

Analysis of Inspection Report Departures

Responsible Official Webinar
June 24, 2020



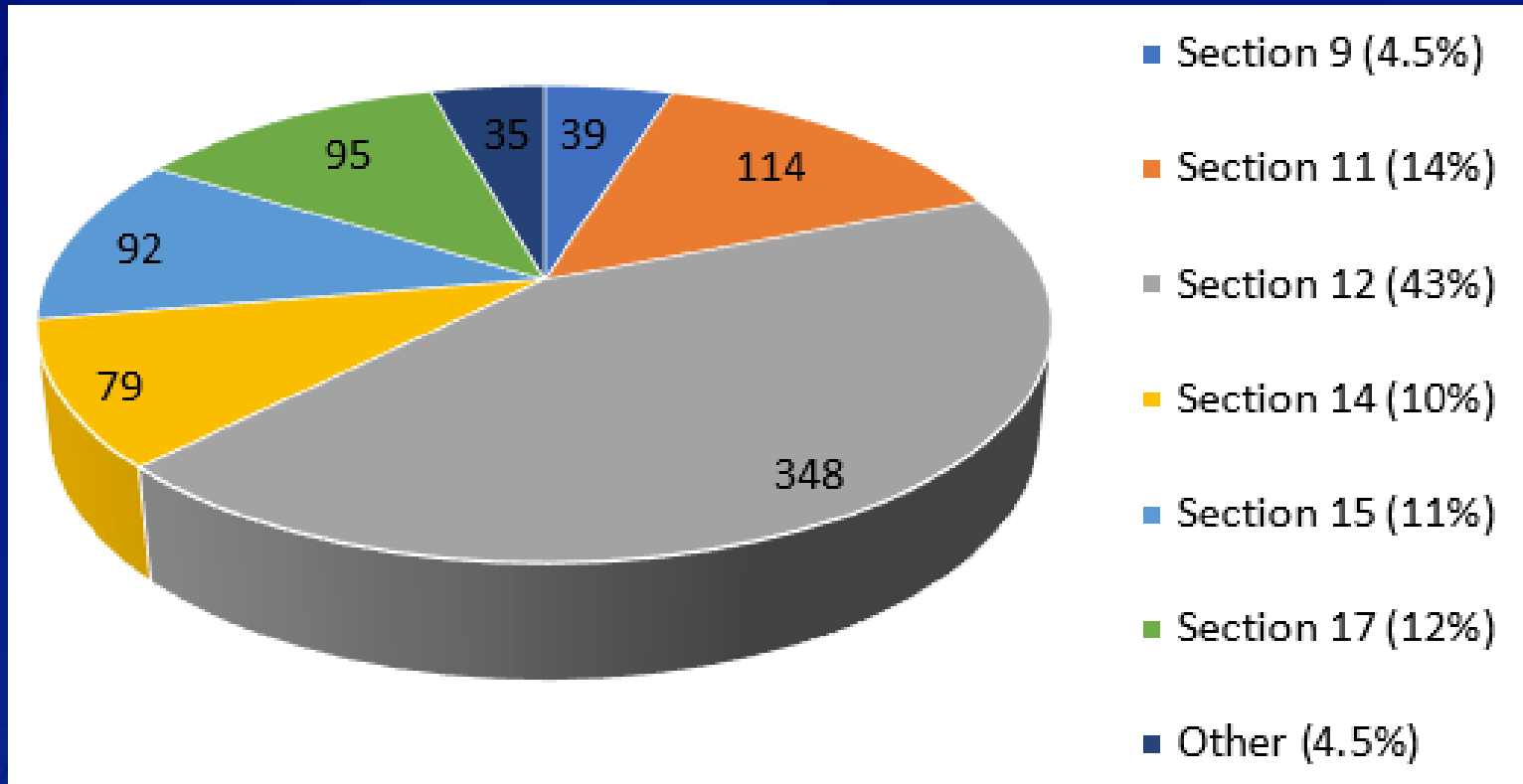
Purpose of This Evaluation

- ❑ **To find answers to the following questions:**
 - What are the most common regulatory departures found during inspections?
 - Are there any trends that can be identified from evaluating the regulatory departures?
 - How could this information be useful to the regulated community?

Materials and Methods

- ❑ **176 inspections from July 2019 to May 2020 were analyzed.**
- ❑ **802 regulatory departures were identified in these inspections.**
 - Averaging 4.5 regulatory departures per inspection.
- ❑ **Data analyzed and graphs generated in Excel.**

