

# Incident Report for Hole Discovered in a Positive Pressure Encapsulating Suit on 10MAR2025

Date: 04APR2025

Authors: (b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and

(b)(3):42 U.S.C. § 262(a)(h); (b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act)

## Summary

A BSL4 user identified a large hole (Attachment A) in the face shield of her positive pressure encapsulating suit when conducting a routine suit integrity test on 10MAR2025. Multiple properties of the hole – including its size, location, and appearance – were suggestive of an intentional act to compromise the integrity of the suit. An investigation was conducted by the contract Operations Director, IRF-Frederick federal leadership, and the Division of Safety (DS). Investigators concluded that the hole was produced intentionally, but it was not possible to determine the cause of the hole or who created it. Through interviews with staff members, several safety and personnel issues, not directly related to the occurrence of the suit hole, were identified by the investigative team.

Corrective actions are recommended.

## Investigative Process and Findings

(b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act)

used her positive pressure encapsulating suit (serial number (b)(6) on (b)(6) MAR2025. She reported that she changed her gloves on (b)(6) MAR2025, and the suit was in excellent condition when she departed the containment laboratory on that day. She hung the suit in the N. suit room (b)(6); (b)(6) and badge-access records show she departed the women's N. outer change room at (b)(6) on (b)(6) MAR2025. She did not re-enter the N. suit room (or any other biocontainment suit room) until (b)(6) MAR2025 at (b)(6). At this time, there were multiple individuals preparing to enter the N. suit room according to N. outer change room badge reports and interview statements. (b)(6); (b)(3):42 U.S.C. was present when (b)(6); (b)(6) took her suit off the hanger to conduct the suit integrity test. When (b)(6); (b)(6) attempted to inflate the suit, she noted that the suit failed to inflate, and upon further inspection, noticed a sizable hole at the junction between the face shield and the suit material immediately above the right shoulder. The hole measured approximately 15 cm long, by 5 cm wide. Parts of the perimeter of the hole appeared to be cleanly excised while other areas appeared to be forcefully separated, perhaps ripped apart once the initial opening had been made. A portion (approximately 5 cm by 2 cm) of the face shield within the perimeter of the hole was completely absent, presumably cut or torn away.

(b)(6); showed the hole to (b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness who were present in the suit room at that time. (b)(6); rehung her suit and selected (b)(6); (b)(3):42 U.S.C. suit to wear for the planned biocontainment activities that morning. (b)(6); reviewed (b)(3):42 suit log and noted that (b)(6); had recorded a glove change on the prior day (b)(6) MAR2025). She entered the BSL4, completed her planned activities, and departed the N. outer change room at (b)(6). She reported the hole to (b)(6); (b)(3):42 U.S.C. at approximately (b)(6) on (b)(6) MAR2025. (b)(6) independently conducted a private interview with (b)(3):42 (b)(6) MAR2025. (b)(3):4 reported the large hole in her suit and showed a picture, which she was also asked to provide via email. (b)(3):4 explained that she had left her suit in good repair on (b)(6) MAR2025. (b)(6)

(b)(6)

(b)(6); (b)(3):42 U.S.C. 262a(h)

(b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act)

asked (b)(6); to bring the suit out of the lab to her office. (b)(6); brought down the suit around (b)(6) on (b)(6) MAR2025 and emailed (b)(6); the list of items as well as the pictures of the suit hole.

11MAR2025. A meeting was held between DS and NIAID federal leadership to discuss the hole and information obtained from (b)(6); on (b)(6) MAR2025. The meeting was attended by (b)(6); (b)(3):42, (b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism (b)(6); (b)(6); approached (b)(6); (b)(3):42 on the morning of 11MAR2025 to request an investigation.

