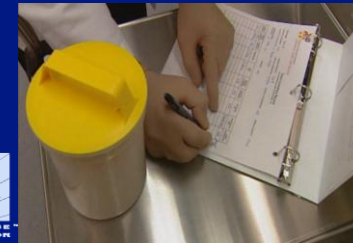


# National Select Agent Program Workshop

## Security Reviews and Considerations



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Agricultural Select Agent Program (ASAP)

Ames, Iowa  
May 10, 2011



Centers for Disease Control and Prevention & Animal and Plant Health Inspection Service  
Select Agent Program



# Regulatory Focus

- ❑ **In compliance with the Bioterrorism Act of 2002, USDA and HHS established regulations to ensure that all entities using or possessing select agents and toxins do so in a safe and secured manner to prevent unauthorized use:**
  - **“Establish and enforce safeguard and security measures to prevent access to listed agents and toxins for use in domestic or international terrorism or for any other criminal purpose.”**  
*[Agriculture Bioterrorism Act of 2002, Subtitle B, Section 212(b) and (c)]*
- ❑ **CFR requires all entities that possess, use and/or transfer select agents and toxins to develop site specific written security plans.**

# Security Review Focus

- ❑ **Two key requirements in 7 CFR 331.11(b), 9 CFR 121.11(b) and 42 CFR 73.11(b) must be addressed in order to develop a successful security plan and program:**
  - **“The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use.”**

# Security Review Focus

## □ Security related CFR Sections:

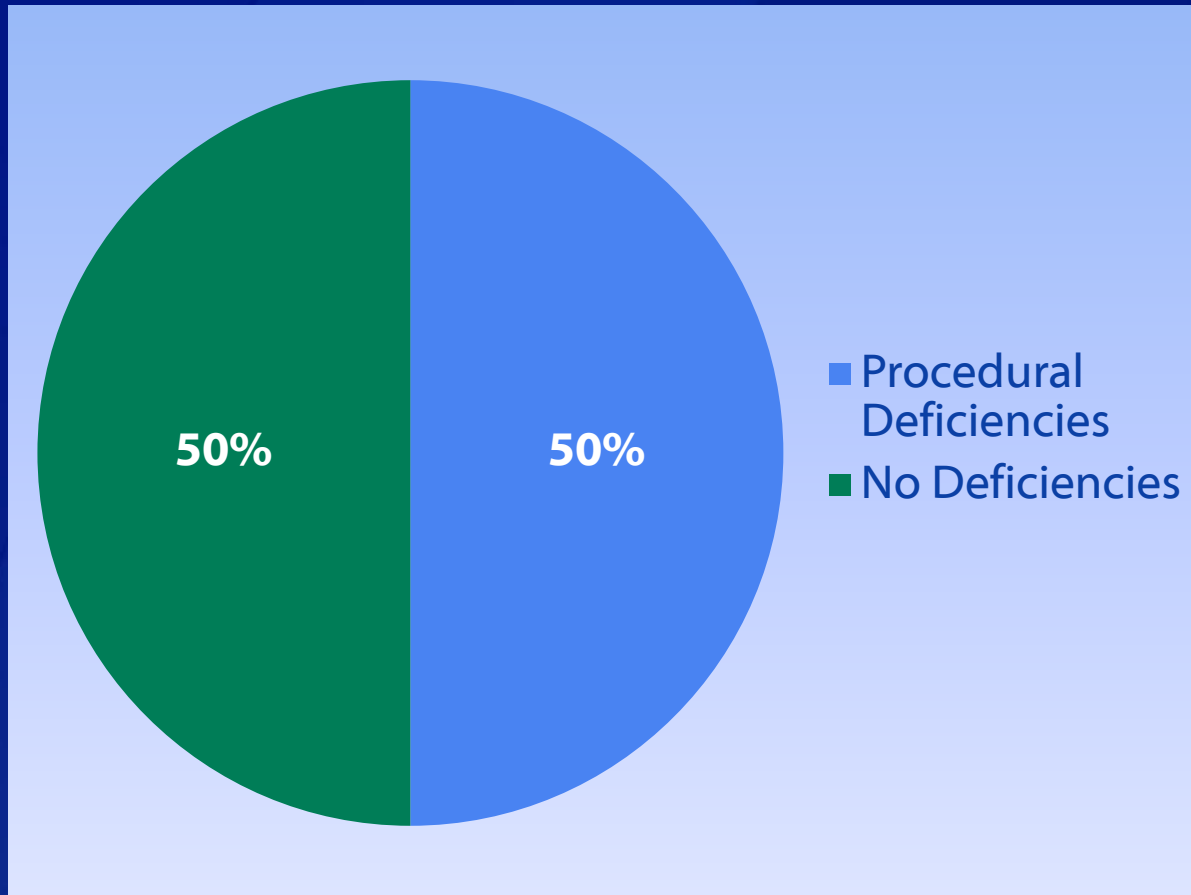
- Security [ 331.11; 121.11; 73.11]
- Incident Response [ 331.14; 121.14; 73.14]
- Training [ 331.15; 121.15; 73.15]
- Records [ 331.17; 121.17; 73.17]

# Data Gathering

- ❑ Security Inspection Checklist [Section 11]
- ❑ Incident Response Checklist [Section 14]
- ❑ Training Inspection Checklist [Section 15]
- ❑ Records Inspection Checklist [Section 17]