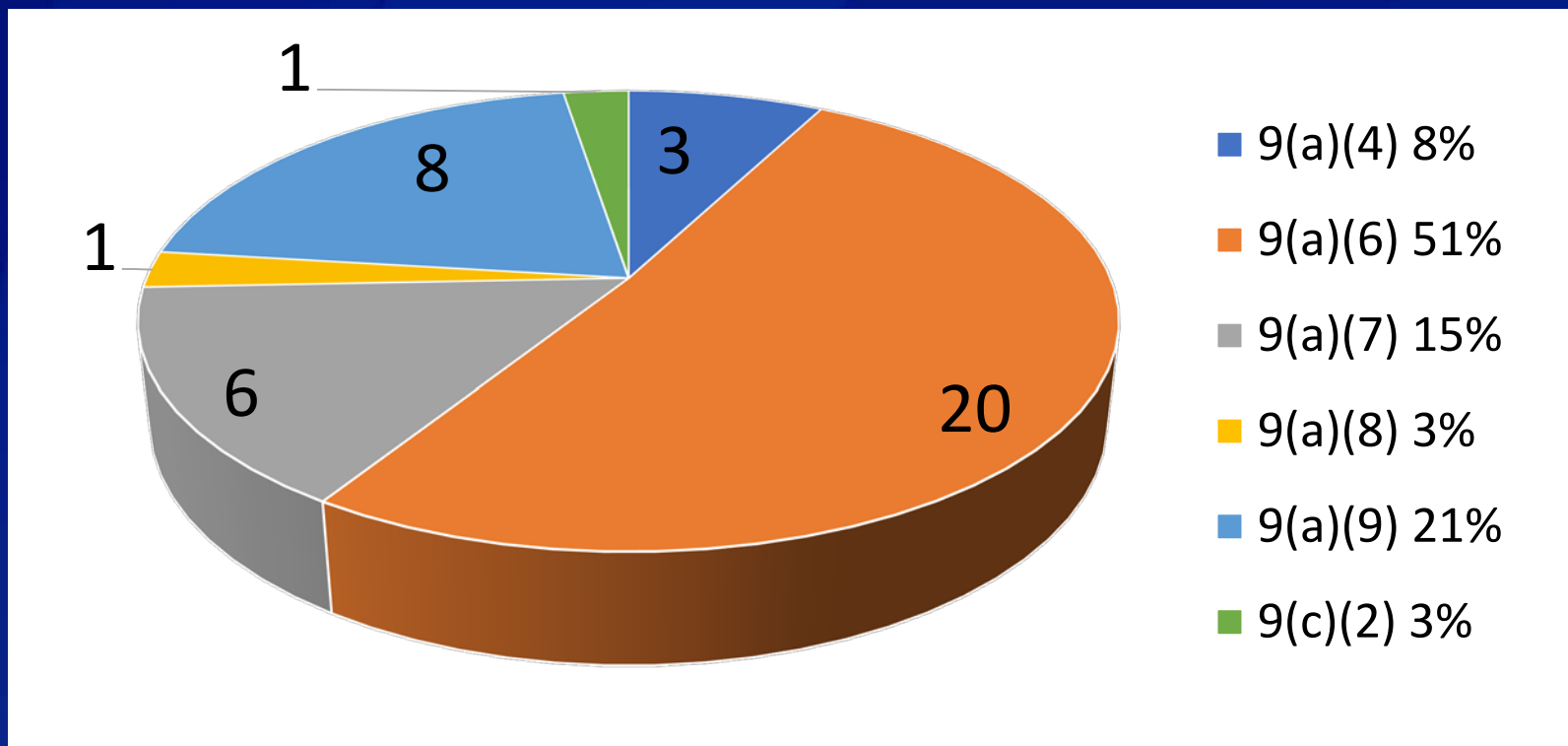
Overall Results



802 Total Departures

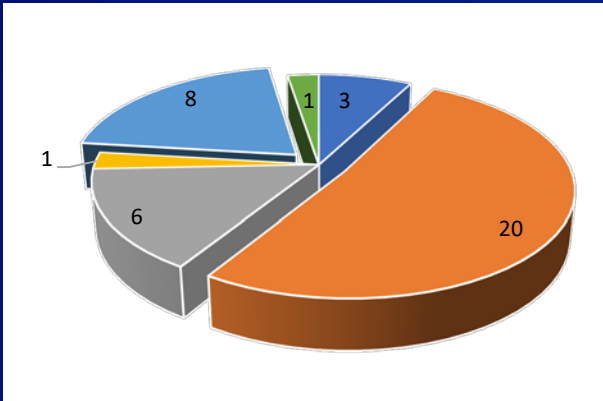
- 348 departures in Section 12
- 114 departures in Section 11
- 95 departures in Section 17
- 92 departures in Section 15
- 79 departures in Section 14
- 39 departures in Section 9
- 35 departures in other Sections

Section 9: Responsible Official Results



39 Section 9 Departures

- 20 departures in 9(a)(6)
- 8 departures in 9(a)(9)
- 6 departures in 9(a)(7)
- 3 departures in 9(a)(4)
- 1 departure in 9(a)(8)
- 1 departure in 9(c)(2)