(b)(6) examined the suit in (b)(6); (b)(3):42 U.S.C. 262a(h) office on 11MAR2025. (b)(6) independently conducted informal interviews on 11MAR2025 with (b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and (b)(6) requested N. outer change room badge access entries/exits for (b)(6) MAR- (b)(6) MAR2025. (Access to the male or female N. outer change rooms is controlled (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act) (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act) Those records show 68 entries (b)(6); (b)(3):42 from the buffer corridor to N. outer change rooms (male or female) and 60 departures (b)(6); (b)(3):42 between the time that (b)(6), departed the outer change room on (b)(6) MAR2025 and the time she entered the N. outer change room before finding the hole in her suit on (b)(6) MAR2025.

On 12MAR2025, (b)(6), met with (b)(6); (b)(3):42 U.S.C. to discuss an initial plan for a formal investigation. The proposed plan was to begin the investigation in an unbiased manner, by interviewing all staff who entered the N. suit room beginning at the first entry on (b)(6) MAR2025 to the time that (b)(6), discovered the hole in her suit. It was agreed that interviews would be conducted by (b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health (or other DS designee), and (b)(6); (b)(3):42 A list of standardized questions was reviewed and agreed upon for these initial interviews (Attachment B). The following individuals were interviewed in person during this phase of the investigation: (b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health (b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act) (b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act)

(b)(6), These interviews were conducted 12MAR-17MAR2025. A picture of the suit hole (with the name of the individual to whom the suit was assigned obscured) was provided to interviewees, who had not previously seen the hole. Attachment C provides a list of individuals interviewed as part of the formal investigation, dates, and attendees.

Following these initial interviews, the investigative team conducted follow up interviews with the aim of learning more about items raised during initial interviews. These were conducted on an ad hoc basis focusing on questions/inquiries related to personnel safety or reliability. These interviews were conducted 17MAR-27MAR2025. Individuals interviewed during this phase of the investigation were (b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act) (b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and All interviewees attended interviews in person, except for the 24MAR2025 interview with (b)(6); (b)(3):42 U.S.C. which she attended remotely via Teams.

(b)(6), provided an email to IRF staff on 14MAR2025 indicating that IRF-Frederick leadership, DOHS, and contract leadership were made aware of an incident involving a positive-pressure suit, that an investigation is being conducted, and, as a reminder, that staff perform the daily suit inspection checks of their positive-pressure suit prior to entering the BSL-4 lab. A copy of SOP SF-6 "Suit Integrity Testing and Donning Inspection" was attached.

(b)(6), inspected the N. suit room and inner and outer change rooms on (b)(6) Mar2025.

(b)(6); (b)(3):42 and (b)(6); (b)(3):42 U.S.C. examined the N. suit room on 14MAR2025.

Various dates: Photos of suit logs for (b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness were obtained by (b)(6) to corroborate statements, primarily statements regarding dates of glove changes, given by individuals during interviews.

