

Incident Response Plan For Entity Name

7 CFR Part 331

9 CFR Part 121

2 CFR Part 73

Preface

Intent: The intent of this document is to provide a template for incident response practices and procedures that entities may use to assist them in developing and implementing the written incident response plan required by the select agent regulations. However, the ideas and suggestions provided in this document do not constitute or establish minimum acceptable standards that would automatically meet the requirements of 7 CFR § 331.14, 9 CFR § 121.14, or 42 CFR § 73.14.

Revisions: This is a living document subject to ongoing improvement. Feedback or suggestions for improvement from registered entities or the public are welcomed. Please submit comments directly to the Federal Select Agent Program at:

CDC: LRSAT@cdc.gov

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Introduction

This document was prepared to assist entities in the development of a site-specific incident response plan required by the select agent regulations (7 CFR § 331.14, 9 CFR § 121.14, or 42 CFR § 73.14). The purpose of this guide is to provide assistance in structuring an incident response plan and assist in identifying the information that should be included in an incident response plan. The user is not limited as to what information to provide.

As an additional reference, the entity should review the [Incident Response Guidance Document](#).

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Site-Specific Risk Assessment (Section 14 (a))

The site-specific **risk assessment** can be part of the Incident Response Plan or under a separate cover. Entities are encouraged to use the [Risk Assessment Tool](#). The Site-Specific Risk Assessment should:

- Describe who was involved in the risk assessment process. (e.g. a Principal Investigator, a member of the incident response staff, the Responsible Official, an alternate responsible official, local first responders, or a representative of the Federal Bureau of Investigation’s Weapons of Mass Destruction Directorate (FBI WMDD)).
- Describe the natural and man-made threats you determined to be a threat to your entity and how you made that determination.
- Describe how the threat could affect the security and state of the select agents or toxins (e.g., power outage could defrost freezers).
- Describe the consequence of the incident causing release of an agent or toxin (e.g., mortality, morbidity, or other measures).

Procedures for Different Types of Incidences (Section 14 (b))

When writing procedures, the entity should plan for how the select agents and toxins will be secured during the event of an incident. The incidents selected for inclusion in the plan should be based off of the site-specific risk assessment for the entity. In addition, the entity should provide enough detail for their personnel to successfully mitigate the risk the incident poses. For example:

Tornado (Example)

- General Information: Tornadoes occur everywhere and are frequent. They are unpredictable and can cause a great deal of damage.
- Readiness: The national weather service will issue watching and warnings in the event of severe weather. Be alert and monitor the weather.
- Response actions:
 - PI/RO and Lab staff should monitor weather.
 - When Tornado warning issues all select agent work stops and select agents are secured.
 - When tornado is sighted in area all entity staff will leave the laboratory, remove PPE and go to shelter in place area.
 - When ‘all clear’ is given entity staff can return to normal operations, noting any damage to the laboratory.

Procedures should be written to address how select agents and toxins are handled if the area where they are housed (used or stored) is severely damaged or inoperable for an extended period of time. For example, if a hurricane damages the integrity of the building where the laboratory is located. The plan should address whether the select agents and toxins should be destroyed or transferred to another laboratory on site or another registered entity. Please

note, that if assistance is needed in locating another registered entity, the Responsible Official should contact the Federal Select Agent Program.

Describe procedures for how the entity will respond to each of the different types of incidents listed below (to include but not limited to):

- Theft, Loss, Release of a select agent or toxin
- Inventory discrepancies
- Security breach (physical)
- Security breach (IT)
- Severe weather (hail, thunderstorms, lightning, heavy rains not causing major flooding, strong winds, etc.)
- Natural disasters (volcanoes, earthquakes, floods, tornadoes, hurricanes, blizzards, wildfire, land/mudslides, tsunamis)
- Workplace violence
- Bomb threats
- Suspicious packages
- Facility emergencies (fire, gas leak, explosion, power outage)
- Man-made events (demonstrations, civil disturbances, etc.)

[Procedures for Response to Animal/Plant Exposures \(Section 14 \(c\)\)](#)

Describe procedures for how the entity will mitigate hazards associated with select agents and toxins relating to plants and animals that are intentionally or accidentally exposed to a select agent or toxin. The procedures should also describe how the entity will handle animals and plants that have been accidentally exposed to a select agent.

Contact Information and Lines of Authority, Responsibilities, Coordination (Section 14 (d)(1-6))

Lines of Authority (1-4)

Communication is a key factor in any successful outcome of an emergency. Lines of communication should be well established within the entity as well as outside of the entity. The incident response plan should contain the following information that is clearly accessible to all personnel (for example):

- Name and contact information for:

Name (first, last)	Title	Phone number	Location
	Responsible Official		
	Alternate Responsible Official(s)		
	Biosafety Officer		
	Principal Investigator(s)		
	Facility Operations/Manager		
	Security Officer		
	Veterinarian (if applicable)		
	Building owner/manager (if applicable)		
	Tenant Offices (if applicable)		
	Police		
	Fire		
	Hazmat		
	FBI WMDD coordinator		

Responsibilities (5)

In the incident response plan, please describe the line of authority and communication chain in an emergency. The plan should clearly explain to an individual, who isn't in a leadership position, who they should contact in any emergency situation and their responsibilities in the event of an emergency. Addressing coordination with first responders outside of the entity is especially important to make sure that all responsibilities are covered and there is no overlap in duties. These roles and responsibilities should make sense for the type of emergency that is taking place. For example, in case of an inventory discrepancy, the Principal Investigator may be the first point of contact in the line of authority and communication chain, then the Responsible Official.

