were present in the lab. PPE including respiratory protection were not compromised. The area was decontaminated as per sop. The occupational health physician was immediately notified and personnel are self monitoring. We will follow up with a full report.

Thanks, Dan

Sent from my iPhone



Office of Science Policy National Institutes of Health 6705 Rockledge Drive Suite 750, MSC 7985 Bethesda, MD 20892-7985 (301) 496-9838 (Phone) (301) 496-9839 (Fax) http://osp.od.nih.gov

February 18, 2016

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 February 4, 2016, and February 15, 2016, reports to the National Institutes of Health (NIH) Office of Science Policy (OSP) regarding an incident in which a researcher was bitten by a mouse infected with mouse adapted SARS CoV.

From your report, we understand that the researcher was weighing the mouse, and while transferring the animal from its cage to the weighing container, it bit her. The researcher was wearing two pairs of gloves and other appropriate personal protective equipment (PPE), including a powered air purifying respirator at the time of the incident. The researcher returned the mouse to its cage and immediately followed the post exposure protocol detailed in the laboratory standard operating procedure (SOP). She disinfected her gloves with 70% ethanol before removing them, allowed the wound to bleed, and washed her hands with soap and water. She then proceeded to the University Employee Occupational Health Clinic. The medical director instituted a ten day medical monitoring period during which the researcher was required to wear a surgical mask in public and report temperatures twice daily. The incident was also reported to the Centers for Disease Control and Prevention (CDC) as required under the Select Agent regulations.

You state in your report that all containment practices and SOPs were properly followed, and the mouse had no prior tendencies towards aggressive behavior. In response to this incident, enhancements to the SOP such as engineering controls, additional PPE, and the use of anesthetics were considered. However, because possible enhancements could potentially interfere with the experimental procedures, and introduce additional experimental variables, it was decided not to institute any additional requirements at this time.

Daniel Eisenman, Ph.D., RBP, SM(NRCM), CBSP February 18, 2016 Page 2

No further information is required regarding this incident. However, if the researcher involved in the incident has not undergone recent animal handling training, we recommend that a refresher training be considered. 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,	
Personal Info	
D D 1	· ·

Ryan Bayha Senior Analyst for Biosecurity and Biosafety Policy Office of Science Policy

cc: Denise Gangadharan, Ph.D., Associate Director for Science, Division of Select Agents and Toxins, CDC

Doug Cyr, Institutional Biosafety Committee Chair, UNC

Mary Beth Koza, Director, Environmental Health and Safety, 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

From:

Eisenman, Dan <disenman@email.unc.edu>

Sent:

Monday, February 15, 2016 6:56 PM

To:

Bayha, Ryan (NIH/OD) [E]

Cc:

Koza, Mary Beth Christine; Cyr, Douglas M.; Harris, Kathryn (NIH/OD) [C]

Subject:

UNC Incident Report - Incident Date 2-4-16

Attachments:

UNC Incident Report to NIH - Incident Date 2-4-16.pdf

Dear Mr. Bayha,

Please find attached UNC Chapel Hill's follow up report to the incident that occurred on 2-4-16.

Please let me know if you would like any more information.

Thanks,

Dan

Daniel Eisenman, PhD, RBP, SM(NRCM), CBSP Biological Safety Officer / Alternate Responsible Official Environment, Health & Safety University of North Carolina at Chapel Hill

1120 Estes Drive Ext. Campus Box 1650 Chapel Hill, NC 27599-1650

Office: 919-962-5722 Fax: 919-962-0227

Email: eisenman@ehs.unc.edu

----Original Message-----From: Eisenman, Dan

Sent: Thursday, February 04, 2016 12:01 PM

To: bayhar@od.nih.gov

Cc: Koza, Mary Beth Christine < MBKoza@ehs.unc.edu>

Subject: UNC initial report

Dear Mr. Bayha,

This is an initial report of an incident that occurred moments ago. A researcher was bitten by a mouse infected with mouse adapted SARS in a BSL3 facility. The individual washed her hands and notified the PI and EHS as per SOP and is en route to the occupational health clinic for evaluation. The clinic director has been notified. We will follow up with a full report.

Dan Eisenman Biological Safety Officer UNC Chapel Hill

Sent from my iPhone

ENVIRONMENT, HEALTH & SAFETY

1120 ESTES DRIVE EXTENSION CAMPUS BOX 1650 CHAPEL HILL, NC 27599-1650 T 919.962.5507 F 919.962.0227 ehs.unc.edu

February 15, 2016

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: Mouse Bite Involving a Mouse Infected with Mouse Adapted SARS CoV

As required by Appendix G-II-C-2-q of NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, on February 4, 2016, the University of North Carolina at Chapel Hill ("UNC") submitted an initial report of a researcher bitten by a mouse infected with mouse adapted SARS CoV. The incident was immediately reported to Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy at the National Institutes of Health. This letter constitutes UNC's follow up report describing the incident and the ensuing response.