## Findings

1. It is not possible based on available information to determine the individual(s) involved in creating the suit hole. The hole could have been created at any of a number of times between (b)(6) MAR2025, when (b)(6), reported hanging her suit after completing BSL4 activities, until shortly before she discovered the damaged suit on (b)(6) MAR2024. The (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act) No one interviewed had witnessed creation of the hole, admitted to being involved, or had any direct knowledge of how the hole was made. An examination of the N. suit room by the investigators did not reveal any unusual physical objects that could reasonably be used to cut or tear a suit, and there was nothing in the physical structure (e.g. hinges, hangar racks, etc.) that could reasonably cause a hole of the sort that was discovered on (b)(6) MAR2023.
  - a. Based on the opinion of numerous subject matter experts – individuals with many years of experience in the use, routine inspection, and repair of the Honeywell PPE suits at IRF-Frederick – the investigative team concludes the hole was intentionally created.
  - b. Scissors, present in the N. suit room to aid in minor suit repairs, may have been used. Alternatively, an object may have been brought in from elsewhere in the building and then removed after the hole was created. The triangular piece of the face shield that was cut away completely was never located.
2. (b)(6); (b)(3):42 U.S.C. violated biosafety protocols by knowingly entering inaccurate information on a BSL4 Suit Integrity Test Log. Violations occurred 09MAR-19MAR2025. DS SOP SF-6, "BSL-4 Positive Pressure Suit Integrity Testing", requires a) outer suit gloves to be changed after seven calendar days, b) that an Integrity Test be completed immediately after a manipulation such as a glove change, and c) that a suit integrity test log entry should only be completed when an integrity test is completed. Investigators obtained a photo of the BSL4 Suit Integrity Test Log for (b)(6), 's PPE suit (serial number (b)(6)) on 19MAR2025 to corroborate statements by (b) that she reviewed the Suit Integrity Test Log before using this suit for BSL4 activities on (b)(6) MAR2025. (b)(6), claims that she examined the suit log and noted an entry for (b)(6) MAR2025 indicating that (b)(3):42 had changed gloves on that day. In the photo taken on (b)(6) MAR2025, (b)(6), suit log showed no entry for (b)(6) MAR2025. A glove change was documented for (b)(6) MAR2025; however, the date had apparently been created by writing over a previous entry dated (b)(6) MAR2025. The write over was initialed (b)(6), and there was no explanation provided on the suit log form for the altered date. (b)(6), was interviewed about the suit log entries on 24MAR2025, and an account of the information she provided during the interview is as follows:
  - a. (b)(6), created a suit-log entry on (b)(6) MAR2025 indicating among other items that she had changed her suit gloves. (b)(6), stated that she had made the entry but then changed her mind and decided not to change her suit gloves on this day. She did not offer an explanation for not crossing out the (b)(6) MAR2025 entry.

b. (b)(6) entered the BSL4 lab on (b)(6) MAR2025 and claims that she changed her gloves before entering on this day. (b)(6); (b)(3):42 U.S.C. 262a(h) was present in the N. suit room with (b)(6); (b)(3):42 U.S.C. 262a(h) on this day and recalled when interviewed that he thought that (b)(6); (b)(3):42 U.S.C. 262a(h) had changed gloves. There was no entry dated (b)(6) MAR2025 on (b)(6); (b)(3):42 U.S.C. 262a(h) suit log.

c. (b)(6) entered the BSL4 lab on (b)(6) MAR2025 and claims that she changed her gloves before entering on this day. She claims that all the information she had entered for (b)(6) MAR2025 was accurate for the actions taken on (b)(6) MAR2025, so she decided to write over the date and initial the write over.

3. (b)(6); (b)(3):42 U.S.C. violated biosafety protocols by failing to follow procedures for reporting and repairing a hole in her suit. DS SOP SF-09, "BSL-4 Suit Inspection and Patching", indicates that "small holes...can be temporarily patched with duct tape until permanent repairs can be made or coordinated with the High Containment Master Technician." (b)(6); (b)(3):42 U.S.C. reported when interviewed on 24MAR2025 that liquid had infiltrated her suit on multiple occasions when deconning her suit in the chemical shower and that she had not reported these leaks or coordinated repairs with the High Containment Master Technician or DS. She provided four entries on her BSL4 Suit Integrity Test Log for repairs occurring September 2024 to March 2025.

4. An incident was identified in which regulations for virus inactivation were not followed, specifically, inactivated tissue samples were transferred out of BSL4 containment before the PI had authorized the transfer. Obtaining a CDC PI signature is required before physically transferring samples from containment per "Guidance on the inactivation or removal of select agents and toxins for future use" (7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73; September 2018).

- This incident was investigated because (b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism) reported to DS that (b)(6); (b)(3):42 U.S.C. had instructed individuals in the Pathology/Histology team to remove tissue samples undergoing inactivation from BSL4 containment before the PIs signature was obtained. This event involved inactivated samples documented in items 3184 and 3185 of the DCR IRF Sample Inactivation and Removal System. Inactivation forms show that the samples were removed from containment by (b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism) on 19APR2025. N. suit room entry/exit logs show that both of the individuals had departed the N. suit room (presumably with the inactivated samples in hand) by 1:08 PM, but the CDC PI did not sign the inactivation forms until 1:54 PM (item 3184) and 1:55 PM (item 3185). (b)(6); (b)(3):42 U.S.C. 262a(h) were not questioned about this event. The tissues were confirmed to have been exposed to inactivating agent for the required 72 hour period.