Section 9: Responsible Official

Two most often Section 9 regulations cited in inspection reports

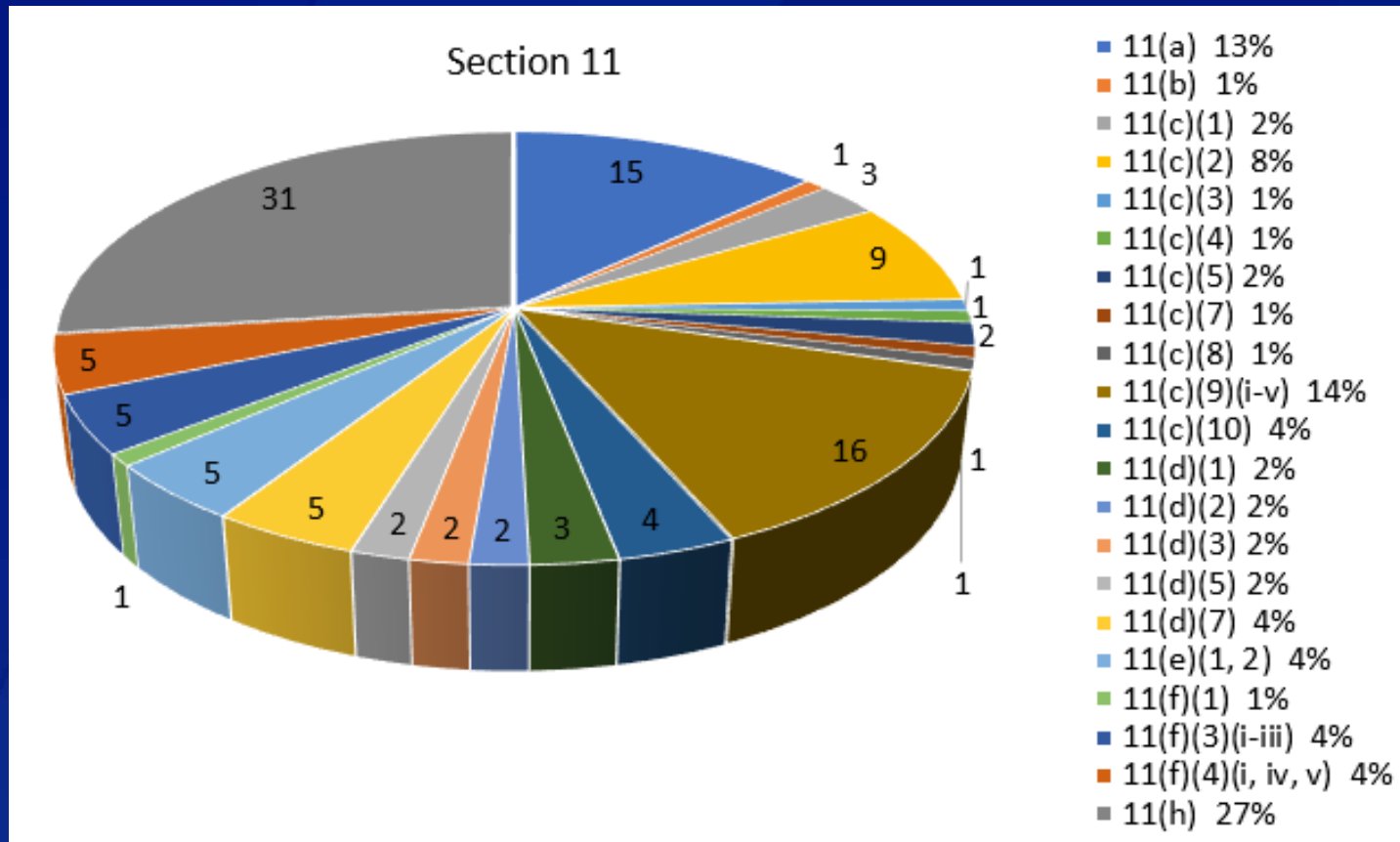
❑ 9(a)6 Annual Inspections.

- Annual inspections not conducted for each registered space where select agents or toxins are stored or used.
- Results and/or corrections resulting from annual inspections were not documented.

❑ 9(a)(9) Validated inactivation procedures or viable select agent removal methods.

- Not reviewed annually or after any change in Principal Investigator, change in procedure, or failure.
- Not documented or training not conducted if there are any changes to the procedure.

Section 11: Security Results

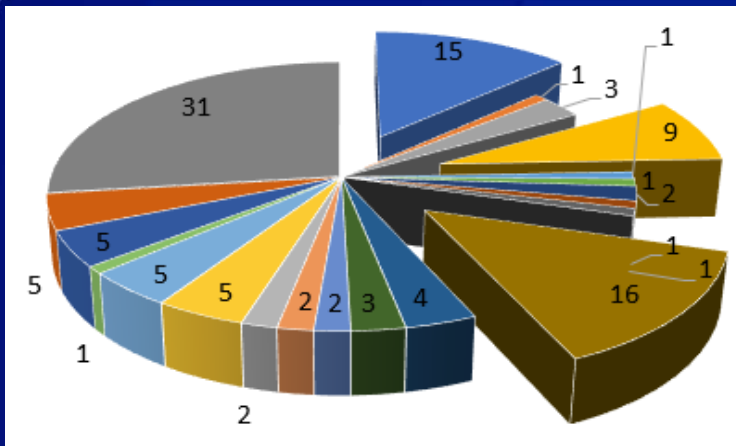


114 Section 11 Departures

- ❑ 31 departures in 11(h)
- ❑ 16 departures in 11(c)(9)(i-v)
- ❑ 15 departures in 11(a)
- ❑ 9 departures in 11(c)(2)
- ❑ 43 departures in other parts of Section 11

Section 11: Security

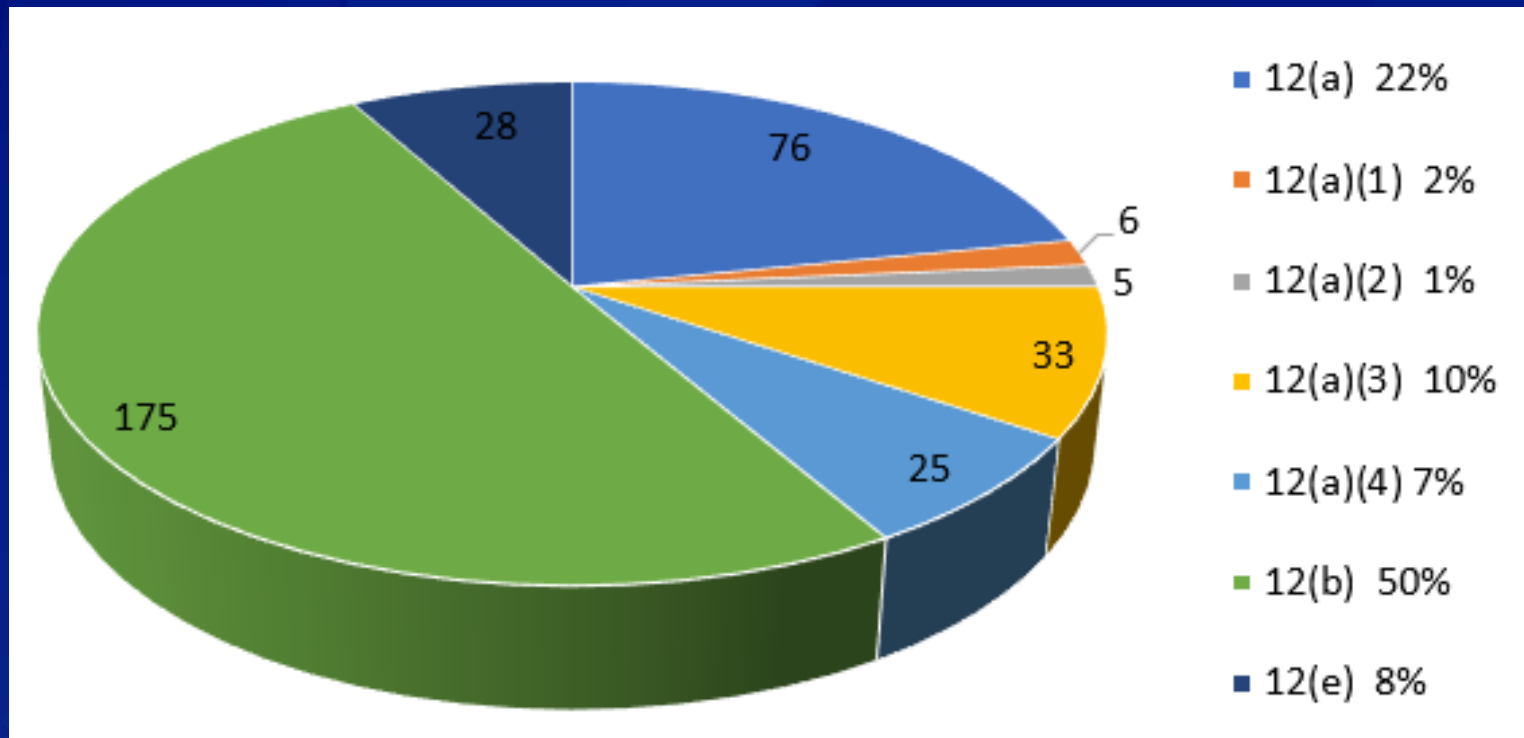
Three most often* Section 11 regulations cited in inspection reports