On February 4, 2016 a researcher was weighing mice at ABSL-3 containment within a biological safety cabinet while wearing scrubs, Tyvek suit, boot covers, Tyvek apron, double gloves and a PAPR when she was bitten by a mouse that was two days post infection with mouse adapted SARS CoV (MA15). While the moue was being transferred by the tail from the cage to the weighing container, it climbed up its own tail and bit the researcher on the right ring finger. The mouse bit through two sets of gloves and broke the researcher's skin. The mouse was returned to its cage and the researcher began following the post exposure procedure as detailed in the lab SOP. She disinfected her gloves with 70% ethanol prior to removing them. She allowed the wound to bleed for a minute prior to washing her hands with soap and water for five minutes. She then notified the lab manager who then contacted the PI and the Biological Safety Officer. The individual was instructed to exit the facility and proceed immediately for evaluation at the University Employee Occupational Health Clinic (UEOHC). Upon being notified, the Biological Safety Officer immediately notified the Medical Director of the UEOHC. The Medical Director discussed medical monitoring and options for isolation with the individual, PI, Biological Safety Officer and the Responsible Official.

The individual reported to the UEOHC in an afebrile state but with a baseline runny nose. A ten day medical monitoring period was instituted and passed without incident. During the medical monitoring period the researcher was required to wear a surgical mask while in public and at work and report temperatures and symptoms to the Medical Director twice daily. Per the lab's BSL-3 SOP, the individual would have been evaluated at UNC Hospitals if fever or other symptoms of infection developed. UNC Hospital Epidemiology / Infection Control were notified. As the incident involved a select agent, the incident was immediately reported to the CDC and updates were provided to the CDC throughout the medical monitoring period.

On June 19, 2015 UNC's EHS and members of the UNC Hospitals Emergency Department and Epidemiology / Infection Control conducted a tabletop drill to prepare for incidents involving BSL-3 researchers experiencing exposures to SARS, MERS or 1918 influenza.

This incident was reviewed as well as the associated containment practices and SOPs. The mouse involved was a standard B6 with no prior tendencies towards aggressive behavior. All containment practices and SOPs were properly followed. Enhancements to existing containment practices and SOPs (engineering controls, PPE and anesthetics) were discussed but were deemed as unnecessary and potentially detrimental to research as they could interfere with experimental procedures and introduce additional experimental variables so no changes to containment practices or SOPs will be instituted at this time. We will re-evaluate if a reoccurrence takes place.



ENVIRONMENT, HEALTH & SAFETY

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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

From:

Bayha, Ryan (NIH/OD) [E]

Sent:

Thursday, February 04, 2016 12:03 PM

To:

Harris, Kathryn (NIH/OD) [C]

Subject:

FW: UNC initial report

----Original Message----

From: Eisenman, Dan [mailto:disenman@email.unc.edu]

Sent: Thursday, February 04, 2016 12:01 PM

To: Bayha, Ryan (NIH/OD) [E] <bayhar@od.nih.gov> Cc: Koza, Mary Beth Christine <MBKoza@ehs.unc.edu>

Subject: UNC initial report

Dear Mr. Bayha,

This is an initial report of an incident that occurred moments ago. A researcher was bitten by a mouse infected with mouse adapted SARS in a BSL3 facility. The individual washed her hands and notified the PI and EHS as per SOP and is en route to the occupational health clinic for evaluation. The clinic director has been notified. We will follow up with a full report.

Dan Eisenman Biological Safety Officer UNC Chapel Hill

Sent from my iPhone



Office of Science Policy National Institutes of Health 6705 Rockledge Drive Suite 750, MSC 7985 Bethesda, MD 20892-7985 (301) 496-9838 (Phone) (301) 496-9839 (Fax) http://osp.od.nih.gov

April 27, 2017

Jessica Poole, M.S.
Associate Biological Safety Officer
Environment, Health and Safety
University of North Carolina at Chapel Hill
1120 Estes Drive Ext.
Campus Box 1650
Chapel Hill, NC 27599-1650

Dear Ms. Poole:

Thank you for your April 18, 2017 and April 24, 2017, reports to the National Institutes of Health (NIH) Office of Science Policy (OSP) regarding an April 18, 2017, incident in which there was a spill in a biosafety level 3 laboratory at the University of North Carolina at Chapel Hill.