## Findings Summary

It is not possible based on available information to definitively determine the individual(s) involved in creating the suit hole. Safety protocols pertaining to appropriate reporting of suit issues outlined in SF-09 were violated by (b)(6); (b)(3):42 U.S.C. when she failed to report a hole in her suit that was detected while exiting the chemical shower, on multiple occasions as suggested by (b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism) Her

(b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act)

suggestion that this violation was consistent over the entire group was not corroborated. Safety protocols pertaining to the documentation of glove changes was violated on more than one occasion. First by recording information that was not actually done, resulting in another individual utilizing that false information to determine whether the suit was safe to be utilized. Second, when the individual did not record that they did in fact make a change to the integrity of suit, by changing their gloves and presumably performing an integrity test. Issues with the suit, repairs, or other problems were not documented or followed up on for that date or others. And third, when an entry was changed 10 days after the original entry was made, without documentation of why the change was made or entry of any previous checks of the suit. Inactivation protocols were violated by

(b)(6); (b)(3):42 U.S.C. 262a(h) (Public [REDACTED] when they removed samples from the BSL4 prior to obtaining PI signature on the inactivation forms.

## Areas of Concern

(b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act)

(b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act); (b)(6)

- i. Event 1. On [REDACTED] (b)(6) JUL2021, individuals from CM reported the N. women's outer change room was untidy, with masks strewn about and thrown away, and "stuff on the floor." (b)(6); (b)(3):42 dosimeter and ring badge was missing from the inner change room. Badge access records show that (b)(6); (b)(6) was the last person to depart the women's outer change room on (b)(6) JUL2021, although another individual entered and departed, spending about 1.5 min in the change room after midnight on (b)(6) JUL2021. This incident was not reported to management outside of CM and no incident investigation was conducted. It is not possible based on available information to determine who had generated the mess.
- ii. Event 2. On [REDACTED] (b)(6) SEP2021 a CM staff member, (b)(6); (b)(6), reported that the N. inner change room had been left in disarray, similar to Event 1. (b)(6); (b)(3):42 reported that her phone and headset also were missing. (b)(6); (b)(6) had been present in the N. suit room in the afternoon but two other individuals had access to the N. inner change room afterward according to badge-access records. This incident was not reported to management outside of CM and no incident investigation was conducted. It is not

possible based on available information to determine who had generated the mess.

- iii. Event 3. On (b)(6)EB2023, a member of CM team, (b)(6); (b)(3):42 reported to the Operations Director that (b)(6); (b)(3):42 U.S.C. was acting confused and erratic in the morning. Later that day, personal items in the N. inner change had been overturned and a Pathologist's suit log was found crumpled up and discarded in the trash, after (b)(6); (b)(3):42 U.S.C. and others has accessed the area according the badge records. This incident was investigated by DS and the Operations Director, but it was not possible to definitively determine who was responsible for the disruptions.
- iv. Event 4. On (b)(6)SEP2023, staff first entering the N. suit room that morning reported that all suits had been rearranged within the room. The unexplained change in location caused considerable unease and several staff members were suspicious that suits may have been tampered with. According to badge-access records, (b)(6); (b)(3):42 U.S.C. was the last person to exit the N. suit room the prior day. She denied any involvement and reported that she noticed nothing out of the ordinary when she departed. No suits were found to be damaged, and there is no policy that prevents rearranging suits, so no formal investigation was conducted. This incident, in particular, caused considerable unease among users of the BSL4 laboratory and prompted a meeting with BSL-4 users in November 2023.
- v. Investigators did not believe that re-examining these events in detail would assist in determining who may have been responsible for creating the suit hole that was discovered on (b)(6)MAR2025.

(b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act)

iii.

iv.

(b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act)

## Areas of Concern Summary

Reporting of safety concerns or general concerns within the histology group has not been met with appropriate actions or reactions, which has led to a significant breakdown in the trust within the group of its leadership's ability to take safety concerns or other concerns seriously or to address issues within group without retaliation to the party bringing up the issue. It is imperative that this cultural change be addressed to prevent any further breakdown in safety culture within the group or the IRF as a whole.

