

Template for Reporting Incidents Involving Recombinant DNA to the NIH Office of Biotechnology Activities (OBA)

The *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH OBA within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents in BSL-2 laboratories resulting in an overt exposure must be immediately reported to NIH OBA. Spills or accidents occurring in high containment (BSL-3 or BSL-4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH OBA.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Use of this template is not required and other formats may be acceptable.

A separate template for reporting Human Gene Transfer Adverse Events is available at: http://www4.od.nih.gov/oba/rac/adverse_event_template.doc

Please note that submitting this completed template to the NIH OBA does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.

Completed reports may be sent via U.S. mail, courier service, e-mail, or facsimile to:

**Attention: Incident Reports
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
(For all non-USPS deliveries use Zip Code 20817)
Telephone 301-496-9838
FAX 301-496-9839
E-mail: oba@od.nih.gov**

<u>NIH OBA Incident Reporting Template</u>	
Does this incident involve research subject to the <i>NIH Guidelines</i> ?	X Yes If no, this incident does not have to be reported to OBA
Institution name:	University of Wisconsin - Madison
Date of report:	11/09/2013
Reporter name and position:	Jim Turk – Biological Safety Officer
Reporter telephone:	(608)263-9013
Reporter email:	jturk@fpm.wisc.edu
Date of Incident:	11/09/2013
Name of principal investigator:	[REDACTED]

Is this an NIH funded project?	X Yes <input type="checkbox"/> No
If yes, please provide	NIH Grant or contract number: XXXXXXXXXX NIH funding institute or center NIH program officer contact information (name, email etc.)
What was the nature of incident?	Small spill (dropped plate while placing in incubator) outside of BSC while wearing appropriate PPE.
Did the institutional Biosafety Committee (IBC) approve this research?	X Yes If yes, on what date? 4/4/2012
If yes, please provide:	Approval date: 4/4/2012 Approved biosafety level for the research: ABSL-3+ Additional approval requirements:
What section(s) of the <i>NIH Guidelines</i> is the research subject to?	III-D-1-a, III-D-2-a, III-D-3-a, III-D-3-b, III-D-4-b, III-D-4-c(1), III-D-7-b, III-D-7-c, III-D-7d, Appendix G-II-B, Appendix G-II-C-5c, Appendix Q
Has a report of this incident been made to other federal or local agencies? If so, please indicate by checking the appropriate box.	X CDC X USDA <input type="checkbox"/> FDA <input type="checkbox"/> EPA <input type="checkbox"/> OSHA <input type="checkbox"/> Research Funding Agency/Sponsor: (name) <input type="checkbox"/> State/Local Public Health <input type="checkbox"/> Federal/State/ Local Law Enforcement <input type="checkbox"/> Other – please describe:
Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. Include the following information as applicable.	
A description of:	
<ul style="list-style-type: none"> • The recombinant agent or material involved. • The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space). • Who was involved in the incident/violation, including others present at the incident location? Note - please do not identify individuals by name. Provide only position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker). • Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event. • The training received by the individual(s) involved and the date(s) the training was conducted. • The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation. • Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation. • The personal protective equipment in use at the time of the incident/violation. • The occupational health requirements for laboratory personnel involved in the research. • Any medical advice/treatment/surveillance provided or recommended after the incident 	

- Any injury or illness associated with the incident.
- Medical surveillance results (if not available at the time of initial report please indicate when results will be available).
- Equipment failures.

DESCRIPTION OF INDICENT: (use additional space as necessary)

The researcher was wearing a PAPR, scrubs, tyvek, shoe covers, dedicated shoes, another pair of shoe covers, and two pairs of gloves. All SOPs were followed appropriately and the incident is considered a spill and not an exposure. All personnel are trained on a regular basis in accordance with the select agent regulations and go through an extensive mentoring process.

This incident will be used as a training session for the laboratory. The group will discuss what can be done to prevent a spill of this nature from occurring again. Mostly likely it will be as simple as changing the way the plates are carried to the incubator.

