

INCIDENT NOTIFICATION AND REPORTING
MDH FORM 3
(THEFT/LOSS/RELEASE)

This form is available at <https://health.maryland.gov/laboratories/Pages/Office-Of-Laboratory-Emergency-Preparedness-and-Response.aspx>. Answer all items completely and submit it to the Biological Agents Registry (BAR) Program at the Maryland Department of Health (MDH), Laboratories Administration (Labs Admin), Office of Laboratory Emergency Preparedness and Response (OLEPR) within 10 days after the incident has occurred.

Maryland Department of Health, Laboratories Administration
Office of Laboratory Emergency Preparedness and Response
Biological Agents Registry Program
1770 Ashland Avenue, Room 134
Baltimore, MD 21205

Fax: 443-681-4509
E-Mail: dllepr_dhmf@maryland.gov

SECTION A – ENTITY INFORMATION					
1. Name of Entity:			2. Entity Registration/ NRE Number (if applicable):		
3. Physical Address (NOT a post office box):		4. City:		5. State:	6. Zip Code:
7. Name of Responsible Official or Laboratory Supervisor:			8. Name of Principal Investigator:		
9. Telephone Number:	10. Fax Number:	11. Email address:			
SECTION B – INCIDENT INFORMATION					
1. Date and Time of Incident:	2. Date of Immediate Notification:	3. Type of Immediate Notification : <input type="checkbox"/> Email <input type="checkbox"/> Fax <input type="checkbox"/> Telephone		4. Location of Incident (bldg., room, equipment, etc.):	
5. Name of Select Agent or Toxin:			6. Strain designation of Select Agent or Toxin:		7. Quantity (Unit (vial, plates, etc.))
8. Type of Incident: <input type="checkbox"/> Theft (After completing Section B. Go to Section C) ♦ <input type="checkbox"/> Loss (After completing Section B. Go to Section D) ♦ <input type="checkbox"/> Release/ Potential Exposure (After completing Section B. Go to Section E) ♦ Note: Please complete Appendix A, event timeline, to provide details on the theft/loss/release incident.			9. Severity of the incident: <input type="checkbox"/> None <input type="checkbox"/> Negligible <input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High		10. What Biosafety Level did the incident occur? <div style="display: flex; flex-wrap: wrap;"> <div style="width: 50%;"> <input type="checkbox"/> BSL2 <input type="checkbox"/> BSL3 <input type="checkbox"/> BSL4 <input type="checkbox"/> ACL 2 <input type="checkbox"/> ACL 3 <input type="checkbox"/> ACL 4 <input type="checkbox"/> NIHBL2N <input type="checkbox"/> NIHBL3N <input type="checkbox"/> NIHBL2-LS <input type="checkbox"/> NIHBL3-LS </div> <div style="width: 50%;"> <input type="checkbox"/> ABSL2 <input type="checkbox"/> ABSL3 <input type="checkbox"/> ABSL4 <input type="checkbox"/> BSL3 Ag <input type="checkbox"/> NIHBL2 <input type="checkbox"/> NIHBL3 <input type="checkbox"/> NIHBL4 <input type="checkbox"/> NIHBL4N <input type="checkbox"/> NIHBL4-LS <input type="checkbox"/> PPQ Agent </div> </div>

Note: Submit completed form only once by either e-mail, fax, or postal mail.

11. Is this incident associated with an APHIS/CDC Form 2 (Transfer): <input type="checkbox"/> Yes (Fill out Appendix B, if incident occurred during transfer.) <input type="checkbox"/> No APHIS/CDC Form 2 transfer #: _____		12. Is this incident associated with an APHIS/CDC Form 4 (Identification): <input type="checkbox"/> Yes <input type="checkbox"/> No APHIS/CDC Form 4 clinical ID#: _____	
SECTION C – REPORT OF THEFT			
1. Type of Theft: <input type="checkbox"/> Forced Entry <input type="checkbox"/> Insider/Insider-assisted access <input type="checkbox"/> Unauthorized access		2. Has Local Law Enforcement been Notified: (If yes, complete sections C3-C5) <input type="checkbox"/> Yes <input type="checkbox"/> No	
3. Local Law Enforcement Agency:		4. Local Law Enforcement Agent Name:	
5. Local Law Enforcement Contact Information (phone/email):		6. Has the FBI been Notified: (If yes, fill out #s C7-8): <input type="checkbox"/> Yes <input type="checkbox"/> No	
7. FBI Agent Name: (First M. Last)		8. FBI Agent Contact Information (phone/email):	
9. Was the stolen BSAT material recovered: <input type="checkbox"/> Yes <input type="checkbox"/> No		10. Was there a potential exposure: (If yes, go to section E- Q: 5-11) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure	

Certification: I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of the select agent regulations may result in civil or criminal penalties, including imprisonment. 7 CFR 331, 9 CFR 121, 42 CFR 73.

