



INCIDENT RESPONSE PLAN GUIDANCE

7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73

August 2021



Centers for Disease
Control and Prevention
Division of Select
Agents and Toxins



Animal and Plant Health
Inspection Service (APHIS)
Division of Agricultural
Select Agents and Toxins

Changes/Highlights

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

CDC: LRSAT@cdc.gov

APHIS: DASAT@usda.gov

Revision History:

October 12, 2012: Initial posting

June 19, 2013: The revisions are primarily edits to correct editorial errors from previous version.

February 10, 2014: Added “Low probability/High consequence Events” to Appendix IV.

September 4, 2014: Added information about continuing laboratory operations after incident.

May 2017: The revisions are primarily changes to the organization to improve usability from previous version.

February 2018: Added the immediate responsibilities.

August 2021: Updated and clarified regulatory requirement language.

Introduction

The select agent regulations ([7 CFR §331.14](#), [9 CFR §121.14](#), and [42 CFR §73.14](#)), require an entity registered with the Federal Select Agent Program to have an incident response plan in place in the event of a natural and/or man-made disaster. The purpose of this guide is to assist the regulated community in developing a site-specific incident response plan to ensure the security and safeguarding of select agents and toxins from natural and man-made disasters.

Please feel free to use the new editable Incident Response Plan Template as the foundation for your entity’s incident response plan.

Incident Response Plan Requirements

Section 14 of the select agent regulations states that every registered entity must develop and implement a written incident response plan.

The incident response plan must fully describe the entity's response to the following events:

- Loss, theft, or release of a select agent or toxin
- Inventory discrepancies
- Security breaches (including information systems access controls to select agents and toxins)
- Severe weather and other natural disasters
- Workplace violence
- Bomb threats and suspicious packages
- Emergencies such as fire, gas leak, explosion, or power outage
- Other natural or man-made events that may threaten the entity

The incident response plan must account for the hazards associated with the select agents and toxins. The plan must outline containment procedures for all select agents and toxins including infected animals and plants.

Incident Response Plan Information

According to Section 14(d), the incident response plan should contain the following information, as applicable for the entity's organization:

- Contact information for the Responsible Official and Alternate Responsible Official(s) (RO and ARO(s))
- Contact information for building owner, where applicable
- Contact information for facilities manager, where applicable
- Tenant office contact information, where applicable
- Contact information for entity's physical security official, where applicable
- Personnel roles and lines of authority/communication
- Planning and coordination with local emergency responders
- Procedures to be followed by employees performing rescue or medical duties
- Emergency medical treatment and first aid
- A list of personal protective and emergency equipment and their locations
- Site security and control
- Procedures for emergency evacuation
 - Evacuation type
 - Exit route assignments
 - Safe distances
 - Places of refuge
- Decontamination procedures

You may also consider creating a quick view guide on the immediate responsibilities for a variety of incidents. See [Appendix I: Sample Incident Immediate Responses](#) for a list of immediate responsibilities to consider in the event of several incident types.

Tier 1 Incident Response Plan Requirements

Entities that possess or use Tier 1 select agents and toxins must comply with additional incident response planning requirements:

- Fully describe the response procedures for failure of intrusion detection (IDS) or alarm system
- Describe notification procedures for the appropriate federal, state, or local law enforcement agencies for suspected criminal activity related to the entity, its personnel, or select agents and toxins

Protecting People First

The primary mission of Federal Select Agent Program (FSAP) is to protect the health and safety of people, as well as animal and plant health. FSAP provides guidance on several topics meant to educate entities on best practices that can prevent an incident such as a theft, loss, or release from occurring. Some of these documents include:

- [Biosafety/Biocontainment Plan Guidance](#)
- [Security Plan Guidance](#)
- [Occupational Health Guidance](#)
- [Guidance on the Transfer of Select Agents and Toxins](#)

However, there is no guarantee that even the best laid plans will prevent every possible incident. Therefore, it is crucial that an entity create specific incident response plans that prioritize human health or public animal and plant health, as applicable.