Experiment set-up: The researcher was working in the ABSL-3+ suite performing growth curve analysis of viruses containing mutations in the PB2 protein (part of the viral polymerase complex), in the virus strain background of A/Muscovy Duck/Vietnam/TY93/2007 (H5N1; referred to as 'TY93'). The viral hemagglutinin (HA) protein of this virus strain possesses a multi-basic cleavage site. Approximately 24 h prior to the incident (on November 8th, 2013), cells in 6-well tissue culture plates were infected at a multiplicity of 0.001 plaque forming units (PFU) per cell (~4 x 10⁵ cells per well). Following the infection, infected cells were covered with approximately 2 ml of media per well, and cultures were incubated.

The spill: The spill occurred during the collection of supernatant samples from the infected cultures at the 24 h time point (on the morning of November 9th, 2013). To collect the virus culture supernatant samples, three 6-well tissue culture plates were transferred by the researcher from the tissue culture incubator into a biosafety cabinet (BSC), and a sample was harvested from each well into 2 ml screw-cap tubes. Following sample collection, the researcher removed all three plates from the BSC (stacked on top of each other) for transfer back into the tissue culture incubator. After opening the external door and the internal glass door of the incubator, the lower half of the tissue culture plate on the bottom of the 3-plate stack slipped from the researcher's hand and fell to the floor. Four wells of this plate were infected (2 wells each with two different virus mutants: [REDACTED] and [REDACTED]), so approximately 8 ml of virus-containing media spilled onto the floor.

Spill clean-up:

1. The researcher immediately closed the incubator doors and returned the plates that were not dropped to the BSC. These plates were later transferred back to the tissue culture incubator, following the spill clean-up procedure.
2. The researcher picked up the dropped plate bottom from the floor and immersed it in a container of 5% MicroChem Plus inside the BSC.

3. The researcher then saturated his outer gloves with 70% ethanol, disposed of them in the biohazard trash, and put on a new pair of outer gloves.
4. Following SOP #33, the researcher covered the area of the spill (~3-inches in diameter) with paper towels, and then flooded the contaminated area and paper towels with freshly made 5% MicroChem Plus.
5. At this time, the researcher observed a few drops of liquid (i.e., media) on the Tyvek suit below the knee, so 70% ethanol to saturate both arms (in entirety) and both legs (from the knee down) of the Tyvek suit, shoe covers, the bottoms of shoes, and 2-3 inches of exposed skin between the bottom of the Tyvek suit and the shoes (i.e., ankles).
6. After waiting 20 minutes, the researcher
 - a. Transferred the disinfectant-soaked paper towels covering the spill into a biohazard autoclave bag inside a gray plastic bin.
 - b. Removed and disposed of his outer gloves into the same biohazard bag.
 - c. Donned a new pair of outer gloves.
 - d. Secured the biohazard bag by tying a knot at the top.
 - e. Sprayed the outside surface of the bag in 70% ethanol.
7. The researcher prepared fresh 1% Virkon S (from powder) and mopped the area of the floor affected by the spill with 1% Virkon S.
8. The researcher saturated the outside surfaces of the tissue culture incubators with 70% ethanol, and cleaned up the BSC according to standard procedures.
9. The researcher contacted the on-call scientist via the emergency iPhone to obtain further instructions, and then exited the ABSL-3+ suite following the standard exit procedure. Additional details about the incident response and communication are described in Section IV below.
10. Following the researcher's exit from the ABSL-3+ suite, a second researcher entered the suite and autoclaved out the disposable trash from the gown room, as well as all trash inside the suite.

IV. Incident Response Communication and Timeline

1. 6:30 a.m. – The researcher spilled ~8 ml of virus-containing media on the floor of the ABSL-3+ suite (room 121), outside of BSC containment.
2. 6:30 – 6:54 a.m. – The researcher cleaned up the spill according to the steps described in SOP #33.
3. 6:55 a.m. – The researcher phoned the on-call scientist via the emergency iPhone. The researcher indicated to on-call scientist that a plate was dropped containing virus onto the floor, and further indicated that was used SOP #33 to clean up the spill. The on-

call scientist asked the researcher to await further instructions within the ABSL-3+ suite.

4. 7:09 a.m. – The on-call phone researcher phoned the lab manager to relay information about the volume of the spill and to discuss how to proceed. Since the volume was close to the amount considered to be a “large” spill (large spills are > 10 ml, and can be considered a potential exposure), it was decided that additional consultation with the Alternate Responsible Official (ARO) would be required before a decision about quarantine could be made.