- 11(a)** Parts of Security plan not implemented.
- 11(c)(2)** Security plan does not describe the procedures to be used to safeguard animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent against unauthorized theft, loss or release.
- 11(c)(9)(i-v)** Does not contain provisions for information security.

***11(h)** Annual plan review and drills and exercises are addressed in a separate slide.

Section 12: Biosafety Results

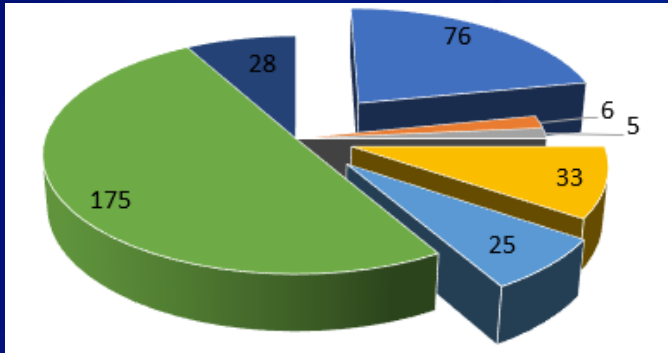


348 Section 12 Departures

- 175 departures in 12(b)
- 76 departures in 12(a)
- 33 departures in 12(a)(3)
- 28 departures in 12(e)
- 25 departures in 12(a)(4)
- 11 departures in other parts of Section 12

Section 12: Biosafety

Three most often* non-12(b) Section 12 regulations cited in inspection reports



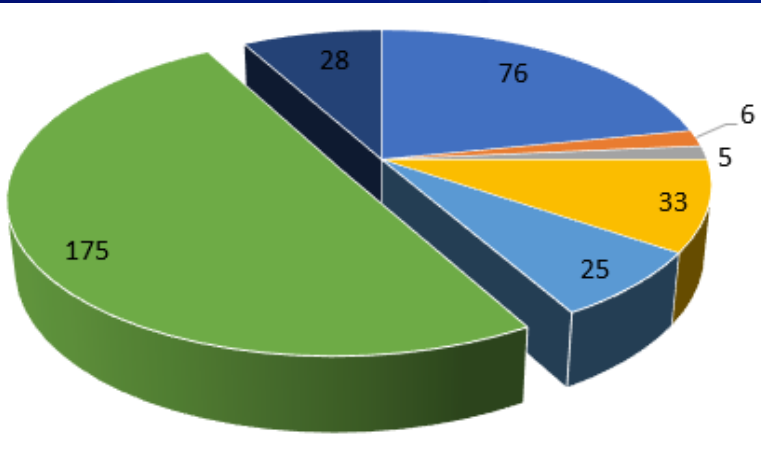
□ 12(a) Biosafety Plan

- Parts of Biosafety plan are not implemented.
 - Biosafety plan does not include procedures for animals accidentally exposed to or infected with select agents.
 - Biosafety plan not updated when procedural changes occur.
- 12(a)(3) Biosafety plan does not contain written procedures for validated methods of decontamination, disinfection, or destruction.
- 12(a)(4) Biosafety plan does not contain procedures for working with select agents and toxins and non-select agents and toxins to prevent cross contamination.

*12(e) Annual plan review and drills and exercises are addressed in a separate slide.