Risk Containment

FSAP recommends identifying what happened to cause the incident, taking immediate action to contain the risk from further spread, and changing appropriate procedures/practices to make sure it does not happen again. Focus efforts on:

- Primary Containment
- Secondary Containment
- Facility Containment

Communications Strategies

FSAP recommends creating a communication strategy for all agencies that the entity may need to contact:

- Identify potentially impacted parties (internal and external)
- Communicate issues with public health authorities

- Examples of the public health authorities to contact:
 - Contact info for State Department of Health and/or State Veterinarian
- Responding to public questions and concerns

Effective Incident Response Planning

We believe an effective incident response plan prioritizes:

1. Protection of human life before property
2. Protection of animal and plant health
3. Consideration of the impact to the laboratory, the facility, and surrounding community
4. Collaboration between entity leadership, first responders, local public health officials, and agriculture authorities
5. Creating of an effective communication strategy for local public health officials and agriculture authorities
6. Entity training with first responders, public health officials, and agriculture authority participation, as appropriate
7. Addressing the primary effect of the hazard, the secondary effects, and the impact the hazard has on the facility workers
8. Focusing on areas inside the laboratory or registered space, where incidents involving select agent and toxins are likely to occur

There are other statutes (federal, state, and local government) that address emergency and incident response. The select agent incident response plan is not intended to preempt or supersede other response agreements or written plans provided that other plans and agreements address and do not conflict with the requirements of Section 14 of the select agent regulations. If an entity chooses to use other plans as a means of meeting these requirements, Section 18 of the select agent regulations requires that this information be made available to FSAP (e.g., FSAP inspectors when inspections are conducted, or as a requirement for registration).

Creating an Incident Response Plan

FSAP has developed a six-step cycle for creating an incident response plan. These steps are general guidelines for creating the series of standard operating procedures (SOPs) to follow Section 14 of the select agent regulations and provide a safe environment for the entity's employees and community.

Step 1: Form a Team.

The incident response planning team should include the following as applicable to the entity's organization and biosafety level (BSL):

- Incident Response Plan Team Lead – Designated individual responsible for coordinating meetings and managing the documentation and distribution of the plan
- Entity Subject Matter Experts (SMEs) – Responsible Official, Principal Investigator, Biosafety Officer,

Occupational health provider

- First Responders – Fire Department, including Emergency Medical and Hazmat, Police
- Organization – Facility Manager, Security, Leadership

Once the team is formed, it should remain engaged throughout the process of developing the incident response plan. Each team member brings both skills and a unique perspective to the situation. At each step, the entity is strongly encouraged to consult team members.

Step 2: Perform a Site-Specific Risk Assessment.

A site-specific risk assessment provides the foundation of an effective Incident Response Plan. The Incident Response Plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review.

Begin the discussion by describing the entity to the responders, with particular attention to the layout of registered spaces. Each group of SMEs in the incident response planning team provides a different perspective and key pieces of information for identifying risks and mitigation methods.

The Entity

1. Identify risks (probable hazards, high consequence events) that cannot be mitigated before a response is required. This should include those required by regulation, [regional natural disasters](#), and other site-specific hazards
2. Identify what protective measures/equipment is in place and where it is located
3. Discuss procedures which may take place during incidents, including man-down drills, evacuation procedures, and others

First Responders

1. Identify what capabilities can be managed by first responders (Fire, including Emergency Medical and HAZMAT, police)
2. Calculate response times to the entity by hazard type for multiple situations
3. Discuss contact and communication procedures beyond calling 911

Facility Management and Safety/Security Personnel

1. Be familiar with the physical capabilities of the building and available emergency equipment
2. Understand the existing organizational policies and procedures for managing incidents
3. Assign responsibility for escorting or granting access to first responders

Step 3: Analyze Facility Capabilities against Hazards

Conduct an analysis of various hazards that may result in the loss, release, or opportunity for the theft of a select agent or toxin. FSAP requires that the entity addresses certain specific hazards, which form the core of the incident response plan. The entity should also analyze their capabilities against any additional hazards identified during the risk analysis.

