



Drills and Exercises Guidance

(7 CFR § 331.11, 9 CFR § 121.11, 42 CFR § 73.11
(Security))

(7 CFR § 331.12, 9 CFR § 121.12, 42 CFR § 73.12
(Biosafety))

(7 CFR § 331.14, 9 CFR § 121.14, 42 CFR § 73.14
(Incident response))

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Introduction

Registered entities are required to conduct drills or exercises at least annually to test and evaluate the effectiveness of their security, biosafety and incident response plans. This regulatory requirement is specified in the select agents and toxins regulations ([42 CFR Part 73](#), [9 CFR Part 121](#), and [7 CFR Part 331](#)) in sections 11 (Security), 12 (Biosafety), and 14 (Incident Response). The terms “drills” and “exercises” are used to denote an activity that can be used to test and evaluate the efficacy of an entity’s security plan, biosafety plan, and/or incident response plan. A drill and/or exercise provides an opportunity to detect flaws in an entity’s plan by identifying possible gaps and shortfalls in policies and/or procedures. The intent of this guidance is to assist the regulated community in developing and planning drills or exercises.

Conducting Drills/Exercises for Security, Biosafety, and Incident Response Plans

The select agents and toxins regulations for Security ([42 CFR § 73.11](#), [9 CFR § 121.11](#) and [7 CFR § 331.11](#)), Biosafety ([42 CFR § 73.12](#), [9 CFR § 121.12](#) and [7 CFR § 331.12](#)), and Incident Response ([42 CFR § 73.14](#), [9 CFR § 121.14](#) and [7 CFR § 331.14](#)) state that registered entities are required to conduct drills or exercises at least annually to test and evaluate the effectiveness of their security, biosafety and incident response plans and revise them as necessary. A drill and/or exercise provides an opportunity to detect flaws in entity's plans by revealing possible gaps and shortfalls in policies and/or procedures.

Drills and exercises are activities that test and evaluate the response to a particular event. Testing an entity's plan helps to clarify roles, evaluate policies and procedures, build relationships with partners and develop knowledge. Whether an event is natural or man-made, the goal of the security, biosafety, and incident response plans should be to provide the best possible preparation to safeguard select agents and toxins and to protect human, plant and animal health. For a low probability, high consequence event, mistakes or misunderstandings in executing a plan can result in undesirable and preventable outcomes. Therefore, proper preparation not only in written format but in practice is necessary to establish greater consistency in maintaining security and biosafety and responding to an incident.

Drills and exercises should be based on vulnerabilities that identify the types of risks or potential hazards that have a probability of occurring at an entity, an actual event that did not have the anticipated or required response or outcome, or critical operational gaps that have been previously identified. The following are a few questions that an entity should discuss after conducting a drill or exercise.

- Do our procedures and policies work?
- What worked well and what did not work well (success/failures)?
- Did we identify any critical operational gaps?
- Are responsibilities clearly defined?
- Is the response appropriate, efficient and sufficient?
- How clear are written policies and procedures for the intended audience?
- What are the consequences for issues not addressed?
- Have we documented our drill or exercise with names, dates and findings?
- Do we need to refine, revise, or update our plan(s)?
- If plan(s) have been revised significantly, have appropriate staff been retrained on the changes?
- When do we need to schedule our next drill or exercise for security, biosafety and/or incident response?

Drill and Exercise Best Practices

To meet the select agent regulation requirements for Security ([42 CFR § 73.11](#), [9 CFR § 121.11](#) and [7 CFR § 331.11](#)), Biosafety ([42 CFR § 73.12](#), [9 CFR § 121.12](#) and [7 CFR § 331.12](#)), and Incident Response ([42 CFR § 73.14](#), [9 CFR § 121.14](#) and [7 CFR § 331.14](#)), entities must perform drills and exercises to test their security, biosafety, and incident response plans. There are a number of ways to meet this requirement and ensure the effectiveness of these plans. Best practices for fulfilling the drill/exercise requirements according to regulation include:

- Create a consistent approach that fulfills the specific needs of the entity. Some methodologies include:
 - Develop a drill and exercise program internally.
 - Hire outside organizations to help in developing drills and exercises.
 - Coordinate activities with other entities and/or state groups (e.g., local responders)
 - Decide whether to conduct each drill and exercise separately or combine them.
- Conduct drills and exercises at least once a year that, individually or simultaneously, address the security plan, the biosafety plan, and the incident response plan. These drills and exercises can be tailored to fit the specific needs of the entity. Options include:
 - Discussion-based – workshops, tabletop exercises, etc.
 - Practical – functional exercises and full-scale drills.
- Conduct drills and exercises that cover several policies or procedures from the security, biosafety, and incident response plans.
- Avoid conducting the same exercise each year. Exercise multiple events to evaluate the effectiveness of the entity's overall plans.
- Develop a schedule that accommodates the BSAT program, facility, and the entity.
- Use actual incidents or negative experiences that have occurred to meet the drill or exercise requirement.