# Security Review Documentation

- ❑ **Select Agent Regulations**
  - Requirements to satisfy
- ❑ **APHIS/CDC Form 1, Section 5**
  - Physical security declaration
- ❑ **Entity site-specific written security and incident response plans**
  - Policy and procedures, i.e. operational security
- ❑ **Inspection report**
  - Confirmation

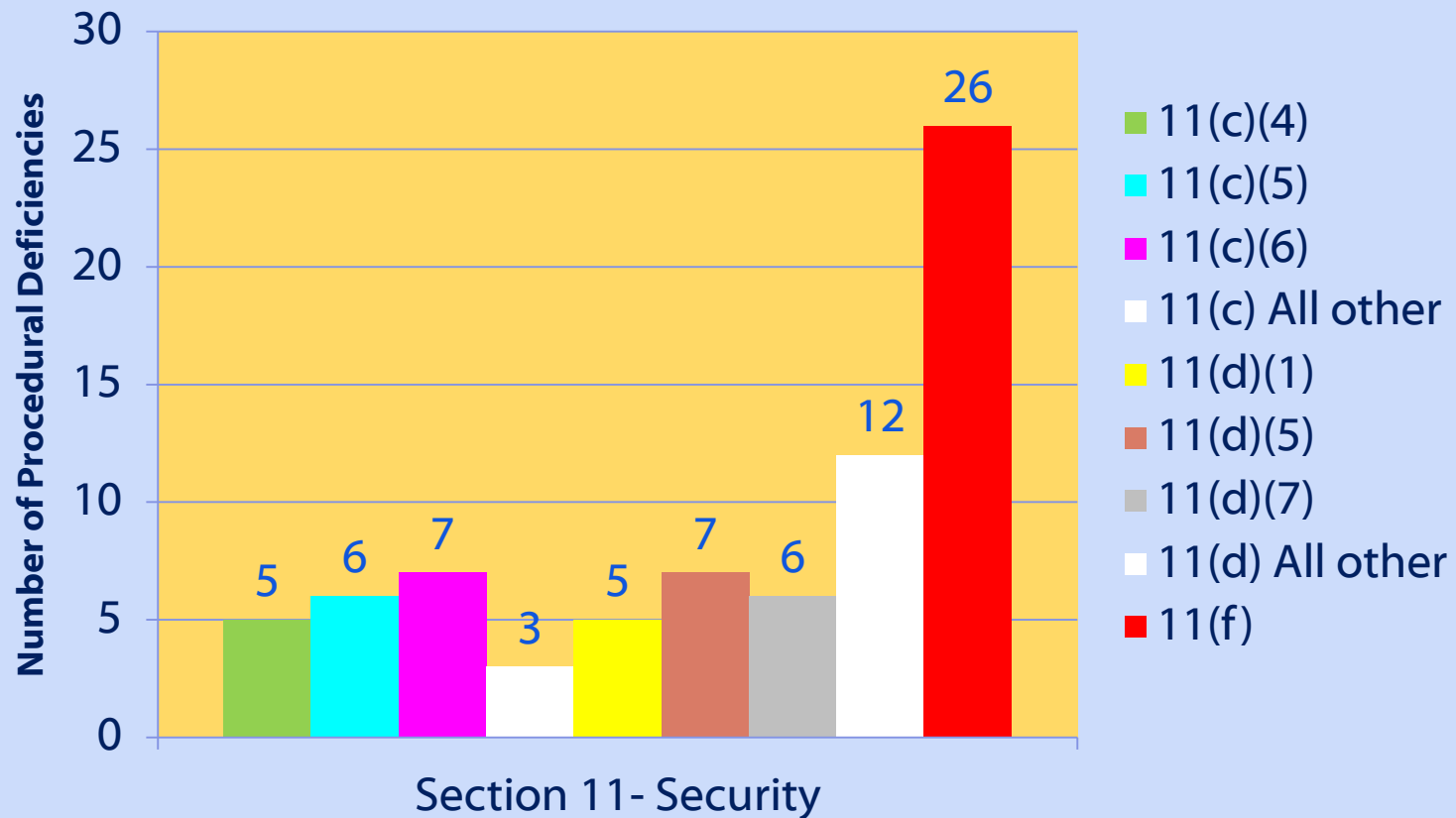


### **2009-2010 ASAP Security Reviews, n=174**

Procedural deficiencies represent 88 of the 174 security reviews performed for the two year period of 2009-2010.