From your report, we understand that researchers were conducting viral titration assays on mouse adapted SARS-CoV mouse lung samples. Lung homogenate was diluted and placed into six-well plates. The plates were placed in a secondary container for transfer from the biological safety cabinet (BSC) to the incubator. As one of the researchers was putting a stack of the plates into the incubator, the top plate got caught on the shelf and dropped. You state in your report that approximately 1.2 mL of liquid from the plate spilled onto the door of the incubator and the floor.

As soon as the spill occurred, the three researchers in the laboratory stopped working and followed the standard operating procedure (SOP) for a spill outside of the BSC. The researchers checked the integrity of their personal protective equipment (PPE), which was intact, and also verified there was no visible contamination of their PPE. Paper towels were soaked in 70% ethanol and placed over the spill. Aerosols were allowed to settle for 30 minutes, during which time the laboratory manager, principal investigator (PI) and biological safety officer (BSO) were notified about the spill. The spill was then cleaned appropriately and all surfaces were decontaminated.

The BSO contacted the Director of the University Employee Occupational Health Clinic, who determined that, based on the size of the spill and the fact the PPE was intact, the researchers did not need to report to the clinic. The researchers were advised to follow the laboratory SOP with

Jessica Poole, M.S. April 27, 2017 Page 2

regards to daily self-monitoring of symptoms, and to notify the PI immediately in the event of respiratory symptoms or a fever.

The actions taken in response to this incident appear appropriate. No further information is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Sincerely,	
Personal Info	

Michelle McKinney, M.S., CBSP Health Science Policy Analyst Biosafety, Biosecurity and Emerging Biotechnology Policy Division, NIH

cc: Mary Beth Koza, Director, Environmental Health and Safety, UNC Carrie D. Wolinetz, Ph.D., Associate Director for Science Policy, NIH Jessica Tucker, Ph.D., Director, Biosafety, Biosecurity and Emerging Biotechnology Policy Division, NIH

Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Biosafety, Biosecurity and Emerging Biotechnology Policy Division, NIH Laura Cochran, Program Assistant (contractor), Biosafety, Biosecurity and Emerging

Biotechnology Policy Division, NIH

From: Poole, Jessica <jmmarsha@email.unc.edu>

Sent: Monday, April 24, 2017 10:51 AM

To: NIH guidelines Cc: Koza, Mary Beth

Subject: UNC Incident 4/18/2017

Attachments: Baric NIH.docx

Good Morning:

I have attached the completed form for the incident that occurred at UNC on 4/18/2017. If you have any additional questions or concerns, please feel free to contact me.

Jessica

Jessica Poole, M.S., rLATG Associate Biological Safety Officer Environment, Health & Safety University of North Carolina at Chapel Hill

1120 Estes Drive Ext. Campus Box 1650 Chapel Hill, NC 27599-1650

Office Phone: 919-962-5726 Cell Phone: 919-883-7020

Fax: 919-962-0227

Email: jmmarsha@email.unc.edu

Does this incident involve research subject to the NIH Guidelines?	⊠YES □NO
	If no, this incident does not require reporting to OSP
Institution Name:	The University of North Carolina at Chapel Hill
Date of Report:	4/21/2017
Reporter name and position:	Jessica Poole Interim Biological Safety Officer
Telephone number:	919-962-5726
Email address:	jmmarsha@email.unc.edu
Reporter mailing address:	1120 Estes Drive Ext. Campus Box 1650 Chapel Hill, NC 27599-1650
Date of incident:	4/18/2017
Name of Principal Investigator:	Ralph Baric

What was the nature of the incident?	□ Failure to follow approved containment conditions □ Failure to obtain IBC approval □ Incomplete inactivation □ Loss of containment □ Loss of a transgenic animal □ Personnel exposure □ Spill □ Other (please describe):	
Did the Institutional Biosafety Committee (IBC) approve this research?		
What was the approved biosafety level of the research?	□BL1 □BL2 □BL2+ □BL3 □BL3+ □BL4	
Has a report of this incident been made to other agencies? If so, please indicate	 ☑CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA 	

DESCRIPTION OF INCIDENT:

