



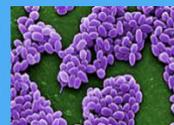
Federal Select Agent Program Webcast November 14, 2014

Agriculture Select Agent Services (USDA/APHIS)
CDC Division of Select Agents and Toxins (HHS/CDC)
Bioterrorism Risk Assessment Group (FBI/CJIS)



WELCOME TO THE 2014 FEDERAL SELECT AGENT PROGRAM WEBCAST

Time	Presentation	Speaker(s)
10:00 am	Opening Remarks	Dr. Freeda Isaac/Dr. Rob Weyant
10:15 am	Incident Response-Accident Analysis and Incident Reporting	Ms. Yvonne Walker/Mr. John Holcomb
11:15 am	Review of Recent High Profile Biosafety Incidents and Overall APHIS/CDC Form 3 Data Analysis	Dr. Rob Weyant
12:15 pm	BREAK	
1:00 pm	Safety Stand Down Guidance “What if we discover select agents stored in unregistered space?”	Dr. Freeda Isaac
2:00 pm	Inspector Experiences “Inspecting under the revised regulations”	Dr. Lyla Lipscomb
3:00 pm	Ask the Directors!	Dr. Freeda Isaac/Dr. Rob Weyant
3:45 pm	Closing remarks	Dr. Freeda Isaac/Dr. Rob Weyant



WELCOME TO THE 2014 FEDERAL SELECT AGENT PROGRAM WEBCAST (2)

SPEAKER INTRODUCTION

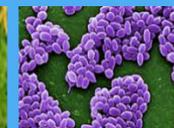
- ❖ **Dr. Freeda Isaac – Director, USDA Agriculture Select Agent Services**
- ❖ **Dr. Rob Weyant – Director, CDC Division of Select Agents and Toxins**
- ❖ **Mr. John Holcomb – Security Specialist, CDC Division of Select Agents and Toxins**
- ❖ **Ms. Yvonne Walker – Security Specialist, CDC Division of Select Agents and Toxins**
- ❖ **Dr. Lyla Lipscomb – Inspector, CDC Division of Select Agents and Toxins**
- ❖ **Dr. Chuck Divan – Unit Director, Operational Services, USDA Agriculture Select Agent Services**



WELCOME TO THE 2014 FEDERAL SELECT AGENT PROGRAM WEBCAST (3)

HOUSEKEEPING

- ❖ **The webcast is one-way audio only**
- ❖ **MAC users should connect using Flash Connection 3**
- ❖ **Closed Caption is available only on the Windows Media File (Connection 1). The captions are embedded into the file and can only be turned on by the end user**
- ❖ **We are unable to provide IT support, please contact your entity IT department if you experience connection difficulties**



WELCOME TO THE 2014 FEDERAL SELECT AGENT PROGRAM WEBCAST (4)

HOUSEKEEPING

- ❖ **At any time during the webcast send questions to selectagentwkshp@cdc.gov**
- ❖ **Each speaker will answer e-mailed questions following their presentation**
- ❖ **Answers to questions not addressed during the webcast, slides and a video of the proceedings will be posted on the Federal Select Agent Program website at <http://www.selectagents.gov> following the broadcast**
- ❖ **Please take a moment to respond to our survey which will be sent to you by e-mail after the broadcast**



OPENING REMARKS

INCIDENT RESPONSE-INCIDENT ANALYSIS AND REPORTING

Von McClee, MS
Chief, Program Services Branch,

Yvonne Walker
Security Specialist
&
John Holcomb
Security Specialist

Centers for Disease Control and Prevention
Office of Public Health Preparedness and Response
Division of Select Agents and Toxins

Federal Select Agent Program
Training



WHAT IS AN INCIDENT?