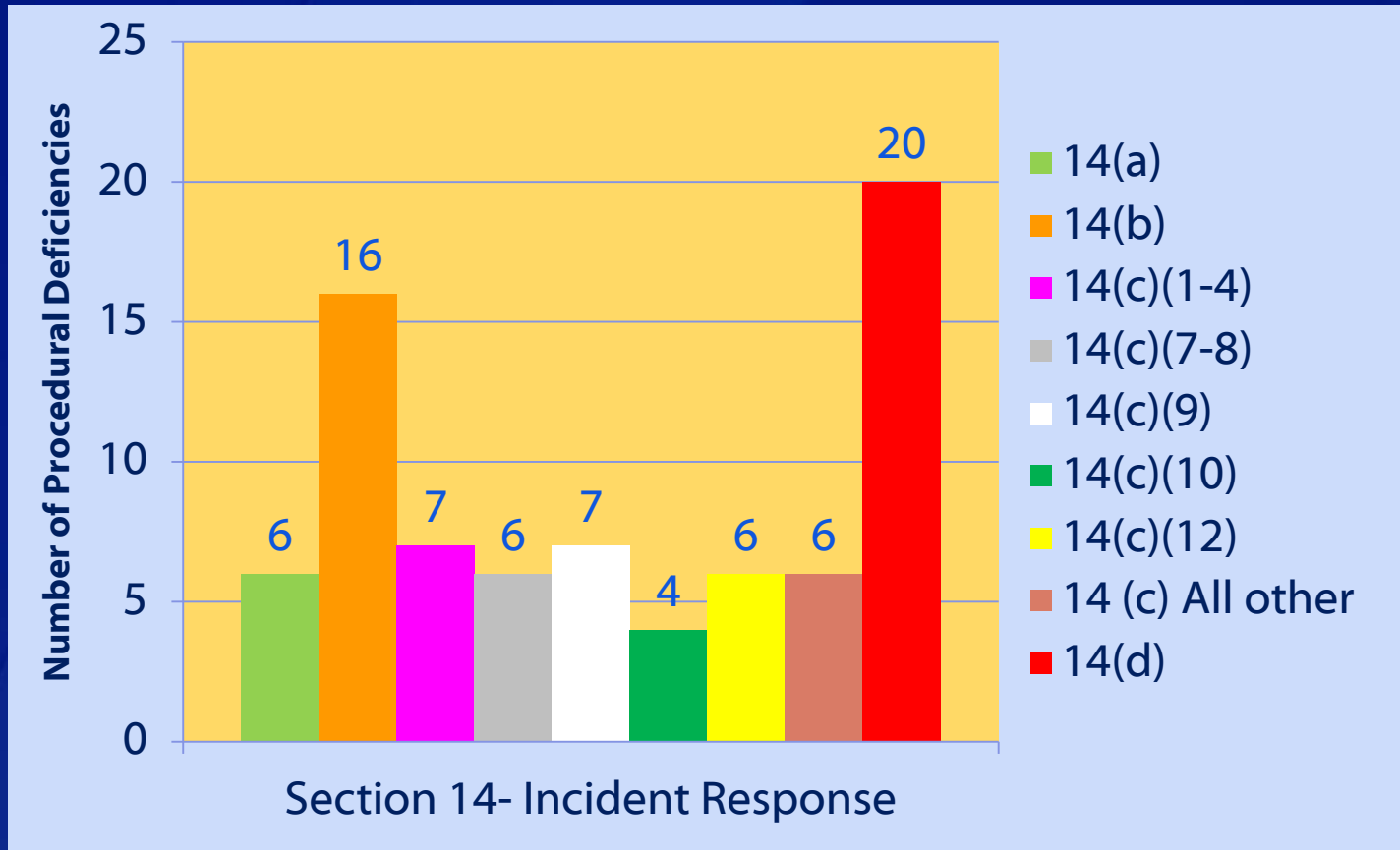
**Agricultural Select Agent Program (ASAP)  
Security Inspection Reviews performed  
of USDA registered entities  
SUMMARY ANALYSIS  
2009-2010**





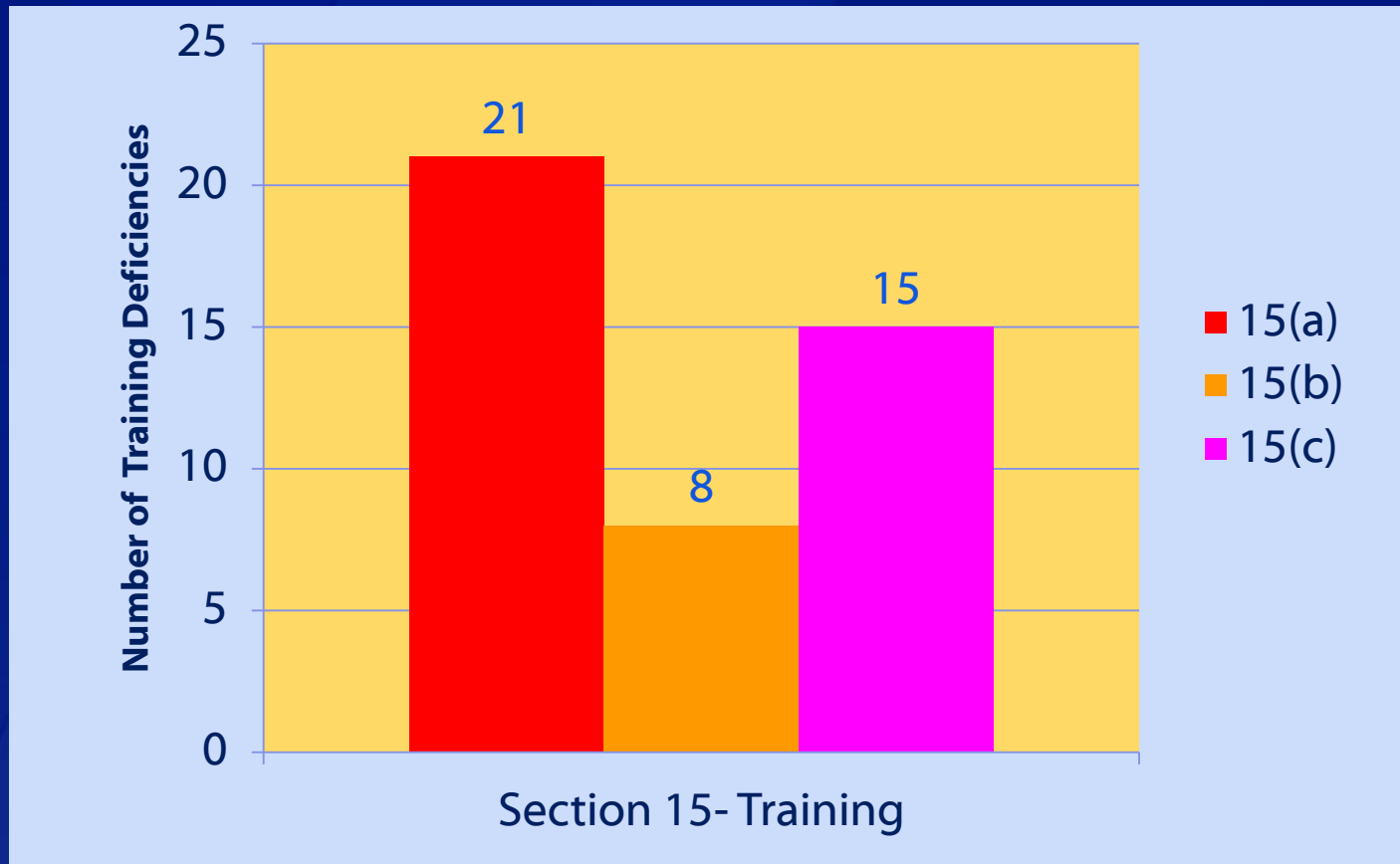
## 2009-2010 ASAP Security Procedural Reviews, n=55