To conduct a facility analysis, create scenarios that demonstrate a series of incident driven actions and events and provide a factual and logical framework for developing an SOP. The scenarios can assist in

guiding discussion and help create an appropriate sequence response action. Some different methods of working through incident response scenarios include:

- **Action/Response** – Each action leads to a reaction and so on until the tasks are complete.
- **Functional** – Each organization talks through its internal SOPs and determines where they should overlap.
- **Walk-Through** – The team physically determines what resources are available, where equipment sits, and where the clean/dirty areas are. Focus on the inside of the laboratory. Building codes will generally ensure the facility can survive likely disasters but may not address loss of primary and secondary containment, animal husbandry issues, spilled, loss of power to a freezer, etc.
- **Second Order Effects** – The team discusses and determines incidents that may lead to other incidents. For example:
 - Earthquake may cause power outage or fire
 - Hurricane may prevent facility access
 - Fire suppression system may flood a containment system

As the team conducts the facility analysis, consider the following questions:

- Who must do what, when, and where?
- What must team members know for each incident type?
- Who conveys incident response information to team members?
- What crucial information must be conveyed about the lab and facility?
- What equipment is needed during a given incident/incident response?
- Who is in charge at each step of the incident response? What decisions must be made?

The answers to these questions will allow the Incident Response planning team to identify the key information that forms the basis of the incident response plan:

- **Condition Expectations and Assumptions** – Assumptions that must be made as a part of incident response planning but may disrupt the plan if they are not met (i.e., clear roads, first responder presence)
- **Logistical Constraints** – Limitations of response team members (i.e., equipment access, mobility limitations)
- **Capability Gaps** – Required capabilities that team members do not have (i.e., missing Personal Protective Equipment, training, etc.)

Step 4: Develop Plans by Incident Category

Create a series of standard operating procedures (SOPs) based on each scenario. An SOP should be a list of simple instructions that anyone can quickly read and follow. Focus on creating plans with common steps that can be applied to various incidents to improve comprehension and reduce training.

Entities are encouraged to develop playbooks. A playbook is a series of simple plans/SOPs that cover the multiple incidents identified in the analysis stage. Instead of focusing on nuances of each event, focus on

common steps and then apply them to various incidents. This not only makes incident response easier for individuals to understand, but it also makes it much easier to train.

Notice Based

- No Notice
- Minimal Notice
- With Notice
- After the Fact

Risk Based

- High (Potential for serious threat/damage)
- Medium
- Low

Incident Based

- Case-by-case
- Natural Disasters
- Facility Emergencies
- Severe Weather

Each SOP should aim to address the following concepts/questions:

1. What incidents does the plan cover?
2. Concept: What are you trying to do? When are you done?
3. Entity and organizational responsibilities/tasks: What will the entity do? Who does it/when? What is the entity responsible for?
4. First responder actions/tasks: What will they/won't they do?
5. Risk containment strategies: How do you prevent further exposure? What is the potential impact on public health, animal and plant health or animal and plant products? How to minimize the impact an incident has on to these concerns?
6. Entity lines of authority: Who has the authority to call this kind of response? Who's next in charge? (include contact information for these individuals)
7. Decontamination procedures: Do you doff? If not, how do you separate contaminated personnel?
8. Emergency equipment: Where is it? How does it apply? Who uses it?
9. Procedures for emergency evacuation, including type of evacuation, exit route assignments, safe distances, and places of refuge: How do you get out? Where do you go once you leave the lab?
10. Personnel accountability: Who accounts for personnel? Who is notified once personnel are accounted for?
11. Procedures to be followed by employees performing rescue or medical duties and the location: Where do you conduct immediate care? Where do you conduct follow up?
12. Location: where will first responders pick up a patient? What amount of decontamination must be done? (doffing, showering out—consult the first responders on their requirements for

transport)

13. Contacts and communication plan: Who calls 911? Who notifies the RO or management? Is anyone else notified?
14. Site security and control: How do you manage access to the facility during and after the incident? Where's the perimeter, etc.?
15. Return procedures: Under what conditions and how do you return to the lab and check containment, etc.?
16. Select agent and toxin (and other high value items) accountability
17. Medical Surveillance (if required)
18. Who conveys incident response information to FSAP and public health and agriculture authorities (e.g., local or state Department of Health, state veterinarians)? How are these authorities contacted?