Coordination (6)

Describe procedures for how the entity personnel will coordinate their efforts with first responders to ensure that select agent and toxin incidences in registered space that are beyond the entity's control will be responded to in a timely manner. Memorandums of Understanding (MOUs) and other types of formal or informal agreements help solidify coordination efforts.

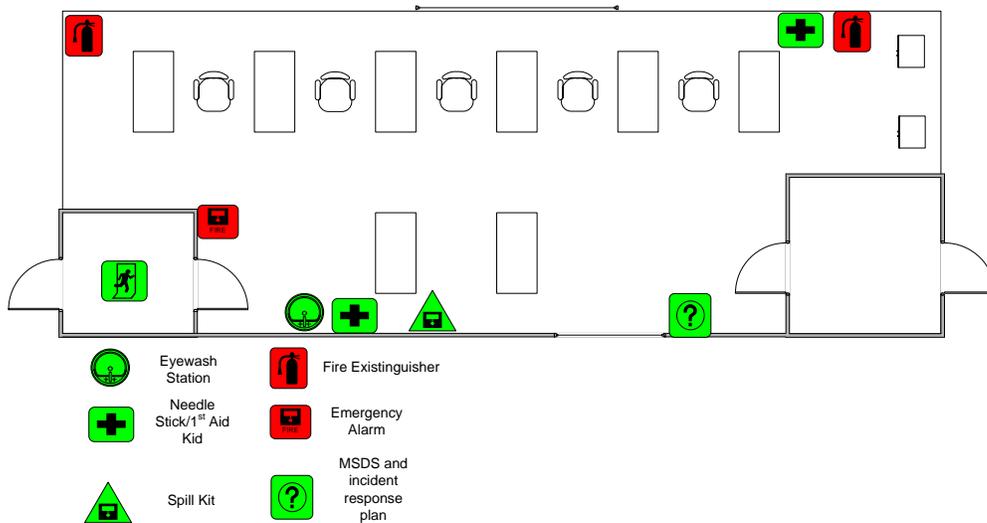
[Procedures for Emergencies including First Responders \(Section 14 \(d\)\(7-12\)\)](#)

Rescue or medical duties (7-8)

Describe procedures for how the entity's staff will handle minor emergencies of a medical nature (e.g., first aid, notification and/or evacuation procedures if further medical treatment is needed). Not every incident that occurs in the laboratory requires outside assistance. The entity's staff should be able to perform basic response actions to an incident (e.g., first aid).

Personal Protective and Emergency Equipment (9)

List and/or describe the personal protective equipment and the emergency equipment located throughout the laboratory or nearby areas for incident response. See example below:



Site Security and Control (10)

Describe the entity's procedures for assuring the select agents are secured during the incident and how they are accounted for after the incident has been concluded. Please note if this information is already addressed in standard operating procedure (SOP) you can reference the SOP in this section. For further clarification please see the Incident Response guidance document.

Evacuation (11)

Describe the entity's evacuation procedures for egress from the laboratories during an incident. The incident response plan should include exit routes, special needs assistance, safe distances from the building and shelter in place procedures. These procedures should correspond with other evacuation policies and procedures for the overall entity, if applicable.

Decontamination Procedures (12)

Describe the entity's decontamination procedures for all types of spills that can occur within the entity. The incident response plan should include procedures for gross decontamination of the area (e.g. room or building) and decontamination of staff. Please note, if this information is already addressed in SOP you can reference the SOP in this section.

Intrusion Detection/Alarm System Failure (Section 14 (e)(1)) (Tier 1 BSAT possessors)

Describe the response to a total failure of the intrusion detection/alarm system. The incident response plan should include what happens to the doors connected to the system, any back-up measures and any response from outside forces to support the failure (i.e., guard force, doors failed secure, etc.) Please note, if this information is already addressed in SOP, reference the SOP or already addressed in the security plan then there is no need to address it in this section.

Notification of "suspicious activity that may be criminal in nature" to local, state or federal law enforcement agencies (Section 14 (e)(2)) (Tier 1 BSAT possessors)

The incident response plan should describe how the entity will respond to and notify local, state and/or federal law enforcement agencies when a suspicious activity that may be criminal in nature has been suspected related to the select agents and toxins, the personnel and the entity. Please note, if this information is already addressed in SOP you can reference the SOP in this section.

Unauthorized and suspicious persons attempting to gain entry into registered areas without proper credentials is an example of suspicious activity that may be criminal in nature. It is important for the entity to clarify who should be involved and their roles in responding to such an incident. They should also train laboratory personnel on what to do when a suspicious activity that may be criminal in nature is detected and proper lines of communication. Please note, if this information is already addressed in the security plan then there is no need to address it in this section. For further guidance see the FSAP document on security.

Drills, Exercise and Annual Review (Section 14 (f))

The select agent regulations require that the incident response plan be reviewed on an annual basis. An incident response plan should be reviewed after any incident, as well as after drills and exercises, and revised as needed.