**11(c)(4)**- Covers removing unauthorized and suspicious persons . **11(c)(5)**- Covers loss or compromising of keys, passwords, etc. **11(c)(6)**- Covers reporting of unauthorized persons, theft, loss, release and alteration of inventory records. **11(d)(1); (d)(5) and (d)(7)**- Covers access approval; procedures for intra-entity transfers; reporting theft, loss, release and alteration of inventory records. **11(f)**- Covers drills, exercises and evaluations.



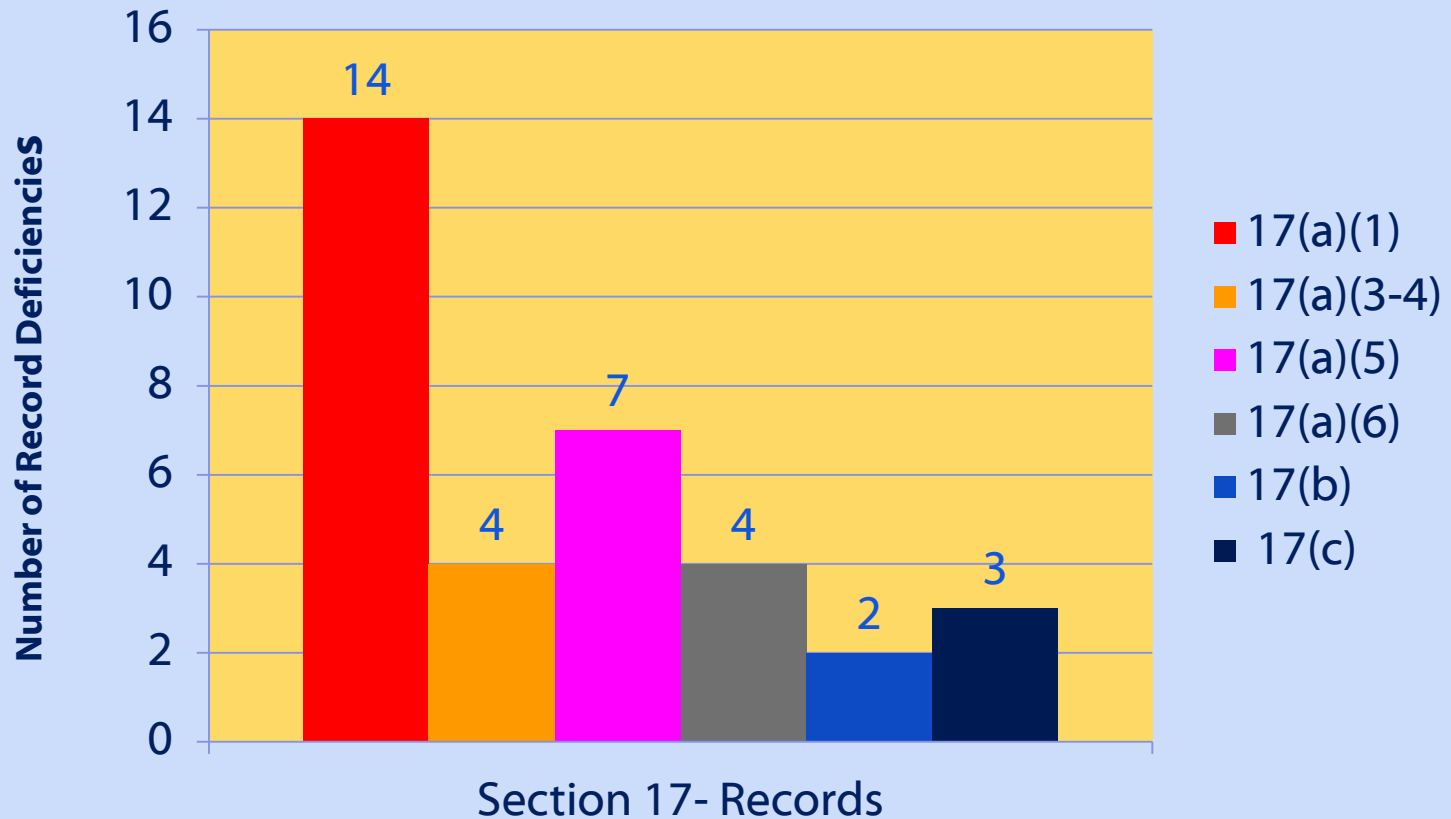
## 2009-2010 ASAP Incident Response Procedural Reviews, n=55