5. 7:15 a.m. – The on-call scientist phoned the ARO and left a message, describing the incident and asking to phone back as soon as possible.

6. 7:21 a.m. –The on-call scientist notified the researcher that additional consultation with the ARO was ongoing, and that the researcher should proceed to the conference room, avoid contact with other people, and wait for further instructions.

7. 7:35 a.m. – The ARO returned the on-call scientist phone call. The situation was summarized for the ARO.

8. 7:41 a.m. – The ARO called the researcher and they discussed the incident and the strains being used. The ARO instructed the researcher to stay in the conference room and while the necessary phone calls were made.

9. 7:52 a.m. – The ARO called the UW Hospital Operator and had the infectious disease fellow on-call paged.

10. 7:55 a.m. – The on-call scientist notified the Principal Investigator about the incident and the response up to this point.

11. 7:56 a.m. – The UW ID Fellow on-call, called the ARO. She explained the situation to him and he consulted with his attending physician.

12. 8:12 a.m. – The ARO phoned to the on-call scientist to give a situational update

13. 8:23 a.m. – The PI replied to the on-call scientist to indicate the receipt of the information about the spill incident, and asked to be kept updated.

14. 8:28 a.m. – The UW ID Fellow called the ARO back and described that they would not treat the individual due to the appropriate disinfection performed by researcher and the risk of exposure through intact skin being very low. The ARO insisted however that the researcher be given a Tamiflu prescription as a precaution as well as for peace of mind. The UW ID Fellow agreed and called the researcher.

15. 8:31 a.m. – The ARO called the researcher and released the researcher from the building. The ARO double checked the well-being of the researcher.

16. 8:34 a.m. –The ARO phoned the on-call scientist to relay the ID Consult team decided to release the researcher without quarantine, and that there would be no need for a Tamiflu prescription. However, as noted above, the researcher requested Tamiflu anyway, and the UW ID Fellow stated that he would phone the researcher with the prescription. The ID Consult Team also instructed that the researcher self-monitor for any change in body temperature (every 12 h, at minimum) or feelings of illness, and The ARO instructed the researcher that such observations must be communicated to the ARO immediately upon observation.

17. The researcher took the first dose of Tamiflu in the afternoon, [REDACTED]

Has the IBC reviewed this incident?	X No If yes, provide minutes
Has the root cause for this incident been identified?	X Yes If yes, please describe: Employee dropped plates while placing in incubator.

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)

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This incident will be used as a training session for the laboratory. The group will discuss what can be done to prevent a spill of this nature from occurring again. Mostly likely it will be as simple as changing the way the plates are carried to the incubator.

Spill clean-up:

1. The researcher immediately closed the incubator doors and returned the plates that were not dropped to the BSC. These plates were later transferred back to the tissue culture incubator, following the spill clean-up procedure.
2. The researcher picked up the dropped plate bottom from the floor and immersed it in a container of 5% MicroChem Plus inside the BSC.
3. The researcher then saturated his outer gloves with 70% ethanol, disposed of them in the biohazard trash, and put on a new pair of outer gloves.
4. Following [REDACTED] SOP #33, the researcher covered the area of the spill (~3-inches in

diameter) with paper towels, and then flooded the contaminated area and paper towels with freshly made 5% MicroChem Plus.

5. At this time, the researcher observed a few drops of liquid (i.e., media) on the Tyvek suit below the knee, so 70% ethanol to saturate both arms (in entirety) and both legs (from the knee down) of the Tyvek suit, shoe covers, the bottoms of shoes, and 2-3 inches of exposed skin between the bottom of the Tyvek suit and the shoes (i.e., ankles).

6. After waiting 20 minutes, the researcher

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8. The researcher saturated the outside surfaces of the tissue culture incubators with 70% ethanol, and cleaned up the BSC according to standard procedures.

9. The researcher contacted the on-call scientist via the emergency iPhone to obtain further instructions, and then exited the ABSL-3+ suite following the standard exit procedure. Additional details about the incident response and communication are described in Section IV below.

10. Following the researcher's exit from the ABSL-3+ suite, a second researcher entered the suite and autoclaved out the disposable trash from the gown room, as well as all trash inside the suite.

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[REDACTED]

NIH OBA Oct08