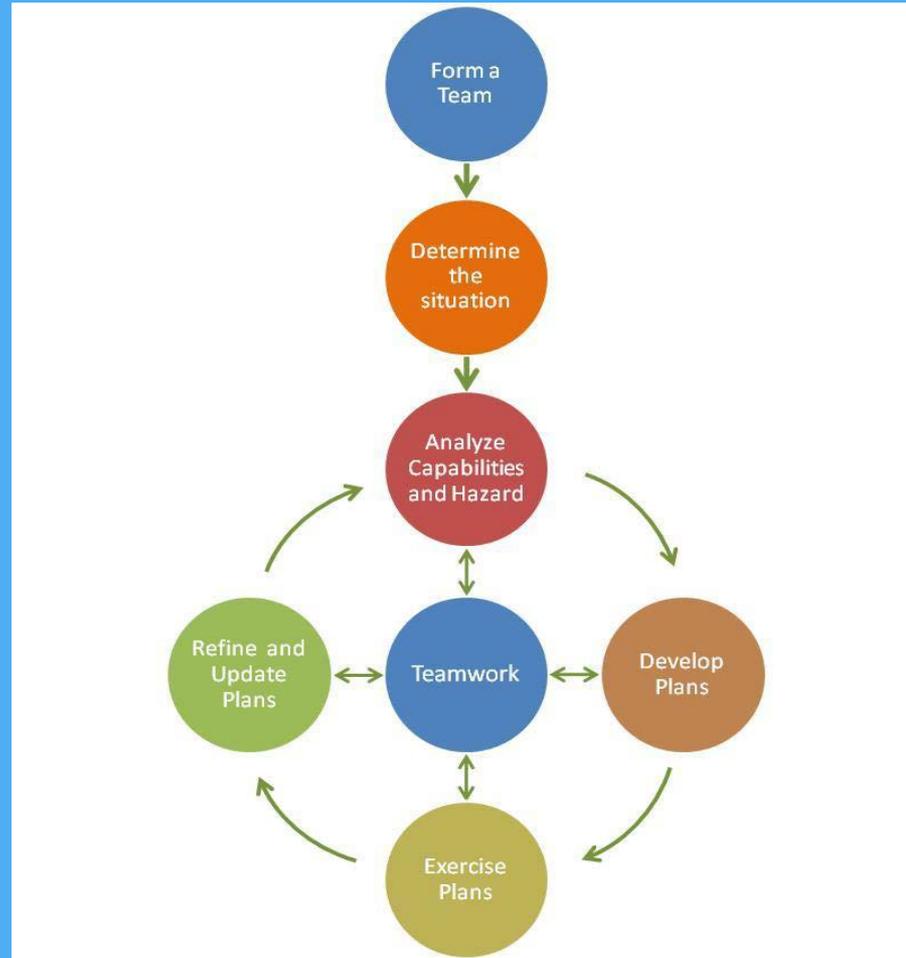
- **An incident is an occurrence, natural or manmade, that requires a response to prevent the theft, loss or release of the select agent or toxin or to protect human life, and animal and plant health.**



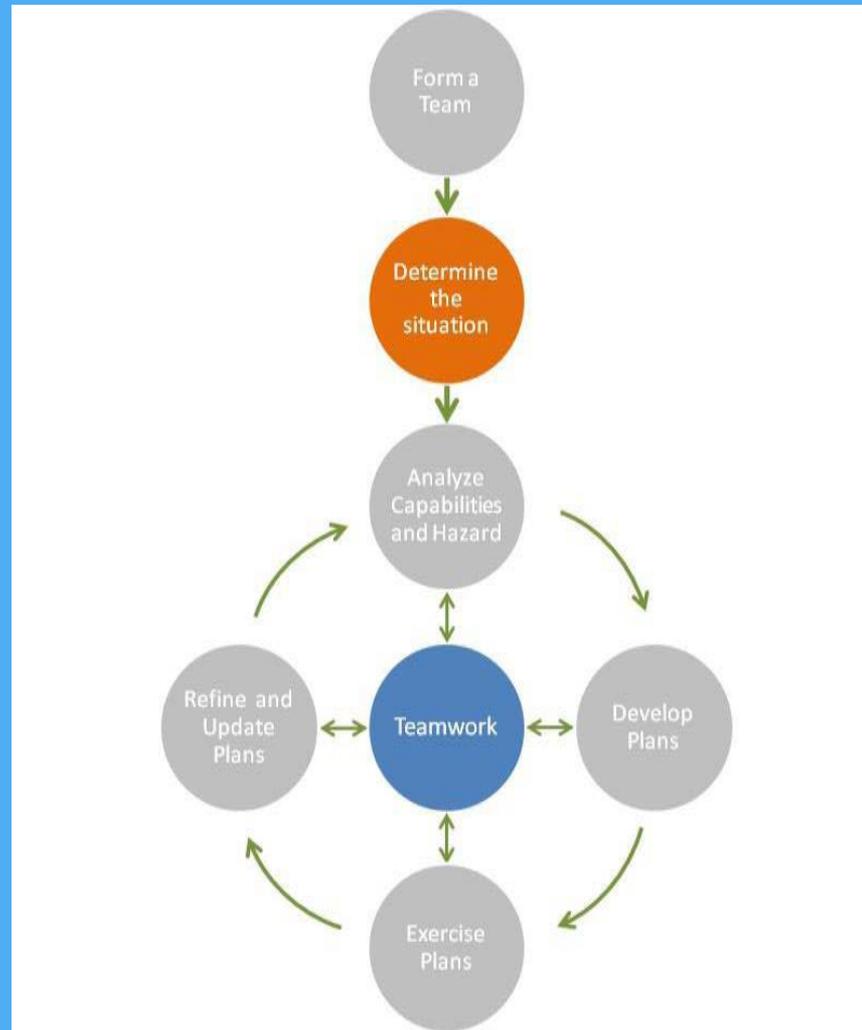
FIVE KEYS TO SUCCESSFUL INCIDENT RESPONSE