**14(a)**- Covers coordinated plans with entity-wide, and workplace availability. **14(b)**- Covers procedures for natural and man-made events and hazards associated with the select agent or toxin. **14(c)(1-4)**- Covers contact information. **14(c)(7-8)**- Covers medical response. **14(c)(9)**- Covers PPE. **14(c)(10)**- Covers site security controls. **14(c)(12)**- Covers decontamination procedures. **14(d)**- Covers drills, exercises and evaluations.



## 2009-2010 ASAP Training Reviews, n=55

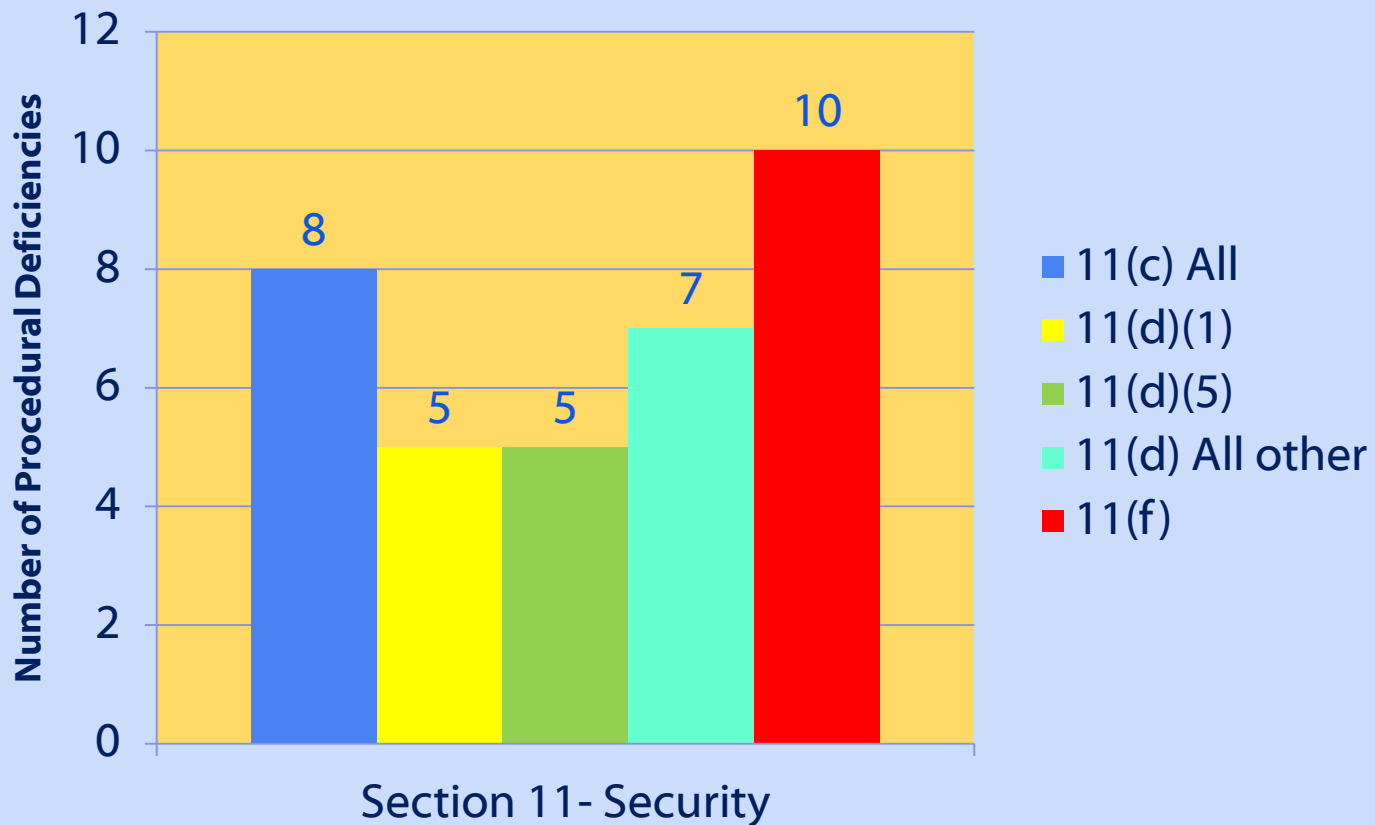
**15(a)**- Covers training in security and biosafety for SRA approved individuals; and non-SRA personnel, such as visitors, etc. **15(b)**- Covers annual refresher training. **15(c)**- Covers training records.