Section 12 (b)

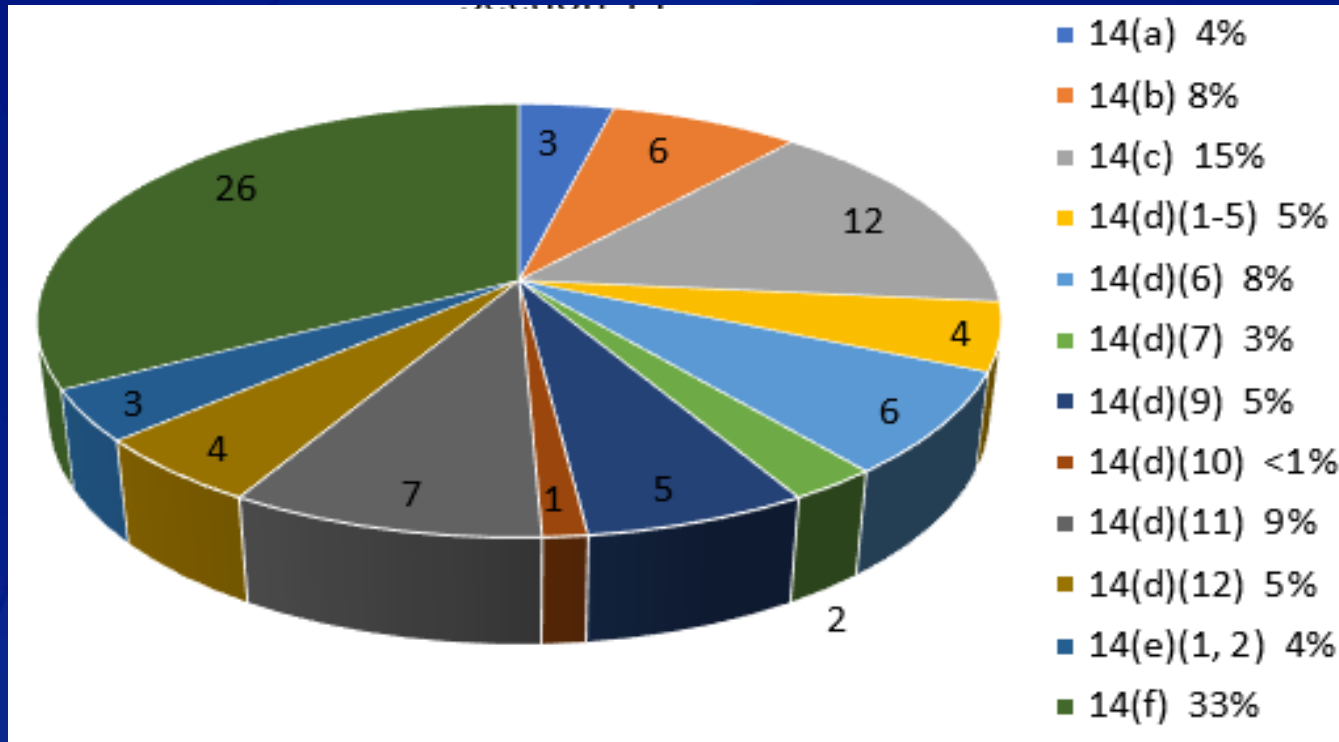
Four most often cited items accounted for 30% of 12(b) departures



- Failure to perform and/or document BSL3/ABSL3* reverification items.
- Posted signage inadequate.
 - Entry/exit procedures missing or different from what is described in Biosafety plan.
 - Incorrect contact information.
- Failure to follow posted entry and/or exit procedures.
- O-rings for centrifuges used with select agents and toxins are cracked or missing.

*<https://www.selectagents.gov/regBSL3ABSL3policy.html>

Section 14: Incident Response Results

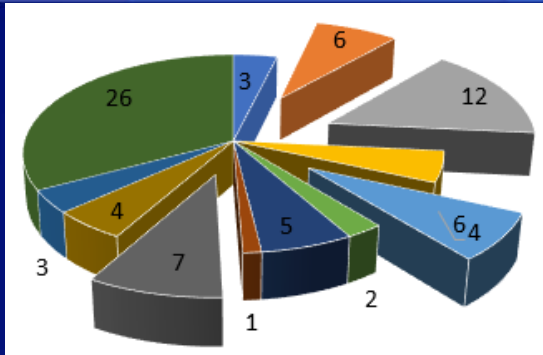


79 Section 14 Departures

- ❑ 26 departures in 14(f)
- ❑ 12 departures in 14(c)
- ❑ 7 departures in 14(d)(11)
- ❑ 6 departures in 14(b)
- ❑ 6 departures in 14(d)(6)
- ❑ 5 departures in 14(d)(9)
- ❑ 17 departures in other parts of Section 14

Section 14: Incident Response

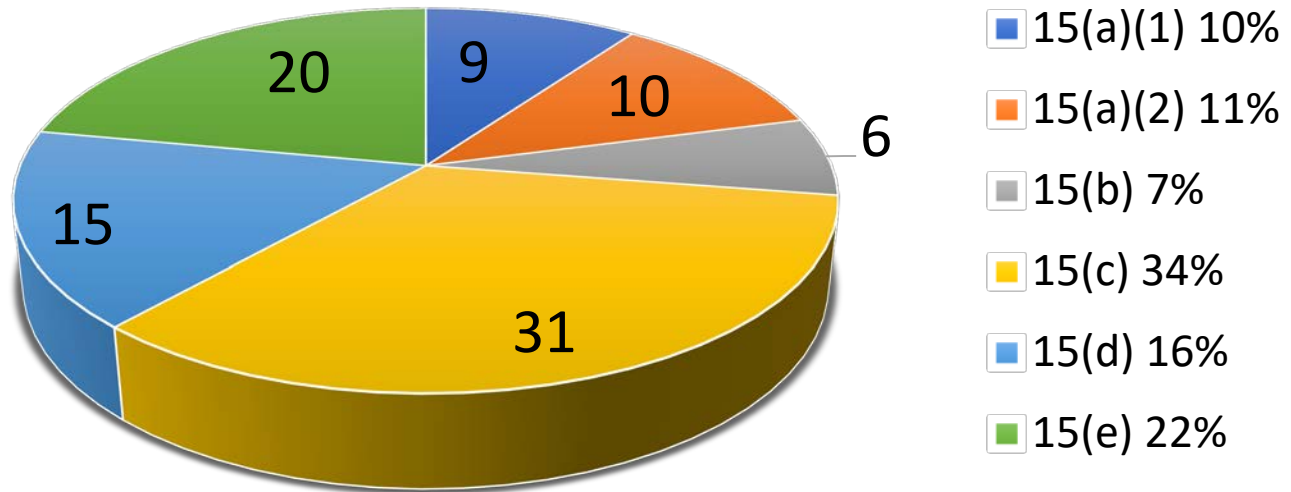
Four most often* Section 14 regulations cited in inspection reports