On April 18, 2017, three researchers (a post doc, a research assistant, and a research associate) were performing work in the BSL-3 laboratory while wearing scrubs, shoe covers, Tyvek suits, double gloves and PAPRs as per lab SOP. Two of the researchers were performing viral titration assays on recombinant mouse adapted SARS-CoV mouse lung samples. The mouse lung was homogenized in 1mL of PBS and was then serially diluted 1:10 six times and then 0.2mL of each of the 6 dilutions was added to one of the wells in the plate of vero cells following removal of the media. For each 6-well plate, there was a total volume of 1.2 mL of serially diluted virus per plate. The starting volume of mouse lung homogenate used was 0.05 mL. After adding the diluted virus to the cells, the researcher put the plates into a bin, as a secondary container, and carried them from the biological safety cabinet to the cell incubator. When the researcher was putting the six-well plates, which were stacked in groups of four, into the top incubator, the top plate got caught on the top shelf and the plate dropped. A maximum of 1.2 mL of virus inoculum spilled on the door of the bottom incubator and onto the floor. The plate that dropped contained lung tissue from a male PARK2 -/- mouse, which was harvested at four days post infection and had been infected with 10⁵ plague forming units of mouse adapted SARS-MA15. As soon as the spill occurred, the three researchers stopped working and immediately began following the SOP for a spill outside of the biological safety cabinet. The researchers checked the integrity of their PPE, which was intact and verified that no visible virus-containing liquid contaminated their PPE. The researcher soaked paper towels with 70% ethanol and placed them onto the door of the bottom incubator and the floor. They allowed the aerosols to settle for 30 minutes. During the 30 minutes, they notified the lab manager via telephone. The lab manager immediately notified the PI and the interim Biological Safety Officer. The interim Biological Safety Officer contacted the Director of the University Employee Occupational Health Clinic. The Director of the University Employee Occupational Health Clinic determined that the researchers would not need to report to the clinic and that no daily symptom/temperature reporting would be necessary based on the size of the spill and since the researchers' PPE was intact. He did advise them to continue to follow the lab SOP in regards to self daily symptom monitoring and if respiratory symptoms or a temperature appears that they notify the PI and EHS immediately. After 30 minutes, the researchers sprayed the two areas with 70% Ethanol and allowed 20 minutes of contact time. The spill was then wiped up with absorbent paper. The absorbent paper was placed into a biohazard bag. The outside of the biohazard bag was surface decontaminated and placed in a container to be autoclaved. The researchers removed their outer gloves and replaced them with a clean pair of gloves after the decontamination process was complete.

All three researchers are compliant with the required trainings and completed their yearly BSL-3 lab trainings on 12/9/2016. This training includes: respiratory protection, lab procedures, emergency procedures, select agent requirements, medical surveillance, signs and symptoms monitoring, and dual use research of concern. All three researchers are compliant with the University's medical surveillance program and have had their yearly physical.

Has the IBC reviewed this incident?	□YES ⊠NO The next IBC meeting will be held on 5/3/2017 and the committee will be informed about the incident.
Please describe the root cause of this incident:	The root cause of the incident was the top plate in the stack hit the top shelf of the incubator, which caused the plate to fall from the stack and the contents inside to spill onto the door of the bottom incubator and the floor.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The laboratory procedures and policies were reviewed and it was determined that the policies and procedures that are currently in place addressed the incident appropriately and that no additional polices or procedures need to be implemented.

From:

Poole, Jessica <jmmarsha@email.unc.edu>

Sent:

Tuesday, April 18, 2017 3:35 PM

To: Cc: NIH guidelines Koza, Mary Beth

Subject:

UNC Spill Initial Report

Good Afternoon:

This is an initial report of a spill that occurred on 4/18/2017. Two employees were performing viral titration assays in the BSL3 on recombinant mouse adapted SARS-CoV mouse lung samples. The mouse lung was homogenized in 1mL of PBS and then serially diluted 1:10 6 times before being added to 6 well plates of vero cells. The media on top of the cells was removed and 200uL of each dilution was added to one well per plate for a total volume of 1.2mL per plate. The plates were then taken to the incubator to incubate at 37C for one hour. When the plates were transferred to the incubator (stacks of 5 plates) the top plate's lid caught the shelf and the plate was knocked to the floor. There was some diluted virus on the door of the bottom incubator and some on the floor but there was no more than 1.2mL spilled. The spill was decontaminated with 70% ethanol and allowed to sit for 30 minutes before additional disinfectant was added and the spill cleaned up. All PPE for both women was intact and functioning properly during this time. I will be following up with a full report. If you have any immediate questions or concerns, please feel free to contact me.

Jessica

Jessica Poole, M.S., rLATG Associate Biological Safety Officer Environment, Health & Safety University of North Carolina at Chapel Hill

1120 Estes Drive Ext. Campus Box 1650 Chapel Hill, NC 27599-1650

Office Phone: 919-962-5726 Cell Phone: 919-883-7020

Fax: 919-962-0227

Email: jmmarsha@email.unc.edu