## 2009-2010 ASAP Record Reviews, n=55

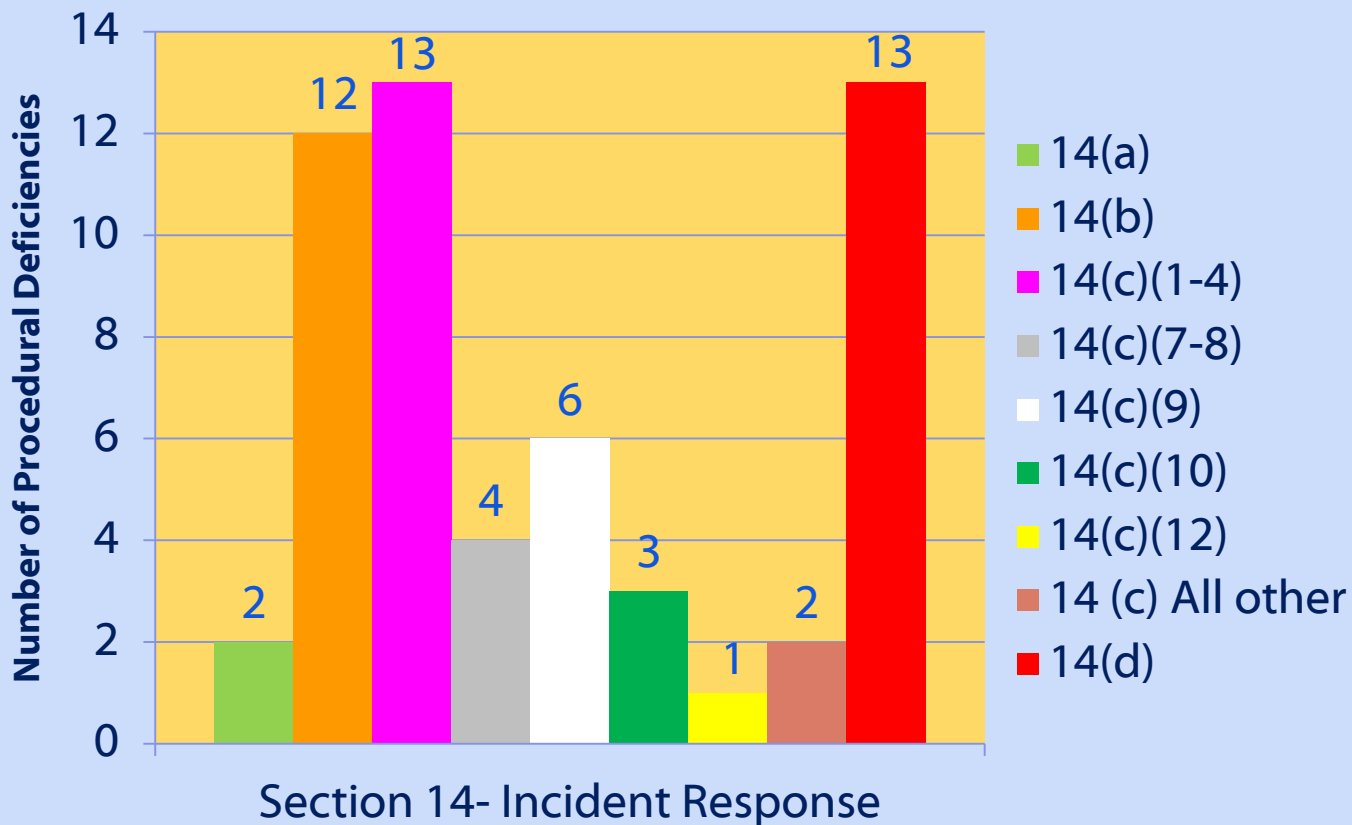
**17(a)(1)**- Covers accurate and current inventory. **17(a)(3-4)**- Covers authorized access and entry logs. **17(a)(5)**- Covers accurate and current records. **17(a)(6)**- Covers written discrepancies.

**Agricultural Select Agent Program (ASAP)  
Security Inspection Reviews performed  
of CDC/DSAT registered entities with  
USDA-only select agents  
SUMMARY ANALYSIS  
2009-2010**