Create a Recovery Plan

Create a recovery phase for incidents that may cause damage to a laboratory. The recovery plan should include procedures for emergencies that would prevent entities from returning to normal operating conditions (i.e., laboratory is damaged and nonoperational). This section of the plan should answer the following questions:

- What happens when the laboratory cannot return to normal operations after an incident?
- When will the laboratory be able to return to normal operations?
- Will work with select agents and toxins continue in another registered space?
- Will select agents and toxins be stored in another registered space until the damaged area is operational?
- Will select agents be transferred to another registered entity until the damaged laboratory is operational?

Step 5: Review and Test the Incident Response Plan

To stay in compliance with Section 14 of the select agent regulations, review the plan, and conduct drills or exercises to test and evaluate the incident response plan at least once annually. See the Drills and Exercise guidance document for FSAP recommendations for successful drills and exercises.

Step 6: Refine and Update Plans

Refine and update plan(s) at least annually, after each exercise, or after a plan is executed. Work with the incident response planning team to review the document and make any necessary changes to address the following:

- Results of training (What went well? What can be improved?)
- Any changes to threats or hazards
- Any changes to expectations or assumptions from the original plan
- Any new equipment, its capabilities and locations including first responders (new PPE, new HAZMAT vehicle)
- Any changes to the entity (additional registered space)

- Any changes in key personnel or organizations, including first responders
- Changes to the agents which affect response (adding a Tier 1 agent)
- Specific threats against the entity or its personnel
- Any changes in communications
- Critical changes to regulatory requirements, including those which affect first responders

Regional Natural Disasters

Go to each of the following websites to determine if the organization is at reasonable risk for any of these incidents. Ensure that any reasonable risks are accounted for in a SOP in the Incident Response Plan.

- General: [U.S. Geological Survey Website](#)
- Flood: U.S. [Federal Emergency Management for Floods](#)
- Earthquake: [Earthquake Hazard Map](#)
- Hurricane: [National Hurricane Center](#)
- Tornado: [Tornado Alley Map](#)
- Tsunami: [Tsunami Hazard Map](#)
- Volcano: [Volcano Hazard Map](#)
- Wildfire: [Wildfire Hazard Map](#)

Low Probability/High Consequence Events

Entities are encouraged to plan for “low probability/high consequence” events. A low probability/high consequence event is any event which adversely: 1) affects the safety and security of a registered facility; 2) affects human health and safety; and 3) causes environmental degradation.

Consider not only these types of events but potential secondary incidents that may occur because of an incident such as:

- System Failures
- Radioactive Leaks
- Extreme Flooding
- Power Failures
- Access Loss
- Damaged Equipment

Regulatory Requirements

Section 14 (b) Requirements:

Examples of what the incident response plan should describe as part of the entity’s response is included in the chart below.

Incident	Definition of Incident	Examples	Likelihood of Advance Notice
Inventory discrepancies	Inventory discrepancies occur when there are errors or omissions in the written inventory record.	Mislabeled vials; incomplete records	No Notice
Security breaches/ Suspicious activity	A security breach occurs when there is a disruption in the established security network or a failure to follow the entity’s written security policies and procedures. Breaches involve all levels of security including physical security (hardened, fixed systems), operational security (personnel reliability) and information systems (electronic and hard copy material).	Computer hacking; unauthorized personnel in laboratory	No Notice
Severe weather and other natural disasters	Severe weather and natural disasters vary from one geographic location to another within the United States. Severe weather situations and natural disasters include tropical storms, hurricanes, tornadoes, windstorms, thunderstorms, lightning, hail, floods, earthquakes, fires and winter storms (not all inclusive). To assist in determining if the entity is in an affected area, refer to Tab IV “Evaluating Natural Hazard.”	Tornado; Flood	Minimal Notice for tornado, severe weather or storm, hurricane, floods No Notice for earthquakes
Workplace violence	Workplace violence is any act or threat of physical violence, harassment, intimidation, or other threatening disruptive behavior that occurs at the work site. It ranges from threats and verbal abuse to physical assaults and even homicide. It can affect and involve employees, clients, customers, and visitors.	Active shooter, Worker-on-worker abuse, Crime in conjunction with violence (robbery, theft, trespassing)	Minimal Notice
Bomb threats and suspicious packages	Bomb threats and suspicious packages have become common means to disrupt workplace activity. Most agencies at the academic, state, and federal levels have their own bomb threat and suspicious packages procedures.	Suspicious package or bomb threat	Minimal Notice
Fire	Fires can occur without notice and cause death, injury, property destruction and economic loss.	Unintentional or careless, intentional (arson), electrical malfunction, heating	No Notice

