

Drills and Exercises Requirements

2021 Federal Select Agent Program Responsible
Official Webinar Series

June 16, 2021



Objectives

- **Inspection Observations**
- **Regulatory Requirements**
- **Drill or Exercise Examples**



Drill or Exercise Regulations

- **Section 11(h) Security**
- **Section 12(e) Biosafety**
- **Section 14(f) Incident Response**





Guidance: Drills and Exercises

**DRILLS AND EXERCISE
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)

AUGUST 2017

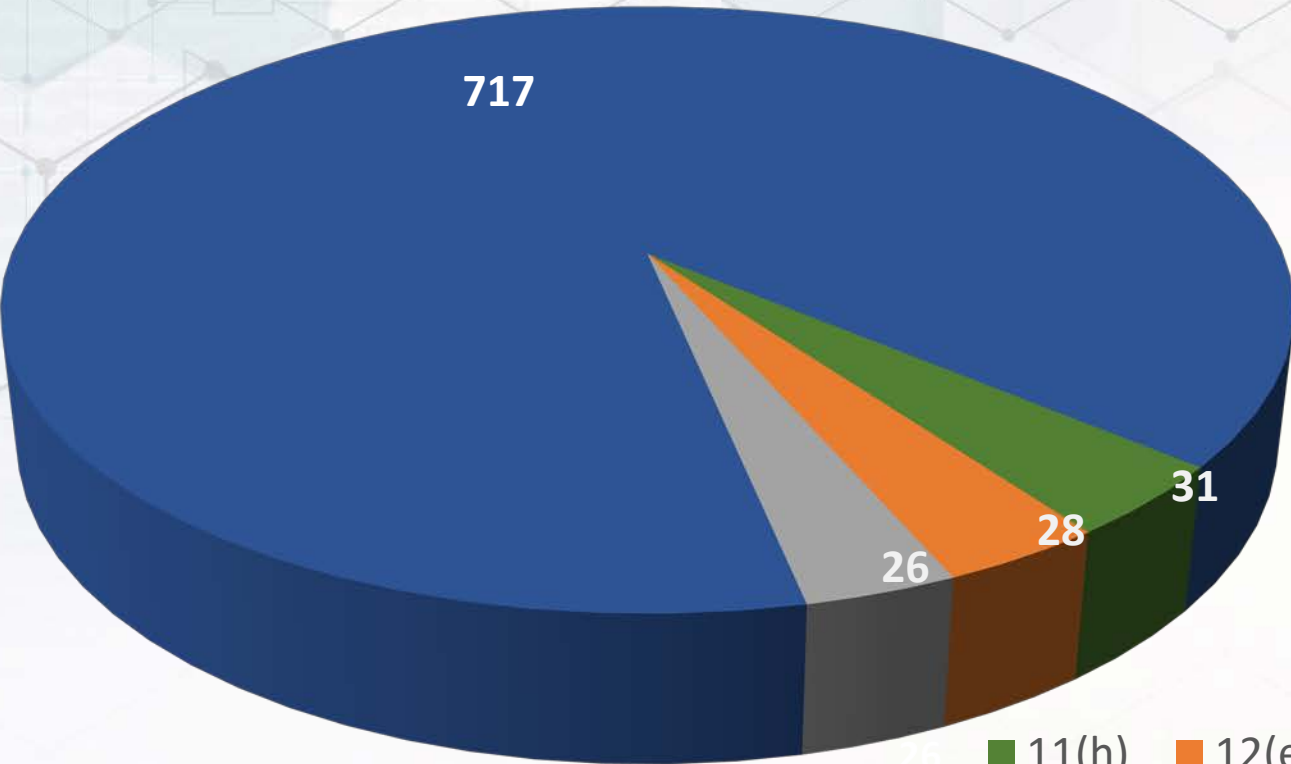
 Centers for Disease Control and Prevention
Division of Select Agents and Toxins

 USDA
Animal and Plant Health Inspection Service (APHIS)
Agricultural Select Agent Program



Inspection Observations: Drills and Exercises

OBSERVATIONS



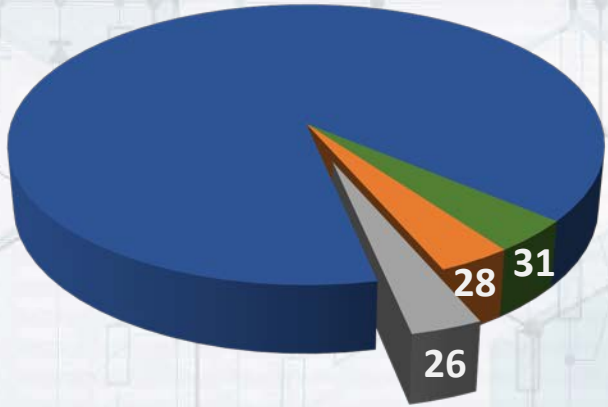
- 85 Drills & Exercises (11%)
- 717 Miscellaneous Plan Statement (89%)
- 802 Total Observations

Dates: July 2019-May 2020

■ 11(h) ■ 12(e) ■ 14(f) ■ Misc Plan Stmt



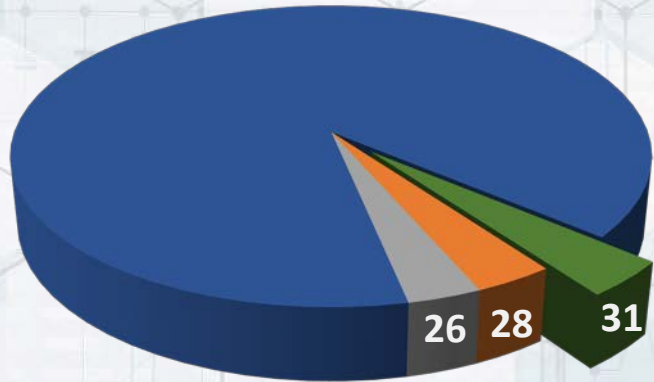
14(f) Incident Response



Top 3 Most Common Observations – Drills & Exercises

- **Failure to update the Incident Response Plan with corrective actions identified by the drill.**
- **Failure to document how the plan was evaluated, problems identified, or corrective actions taken.**
- **The names of registered entity personnel participants were not documented.**