- ❑ **14(c)** Does not include procedures for the appropriate actions to contain plants or animals that have been accidentally or intentionally exposed to or infected with a select agent.
- ❑ **14(d)(11)** Response procedures for specific incidents (e.g., information security breaches, workplace violence, earthquakes, fire). Does not contain or reference procedures for evacuation, including type of evacuation, exit route assignments, safe distances, and places of refuge for each of the registered locations.
- ❑ **14(b)** Lacking response procedures for specific incidents (e.g., information security breaches, workplace violence, fires).
- ❑ **14(d)(6)** Lacking planning and coordination with local emergency responders.

*14(f) Annual plan review and drills and exercises are addressed in a separate slide

Section 15 Training Results

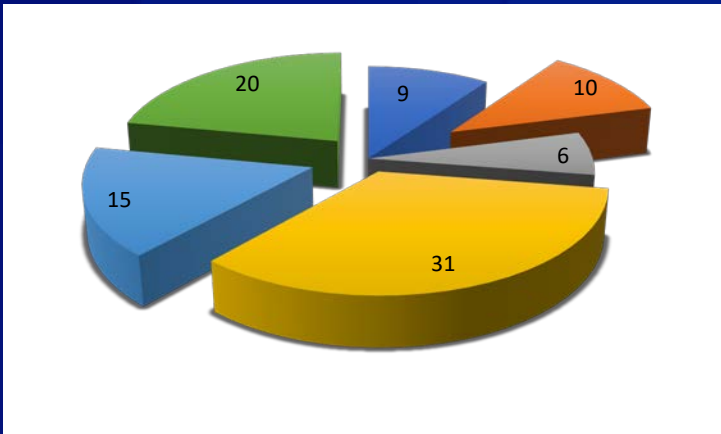


92 Section 15 Departures

- 31 departures in 15(c)
- 20 departures in 15(e)
- 15 departures in 15(d)
- 10 departures in 15(a)(2)
- 9 departures in 15(a)(1)
- 6 departures in 15(b)

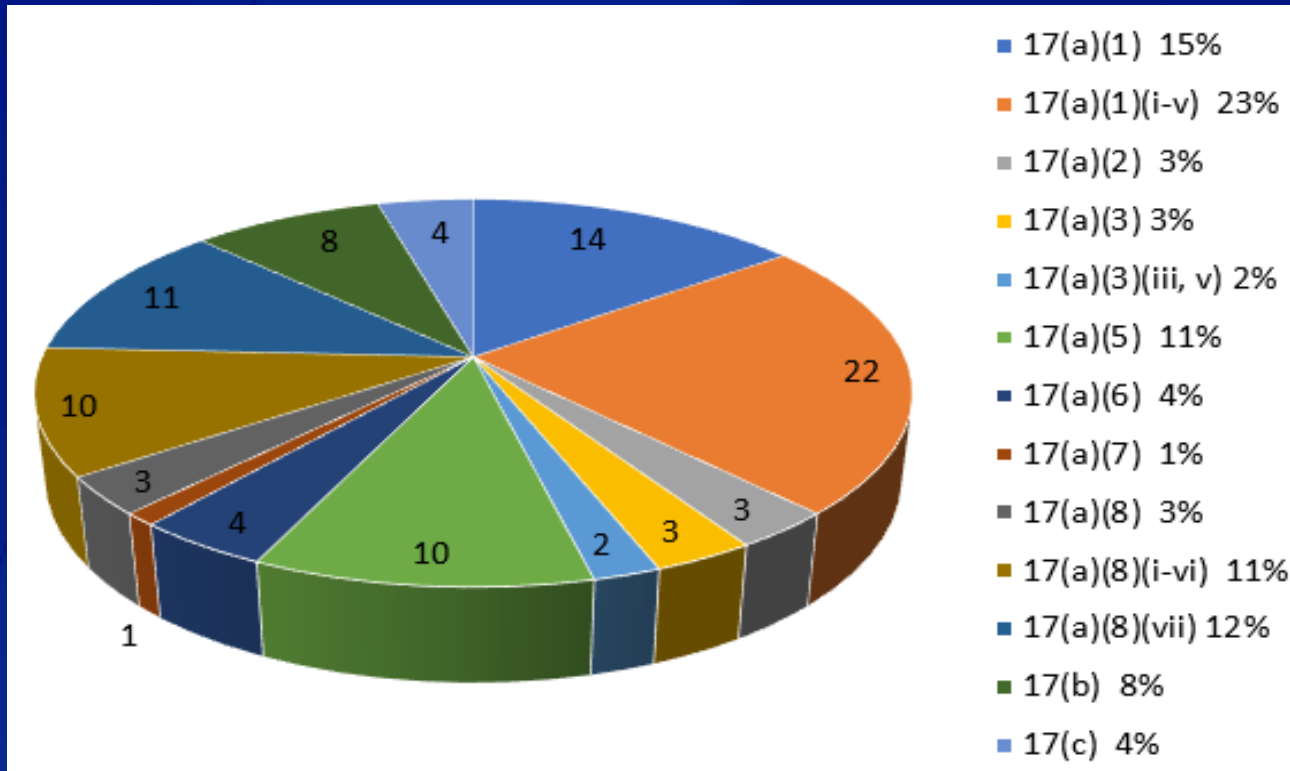
Section 15: Training

Four most often Section 15 regulations cited in inspection reports



- 15(c)** Annual refresher training not provided.
- 15(e)** Contact information for HHS or USDA Inspector General hotline information not provided [9(a)(7)].
- 15(a)(2)** Failure to provide visitor training.
- 15(d)** Record of training was insufficient or missing.