Gas leak	A gas leak is a non-expected release of natural gas that can create a potentially dangerous situation - either because the released gas is poisonous or because it can ignite and create an explosion.	Smell of gas; sound of gas being released from an open line.	Minimal Notice
Explosion	Explosion is the sudden loud release of energy and a rapidly expanding volume of gas that occurs when a bomb detonates, or gas explodes.	Bomb detonates or gas explodes	No Notice
Power outage	A power outage occurs when electrical power goes out unexpectedly. This may disrupt facility operations, ventilation and security features, communications, water, local utility, and transportation.	Can be caused by severe weather or natural disasters, overburdened electrical equipment, excavation or construction, downed utilities.	No Notice

Section 14 Requirements

In the event of an incident such as a theft, loss, or release, the foundation of effective incident response planning is protecting people first, as well as animal and plant health, risk containment, and effective communication. The requirements of Section 14 of the select agent regulations come together as the foundation for creating a strong risk containment and communication strategy in an emergency.

Emergency Contact Information – Collect and document site- specific contact information for each person identified as having an incident response role. Focus on support units that are available within the geographic region of the facility, especially if the entity is relying on local support of first responders. Entities associated with larger parent organizations (i.e., colleges, universities, federal or state campuses and research medical institutions) need to incorporate or integrate their site-specific incident response requirements with established entity-wide emergency response programs.

Personnel roles and lines of authority and communication – Assess the roles and responsibilities of each person identified as having an incident response role ahead of time. Ensure that all participants in the response understand the lines of authority and how information is communicated both up and down the chain of command.

Planning and coordination with local emergency responders – Meet with local emergency responders to discuss large scale disasters. Discuss with first responders the roles and responsibilities of each party in the event of a disaster that affects the select agent laboratory or storage area.

Procedures to be followed by employees performing rescue and medical duties – Rescue and medical duties should be limited to only those individuals that are qualified to perform these duties (e.g., paramedic, EMT, registered nurse, physician assistant, medical doctor, osteopathic physician). When qualified individuals are not available, 911 should be called. Train staff to perform emergency first aid and CPR if laboratory is located in a remote area that may cause delayed ambulance response time.

Emergency medical treatment and first aid – Establish provisions for emergency medical treatment and first aid for employees injured on the job. Since occupational injuries and illnesses are work related, workers' compensation rules may apply. Check with the Personnel Department (Human Resources) to determine if employees must report to a prearranged emergency treatment center or clinic. Inform workers of where to go or be transported for emergency medical treatment or first aid. In laboratories that are regulated by state or federal OSHA (Occupational Safety and Health Administration), comply with all applicable regulations (e.g., complete the appropriate OSHA injury and illness recordkeeping forms).

List of personal protective and emergency equipment, and their locations – Identify what personal protective equipment (PPE) and emergency equipment is needed in response to incidents involving select agents and toxins and state where it is located. Include a floor plan showing the PPE and emergency equipment locations in the incident response plan. Examples of PPE include, but are not limited to gloves, protective eyewear, face shields, respirators, foot protection, gowns, and scrubs. Examples of emergency equipment include, but are not limited to fire extinguishers, emergency showers, fire blankets, eye wash stations, and portable lighting.