Signature of Respondent: _____

Title: _____

Typed or printed name of Respondent: _____

Date: _____

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SECTION D- REPORT OF LOSS

1. Type of Loss: <input type="checkbox"/> Inventory/Recordkeeping error <input type="checkbox"/> Sample lost/discarded at entity <input type="checkbox"/> Sample lost in transit (Go to Appendix B to enter add'l info) <input type="checkbox"/> Other: _____		2. Has Local Law Enforcement been Notified: (If yes, fill out #s D3-D5) <input type="checkbox"/> Yes <input type="checkbox"/> No		3. Local Law Enforcement Agency: 	
4. Local Law Enforcement Agent Name: 		5. Local Law Enforcement Contact Information (phone/email): 			
6. Was the FBI Notified: (If yes, fill out #s D7-D8) <input type="checkbox"/> Yes <input type="checkbox"/> No	7. FBI Agent Name: 		8. FBI Agent Contact Information (phone/email): 		
9. Was the lost BSAT material found? <input type="checkbox"/> Yes <input type="checkbox"/> No	10. How long was the BSAT material missing? Date recovered: Duration of loss (hrs/days):	11. Give the date of the last inventory/audit performed, which meets the FSAP regulatory requirement: 		12. Was there a potential exposure: (If yes, complete Section E- Q: 5-11) <input type="checkbox"/> Yes <input type="checkbox"/> No	

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Signature of Respondent: _____

Title: _____

Typed or printed name of Respondent: _____

Date: _____

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SECTION E- REPORT OF RELEASE

1. Type of Potential Exposure/Release (choose all that apply):

- | | |
|--|---|
| <input type="checkbox"/> Animal bite/scratch | <input type="checkbox"/> Equipment/mechanical failure |
| <input type="checkbox"/> PPE failure | <input type="checkbox"/> Package damaged in transit (fill out Appendix B) |
| <input type="checkbox"/> Spill | <input type="checkbox"/> Unintended Animal Infection |
| <input type="checkbox"/> Needle stick/Sharps | <input type="checkbox"/> Unintended Plant Pathogen Release |
| <input type="checkbox"/> Decontamination failure | <input type="checkbox"/> Work performed on an open bench |
| <input type="checkbox"/> Inactivation failure | <input type="checkbox"/> Other _____ |

2. Was there a release outside containment barriers?

(choose all that apply)

- ☐ Release outside primary containment (e.g., biosafety cabinet, leaking storage vial within storage unit)
- ☐ Release beyond secondary containment (e.g., laboratory)
- ☐ Release outside all containment barriers of the facility (e.g., resulting in possible agricultural/environmental/public health threat)

3. What PPE was worn at the time of the incident (choose all that apply)?

- | | |
|---|---|
| <input type="checkbox"/> Hand Protection (gloves) | <input type="checkbox"/> Foot Protection (e.g., booties, shoe covers) |
| <input type="checkbox"/> Head Protectors/Covers | <input type="checkbox"/> Eye/Face Protection (e.g., goggles, face shield) |
| <input type="checkbox"/> Body Protection | <input type="checkbox"/> Respiratory Protection: Type _____ |
| <input type="checkbox"/> Other: _____ | |

4. Did the release result in potential exposure(s)?

☐ Yes

If yes, how many individuals/animals/plants were exposed?

☐ No

5. Did the release result in a laboratory acquired infection or an infection/outbreak in agriculture or in the environment?

- ☐ Yes
- ☐ No
- ☐ Not currently known

6. Has medical surveillance been initiated?

- ☐ Yes
- ☐ No

7. Has prophylaxis or treatment been provided?

- ☐ Yes
- ☐ No

8. Has an internal investigation been initiated to lessen the likelihood of recurrences of incident involving the select agents and toxins at this entity?

- ☐ Yes (If yes, please provide additional details.)
- ☐ No

9. Other than a potential for occupational illness, what other hazards have been identified as a result of this incident?

10. Provide a brief summary of how the laboratory and work surfaces were decontaminated after the incident.

11. Provide a brief summary of the medical surveillance conducted (do not provide names or confidential information).

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Signature of Respondent: _____

Title: _____

Typed or printed name of Respondent: _____

Date: _____

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**APPENDIX A
EVENTS TIMELINE**

Provide a detailed summary of events, including a timeline of what occurred.

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IF THE INCIDENT OCCURRED DURING TRANSFER, COMPLETE SECTIONS A AND B OF FORM 3 AND PROVIDE THE FOLLOWING INFORMATION (INCLUDE A COPY OF THE RELEVANT APHS/CDC FORM 2)

1. Transfer authorization number from APHIS/CDC Form 2:		2. Date Shipped:
3. Name of Carrier:	4. Airway bill number, bill of lading number, tracking number:	
5. Package Description (size, shape, description of packaging including number and type of inner packages; attach additional sheets as necessary):		
6. Package with select agents and toxins received by requestor: <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, date of receipt: _____		7. Package with select agents and toxins appears to have been opened or damaged during shipment: <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, include explanation in box 5 above.
8. Sender was contacted regarding incident: <input type="checkbox"/> No <input type="checkbox"/> Yes	9. Carrier/courier was contacted regarding incident: <input type="checkbox"/> No <input type="checkbox"/> Yes	

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Title: _____

Date: _____

Created: 11/1/18