(b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act)

## Corrective Actions

1. (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act)
2. Retrain all BSL4 staff on inactivation procedures, particularly on the need to obtain a PI signature prior to removal of inactivated samples from containment. Amend SOP SF-24 to clearly emphasize this requirement.
3. Confirmed violations of safety protocols described in SF-06 and SF-09 by (b)(3):42 U.S.C. § have led the investigative team to conclude that (b)(6); (b)(3):42 U.S.C. cannot be trusted to follow appropriate BSL4 safety protocols. We recommend (b)(6); be removed from duties at IRF-Frederick. Reliability is a cornerstone of the NIH Biosurety Program and ensures that work pertaining to high-risk infectious disease research is performed in the safest and most responsible manner possible by a trained, responsible, and reliable workforce personnel.
4. (b)(6); (b)(3):42 U.S.C. § 262(a)(h); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act)
5. Retrain all BSL4 staff on appropriate procedures for repairing and reporting holes in suits, to include instances in which moisture/liquid infiltrates into suits during chemical-shower decons.
6. DS will implement a process to regularly review suit logs for any indications of noncompliance with safety protocols.
7. Conduct a Biosurety Reassessment of the Pathology Team members.
8. Operations Director will work with (b)(6); (b)(3):42 U.S.C. HR to identify ways to effectively communicate safety/personnel concerns when staff feel uncomfortable reporting concerns

to their supervisor or when they feel their supervisor has not appropriately responded to their concerns.

9. Provide (b)(6); (b)(3):42 with additional training to assist in ensuring that staff concerns are received and not dismissed. This is particularly important for any concerns regarding safety or personnel reliability.
10. Provide a verbal report to BSL-4 users on the outcome of this investigation.

# Attachment A



(b)(6); (b)(3):42 U.S.C.  
262a(h) (Public Health  
Security and Bioterrorism  
Preparedness and Response  
Act)

# Attachment B

## Interview Questions for Staff Entering North Suit Room (b)(6) MAR2025

Date: \_\_\_\_\_ Time: \_\_\_\_\_ Interviewee: \_\_\_\_\_

Individuals present: \_\_\_\_\_

A BSL4 user found an unusual hole in their BSL4 suit on [REDACTED] (b)(6) We've reviewed the badge access records and are conducting interviews with everyone who entered on [REDACTED] (b)(6) to learn more about what might have happened. Anything you may have seen or noticed may be important to help us understand how that hole occurred and to prevent something similar from happening again.

1. Access-control records show you entered the change room and North Suit room on [REDACTED] (b)(6) [REDACTED] (b)(6) Do you recall the purpose of your BSL4 entry on [REDACTED] (b)(6)?
2. Do you know how this might have happened?
3. Did you see anything unusual in the change room or suit room when you entered on that day? Either in the physical space or in any personnel interactions?
4. Have you noticed anything in the change room that might accidentally snag or tear a suit during normal use?
5. Can you think of a reason why someone would want or need to create a hole on purpose?
6. Is there anything you would like to mention or discuss that we have not asked about?

We may have additional questions based on the information you have provided. Please feel free to reach out to any of us if you think of something that you feel is important.

# Attachment C

## Interview Schedule

Interviewee	Date	Attendees
(b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act)	(b)(6) ) (b)(3):42 U.S. C 262 (b)(6)	(b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act)
	MAR2025	
	12MAR2025	
	12MAR2025	
	12MAR2025	
	13MAR2025	
	14MAR2025	
	17MAR2025	

(b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act)	17MAR2025 18MAR2025 18MAR2025 19MAR2025 24MAR2025 25MAR2025 25MAR2025 26MAR2025 26MAR2025 27MAR2025	(b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism Preparedness and Response Act)
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\*(b)(6); (b)(3):42 U.S.C. 262a(h) (Public Health Security and Bioterrorism