Site security and control – Maintain site security and control to the best of your ability at all times. During incident response planning, inform first responders that access to restricted areas needs to be controlled during and after each incident. Some of the typical methods used to maintain site security control include a posted armed police officer or guard, FSAP-approved individual controlling access to restricted area, and relocating BSAT to an approved secured location.

Procedures for emergency evacuation – The incident response plan should define the different types of evacuations that may be encountered during an emergency. Post floor plans that show the primary and secondary emergency exit routes on each floor. Include these floor plans in the incident response plan. Determine safe distances for evacuation in the event of a worst-case scenario. When a warning is received regarding an impending disaster, the incident response plan should designate areas for safe refuge until the warning expires or the threat no longer exists. Describe procedures for securing select agents and toxins, if able when a warning is received.

Decontamination procedures – Describe decontamination procedures in the incident response plan. Include decontamination procedures for spills, affected individuals, including emergency responders, and laboratory rooms and areas that require decontamination.

Annual Training – Provide and document annual incident response training for personnel who have access to select agents or toxins. The documentation of incident response training must include name of trained personnel, date, name of training, and how it verified that personnel understood training goals and objectives. For entities with Tier 1 agents insider threat awareness training must be conducted annually with all personnel who have access to select agents or toxins.

Tier 1 Requirements – Entities with Tier 1 agents must provide the following additional information in the incident response plan:

- A plan for how the entity will respond to the failure of the IDS or alarm system
- Procedure for how the entity will notify the appropriate Federal, State, or local law enforcement agencies of suspicious activity that may be criminal in nature and related to the entity, its personnel, or select agents or toxins

Appendix I. Sample Incident Response Immediate Responses

Incident Type	Immediate Responsibilities
Theft or Loss of Select Agents and Toxins	<ol style="list-style-type: none"> 1. Notify local authorities. 2. Notify FSAP. 3. Notify the Federal Bureau of Investigations – Weapons of Mass Destruction Directorate.
Laboratory Acquired Infection (LAI) involving select agents and toxins	<ol style="list-style-type: none"> 1. Contain select agents and toxins. 2. Ensure appropriate medical care is provided to the affected individual(s) and begin medical surveillance. 3. Notify local public health officials 4. Notify FSAP
Bites/scratches from select agent infected animals or Contact with body fluids from select agent infected animals	<ol style="list-style-type: none"> 1. Ensure appropriate medical care is provided to the affected individual(s) and provide medical surveillance 2. Contain the select agents and toxins. 3. Notify FSAP.
Needle sticks/sharps injury involving select agents and toxins	<ol style="list-style-type: none"> 1. Ensure appropriate medical care is provided to the affected individual(s) and provide medical surveillance 2. Contain the select agents and toxins. 3. Notify FSAP.
Release of select agents and toxins outside of secondary containment	<ol style="list-style-type: none"> 1. Contain the select agents and toxins 2. Evacuate the area 3. Decontaminate the area appropriately 4. Perform occupational exposure assessments and ensure appropriate medical care is provided to affected individuals. 5. Notify FSAP.
Occupational exposure to select agents for individuals where medical surveillance has not been provided, including any immunocompromised or pregnant/ lactating women. (open bench work in clinical diagnostic laboratories)	<ol style="list-style-type: none"> 1. Ensure appropriate medical care is provided to the affected individual(s) and provide medical surveillance 2. Contain the select agents and toxins. 3. Notify FSAP.
Failure of validated select agent inactivation procedure – where the material was removed from appropriate registered containment level	<ol style="list-style-type: none"> 1. Move material into registered containment space 2. Assess for potential occupational exposures 3. Notify FSAP.

<p>Discovery: the finding of a select agent or toxin by an individual or entity that was not aware of its existence. Examples include, but are not limited to, the following:</p> <p>(1) A registered individual or entity finds a select agent or toxin not accounted for in its inventory; or (2) A non-registered individual or entity finds a select agent or toxin.</p>	<ol style="list-style-type: none">1. Move material into registered containment laboratory. If not registered, transfer or destroy select agents and toxins.2. Notify FSAP. Note: Non-registered entities should contact FSAP first before transferring material.
---	---