11(h): Security

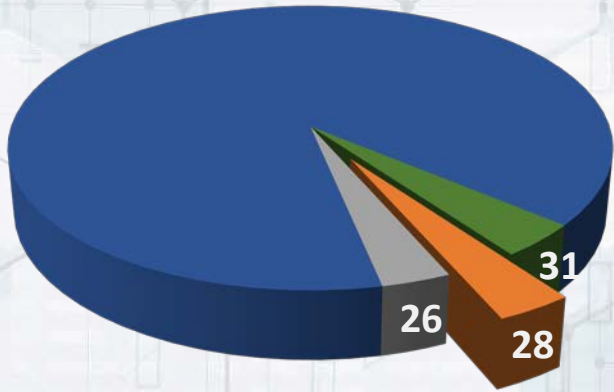


Top 3 Most Common Observations – Drills & Exercises

- **Failure to conduct a drill or exercise to assess the effectiveness of their Security Plan.**
- **Failure to document how the plan was evaluated, problems identified, corrective actions taken or the name of participants.**
- **The names of registered entity personnel participants were not documented.**



12(e) Biosafety



Top 3 Most Common Observations – Drills & Exercises

- **Failure to conduct a drill or exercise to assess the effectiveness of the Biosafety Plan.**
- **Failure to document how the plan was evaluated, problems identified, or corrective actions taken.**
- **The names of registered entity personnel participants were not documented.**

Drill and Exercise Requirements



Annual Drill or Exercise Requirements

Safety, Incident Response, and Security

- **Conduct drills or exercises annually**
- **Test and evaluate effectiveness of each plan**
- **Review/revise plans as needed**
 - **After each drill or exercise**
 - **After an actual incident**



Drill and Exercise Documentation



Annual Drill or Exercise Documentation Requirements

- **How the plan was tested and evaluated**
- **Problems identified**
- **Corrective actions taken**
- **Participant names**



Template: Drills and Exercises Documentation

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
_____	_____
_____	_____
_____	_____

Was Refresher Training Provided: Yes No

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: _____



Template: Drills and Exercises Documentation

Drills/Exercise Documentation Template for Entity XYZ

Name of Drill or Exercise: _____

Brief Description: _____

Mock Type: Discussion Based (e.g., seminar, workshop, tabletop)

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Date(s) of Drill or Exercise: _____



Template: Drills and Exercises Documentation

Section 11 (Security)

Section 12 (Biosafety)

Section 14 (Incident Response)

The Outcome: _____

Entity Participants in the Drill or Exercise:

Name

Title



Template: Drills and Exercises Documentation

Was Refresher Training Provided: Yes No

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: _____



Guidance: Drills or Exercises

- **Vulnerabilities**
- **Actual events**
- **Operational gaps**



Questions to Address: After Drills or Exercises

- **How adequate are written procedures for the intended audience?**
- **What worked well and what did not work well (success/failures)?**
- **Is the response appropriate, effective and efficient?**
- **If plan(s) have been revised significantly, have we tested these components?**



Is it a Training or Is it Really a Drill?

- **Training to prepare for a drill is not a drill.**
For example: Training on Spill Response (step-by-step walkthrough)



Drill and Exercise Examples



Security Drill or Exercise Scenario Examples

- **A door propped open resulting in security breach of the registered space.**
- **Discovery of an unauthorized individual in registered space.**
- **Use of hard key to override the Intrusion Detection System (IDS) to enter registered space.**



Biosafety Drill or Exercise Scenario Examples

- **Exposure of a worker to an agent or toxin scenario to test the medical surveillance protocols.**
- **Personal protective equipment (PPE) failure such as a glove tear or powered air purifying respirator (PAPR) failure.**
- **Large spill of agents or toxins outside of biological safety cabinet (BSC).**



Incident Response Scenario Examples

- **“Man down” in the registered laboratory to evaluate response procedures (combined drill—test all components).**
- **Breach in the electronic information system containing select agent inventory information.**
- **IDS drill—demonstrates 15-minute response time requirement for Tier 1 laboratories.**



Drills and Exercises: Caveats

- **Avoid repetitive scenarios for drills/exercises.**
- **If combining multiple components into one drill/exercise (e.g., “man down”), critique during development to ensure all desired components test and evaluate the plan(s).**



Scenarios: Training or Drill?

- **Entity provided an updated procedure for large-scale spill response to staff. Staff responded to a quiz which required listing the procedural steps. Quiz results were recorded.**
- **Entity tested a new large-scale spill procedure by presenting staff with a spill scenario. Entity asked staff to describe how they would handle it. Staff provided written responses to the scenario to describe their response. Entity conducted an after-action review to determine corrective actions and whether their plans required updates.**



Scenarios: Training or Drill?

- Entity provided an updated procedure for large-scale spill response to staff. Staff responded to a virtual quiz which required listing the procedural steps. Quiz results were recorded. (**Training**)
- Entity tested a new large-scale spill procedure by presenting staff with a spill scenario. Entity asked staff to describe how they would handle it. Staff provided written responses to the scenario to describe their response. Entity conducted an after-action review to determine corrective actions and whether their plans required updates. (**Drill or Exercise**)





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