Section 17: Records Results

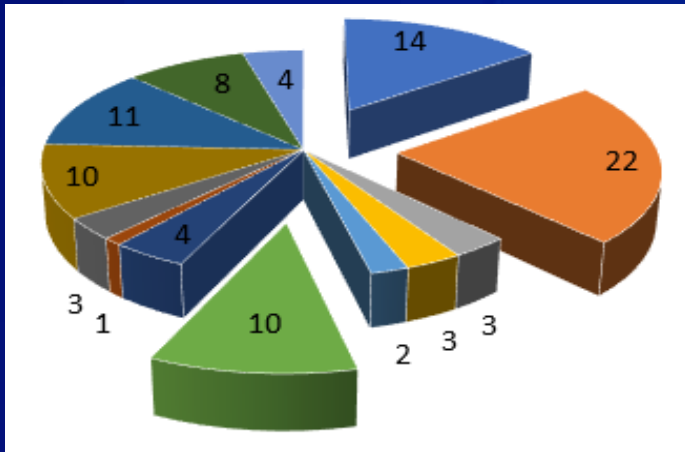


95 Section 17 Departures

- ❑ 22 departures in 17(a)(1)(i-v)
- ❑ 14 departures in 17(a)(1)
- ❑ 11 departures in 17(8)(vii)
- ❑ 10 departures in 17(a)(8)(i-v)
- ❑ 10 departures in 17(a)(5)
- ❑ 8 departures in 17(b)
- ❑ 20 departures in other parts of Section 17

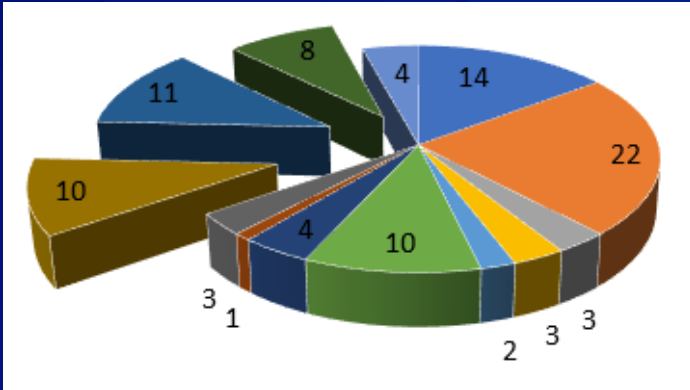
Section 17: Records

Six most often Section 17 Regulations cited in inspection reports (1-3)



- ❑ **17(a)(1)** Inaccurate select agent inventory.
- ❑ **17(a)(1)(i-v)** Parts of inventory record requirements for select agents were missing.
- ❑ **17(a)(5)** Recording entry.
 - Unable to provide access records.
 - Escort's name not recorded.
 - Visitor's name incomplete.

Section 17: Records



Six most often Section 17 Regulations cited in inspection reports (4-6)

□ 17(a)(8)(i-iv) Inactivation.

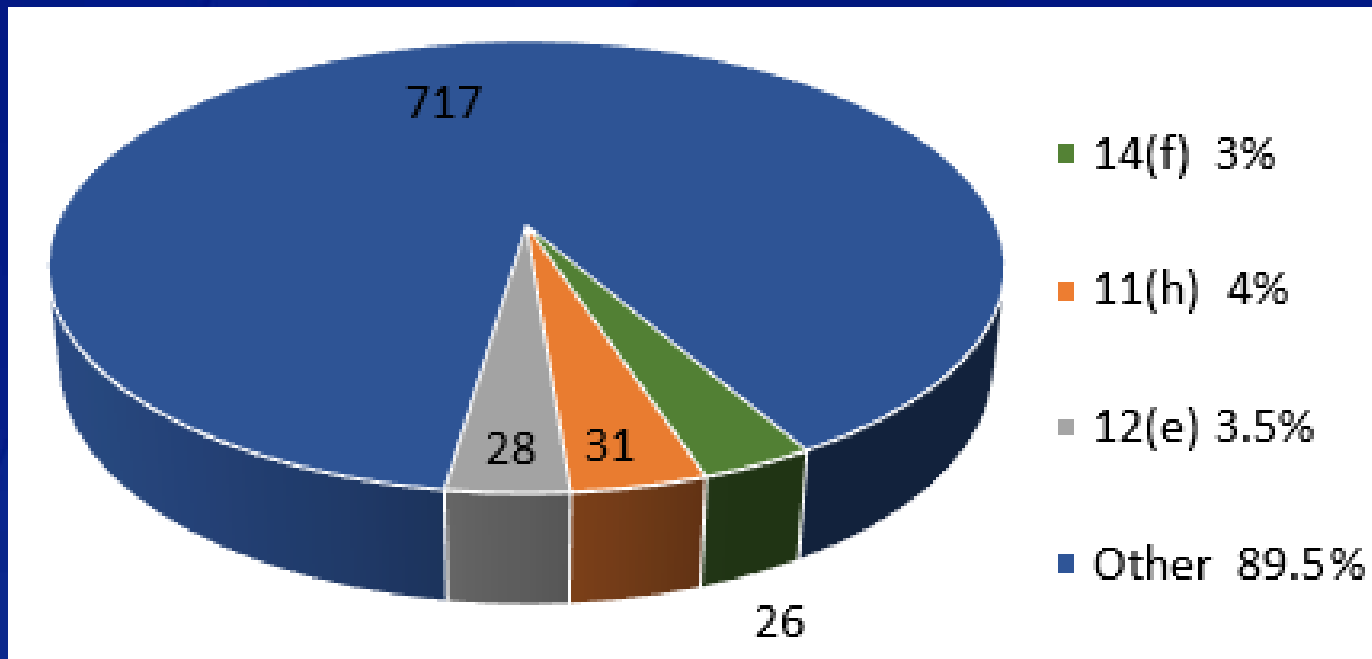
- Missing location where inactivation was performed.
- Missing name of person performing inactivation.