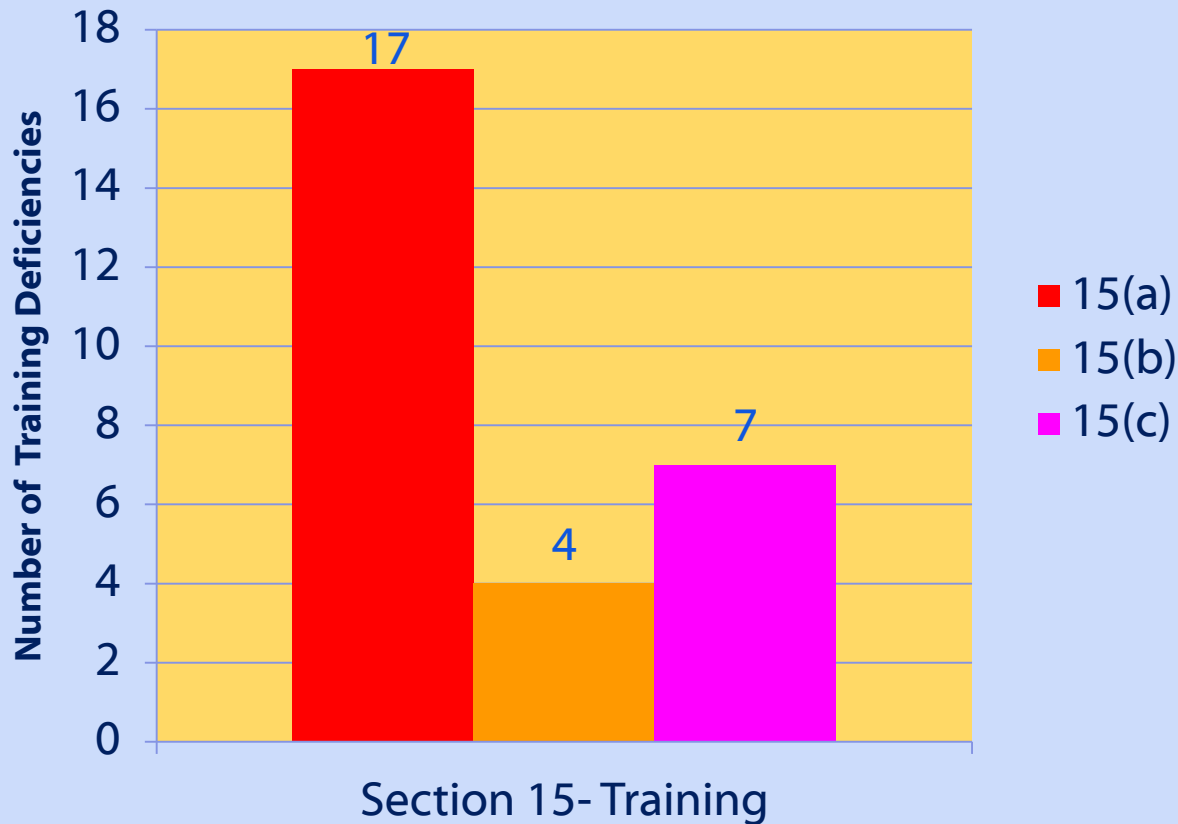
## 2009-2010 ASAP Security Reviews of DSAT entities with USDA-only select agents, n=33

**11(d)(1)** and **(d)(5)**- Covers access approval; procedures for intra-entity transfers; reporting theft, loss, release and alteration of inventory records. **11(f)**- Covers drills, exercises and evaluations.