Examples of Entity Plan Drills/Exercises

Listed below are examples of the kind of drills or exercises that can be planned to test an entity's security, biosafety, and incident response plans. Consider the facility, the agents possessed, work activities and plans when determining the types of drills or exercises to conduct.

Security: A security drill or exercise should involve the entity's security personnel but may also include the local police and/or the Federal Bureau of Investigation Weapons of Mass Destruction Office.

- Consult with security personnel to simulate a break-in of the laboratory and note how soon security responds. For entities registered to possess, use or transfer tier 1 select agents and toxins, the required response time is 15 minutes.
- Simulate discovery of an unauthorized individual in containment.
- Simulate receipt of a suspicious package.
- Simulate an explosion in containment that results in access to the select agent storage area.

Biosafety: A biosafety drill or exercise should involve laboratory staff and biosafety personnel but may also involve engineering staff or individuals from outside the organization. These exercises can occur during or after business hours as needed.

- Simulate the collapse of a person in the laboratory and test how people respond, what communication is conducted, how the person is removed from the laboratory.
- Simulate a power failure that results in the loss of main and auxiliary power sources.
- Simulate a sudden release of large amounts of steam from the autoclave.
- Simulate failure of personal protective equipment (PPE) such as a tear in a glove, failure of a powered air purifying respirator (PAPR), or spill of agents or toxins on a Tyvek suit.
- Simulate release of infected animals. This can be with small animals or large animals depending on the type the entity works with.
- Simulate receipt of a package containing select agents or toxins that is found to be leaking.
- Simulate exposure of a worker to an agent to test the medical surveillance protocols.

Incident Response: An incident response drill or exercise may be structured to involve community emergency responders or state emergency preparedness personnel.

- Simulate any of the natural hazards appropriate for the area such as tornado, hurricane, flood, severe weather, etc.
- Simulate complete disruption of all normal communication systems.
- Simulate a large spill in a laboratory.
- Simulate a directed evacuation while laboratory personnel are working.
- Simulate a breach in the electronic information system for select agent information.

Documenting Entity Plan Drills/Exercises

There is no prescribed method for recording or documenting these activities, and the regulations do not specify precisely what should be included. However, the entity should develop a method that records:

- 1) An identification of which plan or plans have been drilled or exercised;
- 2) A brief description of the drill or exercise;
- 3) The date or dates of the activity;
- 4) The personnel from the registered entity who were involved (we also recommend providing the names of the agencies that participated);
- 5) A brief description of the outcome of the activity (i.e., procedures confirmed or problems identified); and Recommendations or suggestions to address any necessary change(s) to a plan, entity policy, and/or operating procedure (i.e., corrective action).

The following steps represent FSAP best practices. It is not a requirement to follow them, but doing so may help the entity best improve their plans based on the drills and exercises.

1. Implement any recommended changes in policy or operating procedure relevant to security, biosafety or incident response an updated plan, including the date the change was made.
2. Include a dated revision history for each plan, either placed within the plan itself or held separately, as a means for tracking changes. See the Drill/Exercise Documentation template for an example of what an entity may utilize to capture and track their drill or exercise activities.
3. Develop a consistent and organized program to ensure the entity meets the regulatory requirement for drills or exercises.

Drills/Exercise Documentation Template for Entity XYZ

Name of Drill or Exercise: _____

Brief Description: _____

Mock Type: Discussion Based (e.g., seminar, workshop, tabletop)
 Operational (e.g., functional drill or full-scale drill)
 Other _____

Date(s) of Drill or Exercise: _____

Section 11 (Security) Section 12 (Biosafety) Section 14 (Incident Response)

The Outcome: _____

Entity Participants in the Drill or Exercise:

Name	Title
_____	_____
_____	_____
_____	_____

Recommendations for Plan Revision: _____

Plan Revised Yes Not Necessary

Security Plan Date of Revision: _____
 Biosafety Plan Date of Revision: _____
 Incident Response Plan Date of Revision: _____