□ 17(a)(8)(vii) Inactivation certificates.

- Inactivation certificates not generated.
- Inactivation certificates not signed by Principal Investigator.
 - *Principal investigator* is the individual who directs a project or program and who is responsible for the scientific and technical direction of that project or program.

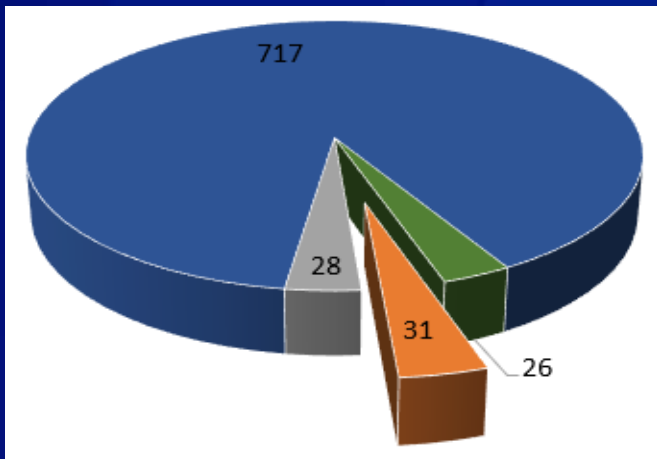
□ 17(b) Illegible records.

Section 11, 12, and 14: Plan Review and Drills and Exercises Results



85 annual plan review and drills and exercises departures

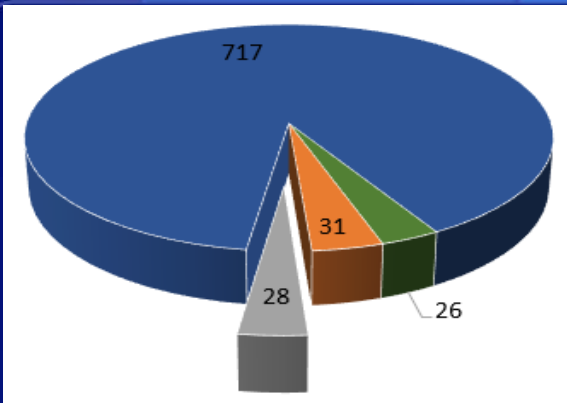
- ❑ 31 departures in 11(h)
- ❑ 28 departures in 12(e)
- ❑ 26 departures in 14(f)



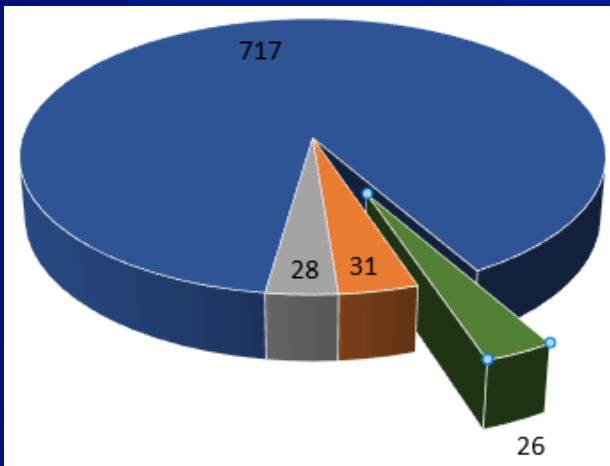
11(h): Security Plan Review and Drills and Exercises

- ❑ Failure to perform annual review of the Security Plan. 13% of 11(h) observations.
- ❑ Drills and Exercises. 87% of 11(h) observations.
 - 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 Plan Review and Drills and Exercises



- ❑ Failure to perform annual review of the Biosafety Plan. 18% of 12(e) observations.
 - Failure to perform annual review of accessory documents that contain required information for the Biosafety Plan.
- ❑ Drills and Exercises. 82% of 12(e) observations.
 - 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, corrective actions taken or the name of participants.
 - The names of registered entity personnel participants were not documented.



14(f): Incident Response Plan Review and Drills and Exercises

- ❑ Failure to perform annual review of the Incident Response Plan. 15% of 14(f) observations.
- ❑ Drills and Exercises. 85% of 14(f) observations.
 - Failure to update the Incident Response Plan with corrective actions identified in the drill after-action report.
 - 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.

Discussion

❑ What are the most common regulatory departures found during inspections?

- Overall, departures in Biosafety Section 12 were most common followed by Security Section 11 and Records Section 17.

❑ Are there any trends that can be identified from evaluating the regulatory departures? YES!!

- 12(b) and 9(a)(6) departures accounted for half of the departures in their respective sections.
- 15(c), 14(f), and 11(h) accounted for a third of the departures in their respective sections.
- Issues with drills and exercises accounted for >80% of the 11(h), 14(f), and 12(e) departures.
- Issues with select agent inventory recordkeeping accounted for 38% of Section 17 departures.

Discussion

□ How could this information be useful to the regulated community?

- Understanding which observations are most common and the trends in observations noted in different sections of the regulations can be leveraged by the regulated community.
 - Entities should examine their own programs to see if gaps are present and actively work to close them.
 - Entities can place emphasis on Sections of the regulations most often cited to improve inspection performance.

Discussion

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