## 2009-2010 ASAP Security Reviews of DSAT entities with USDA-only select agents, n=33

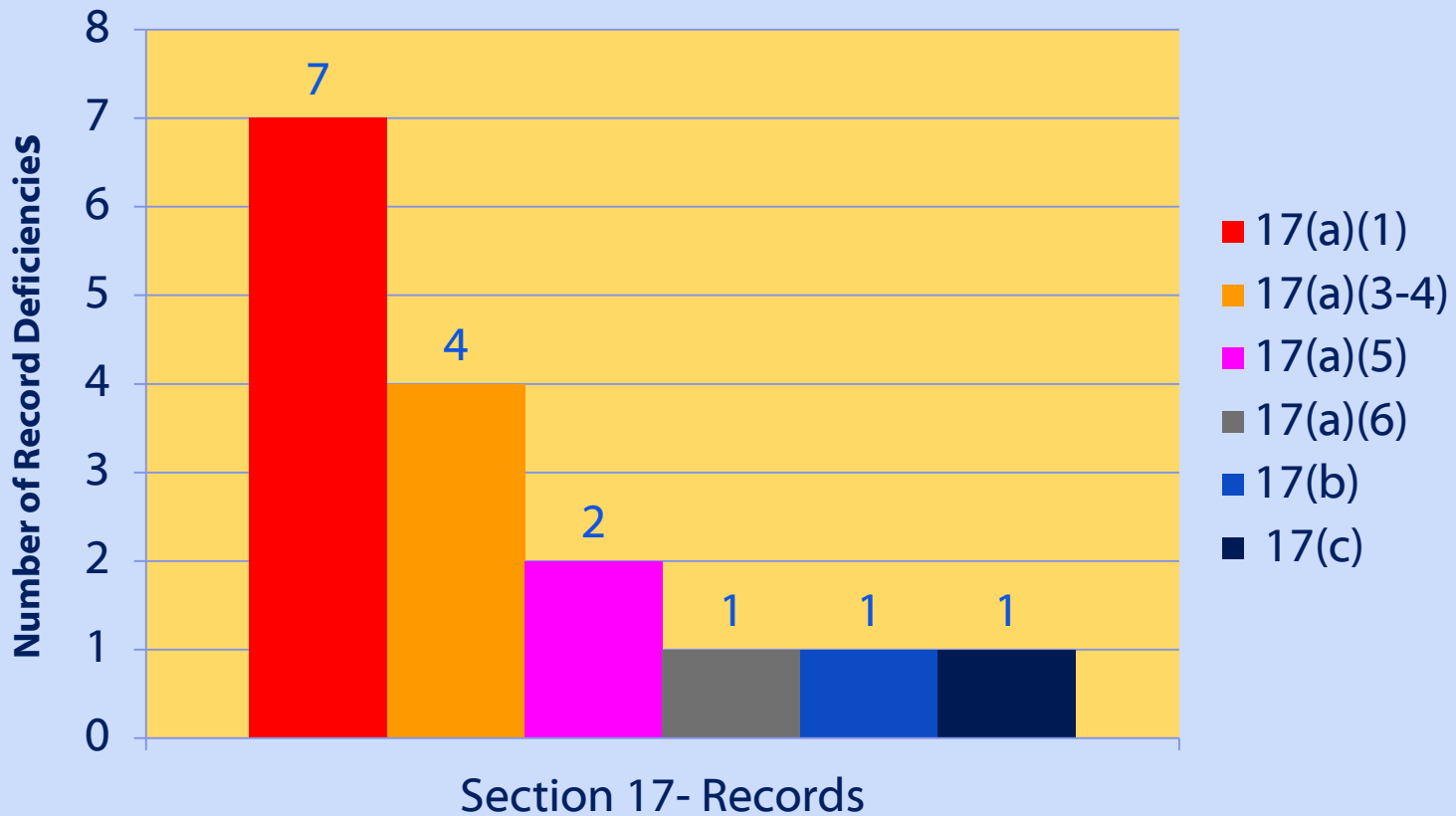
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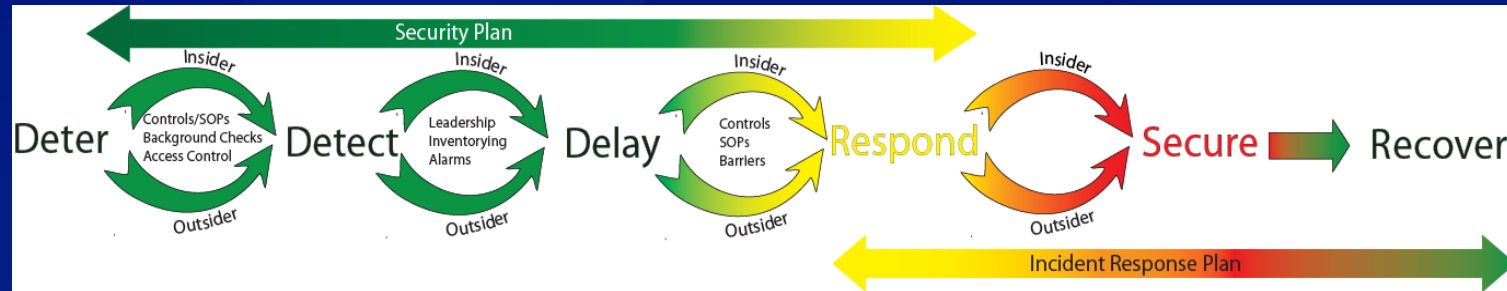


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# Considerations

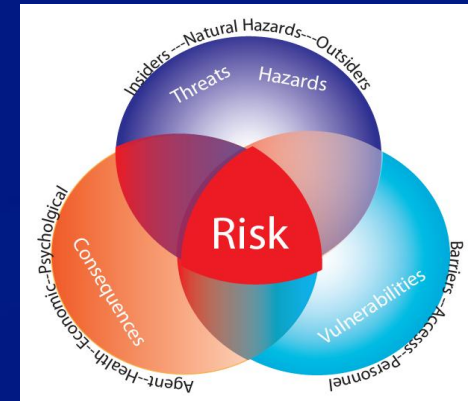
- ❑ Security and incident response plans are linked



- Security=keep it from effecting your lab
- Incident Response= keep it from continuing to happen
- ❑ **Security plan policy and procedures should not be call “911 and run”**
- ❑ **Specifically address the CFR requirements**
  - Focus on procedures and/or policy

# Considerations

- ❑ Risk is the probability of a hazard (natural/human) resulting in unwanted consequences
- ❑ It is a function of:
  - Vulnerabilities: Weakness that can be exploited by a particular threat or hazard
  - Natural Hazards: Harm or Difficulty from natural phenomena
  - Threats: Credible adversary with intent and capability to access the select agent
  - Consequence: Human, Economic, Psychological, Financial (cost of replacing the science)



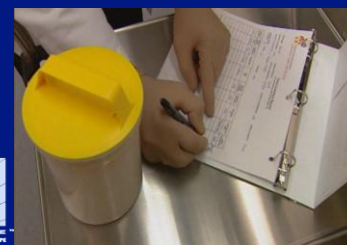
# Considerations

- ❑ Know your hazards based on your location
- ❑ Know what they will do to the inside of the facility or laboratory (not just the building)
- ❑ Know what they will do to the entire entity
- ❑ Know the effects of the natural hazard or event on operations



Japanese Earthquake:  
Fume hood was in fact torn  
from the wall

# Discussion



## For more information, please contact Select Agent Program

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E-mail: [Agricultural.Select.Agent.Program@aphis.usda.gov](mailto:Agricultural.Select.Agent.Program@aphis.usda.gov) (APHIS) or [lrsat@cdc.gov](mailto:lrsat@cdc.gov) (CDC)

Web: <http://www.selectagent.gov/>

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Select Agent Program.



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