- 1) It is focused on protecting human life before property
- 2) It is focused on the impact to the laboratory and not just the facility
- 3) It is the result of collaboration between entity leadership and responders
- 4) The responders participate in entity training
- 5) It addresses the primary effect of the hazard, the secondary effects, and the effect it has on the people who work at the facility

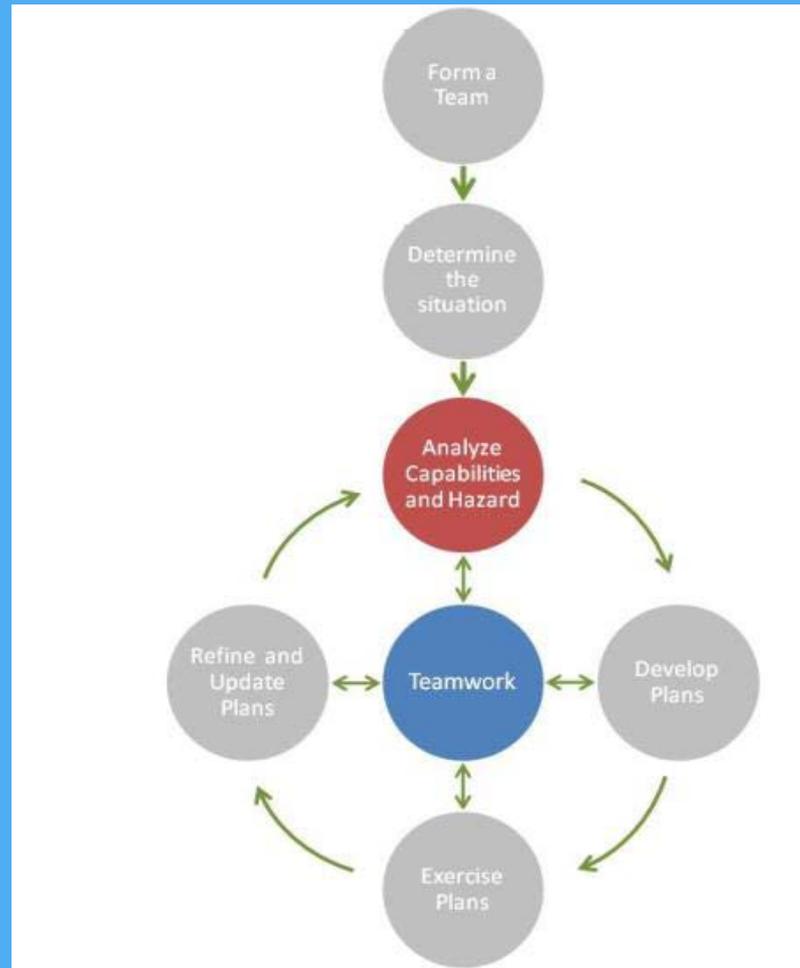
TEAMWORK MAKES THE TEAM WORK



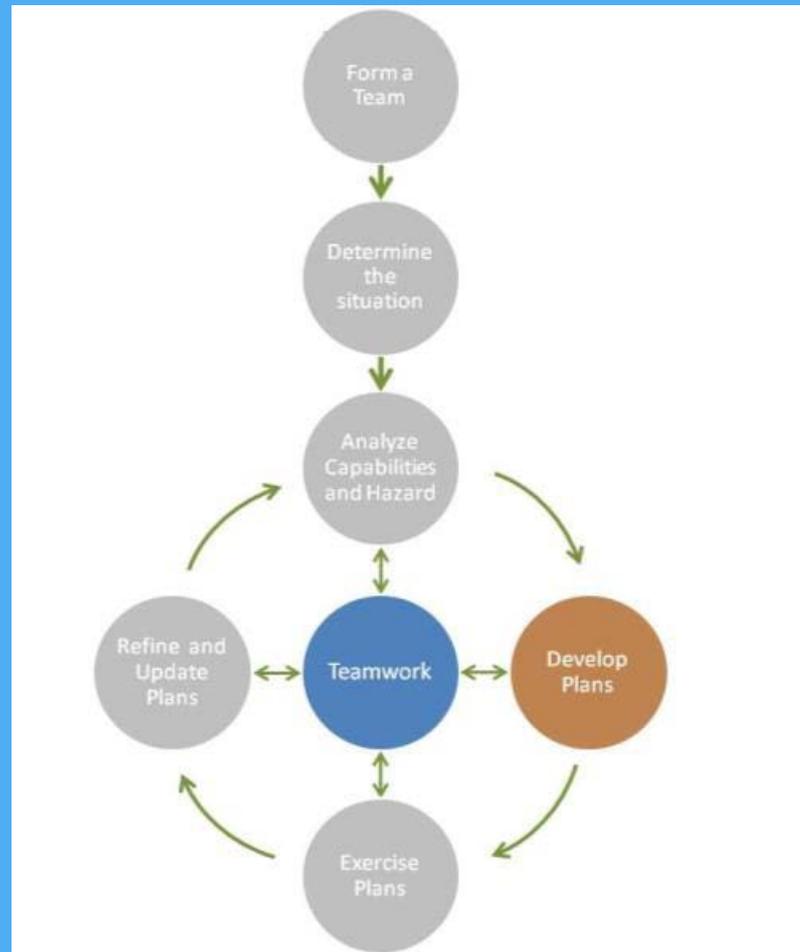
TEAMWORK MAKES THE TEAM WORK (2)



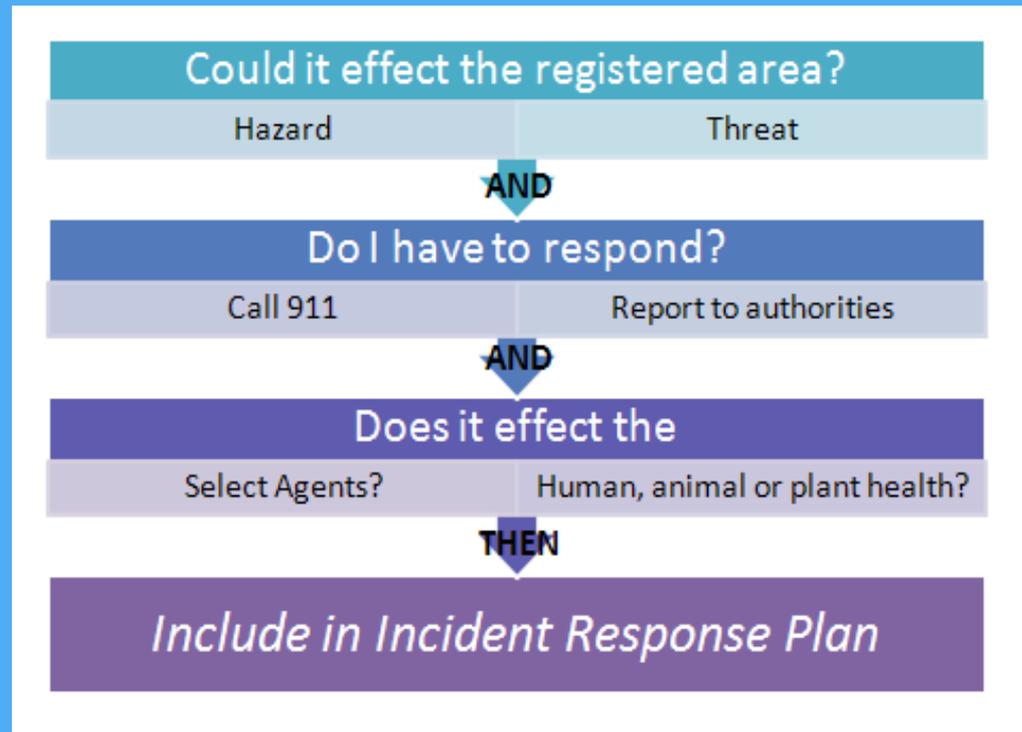
TEAMWORK MAKES THE TEAM WORK (3)



TEAMWORK MAKES THE TEAM WORK (4)



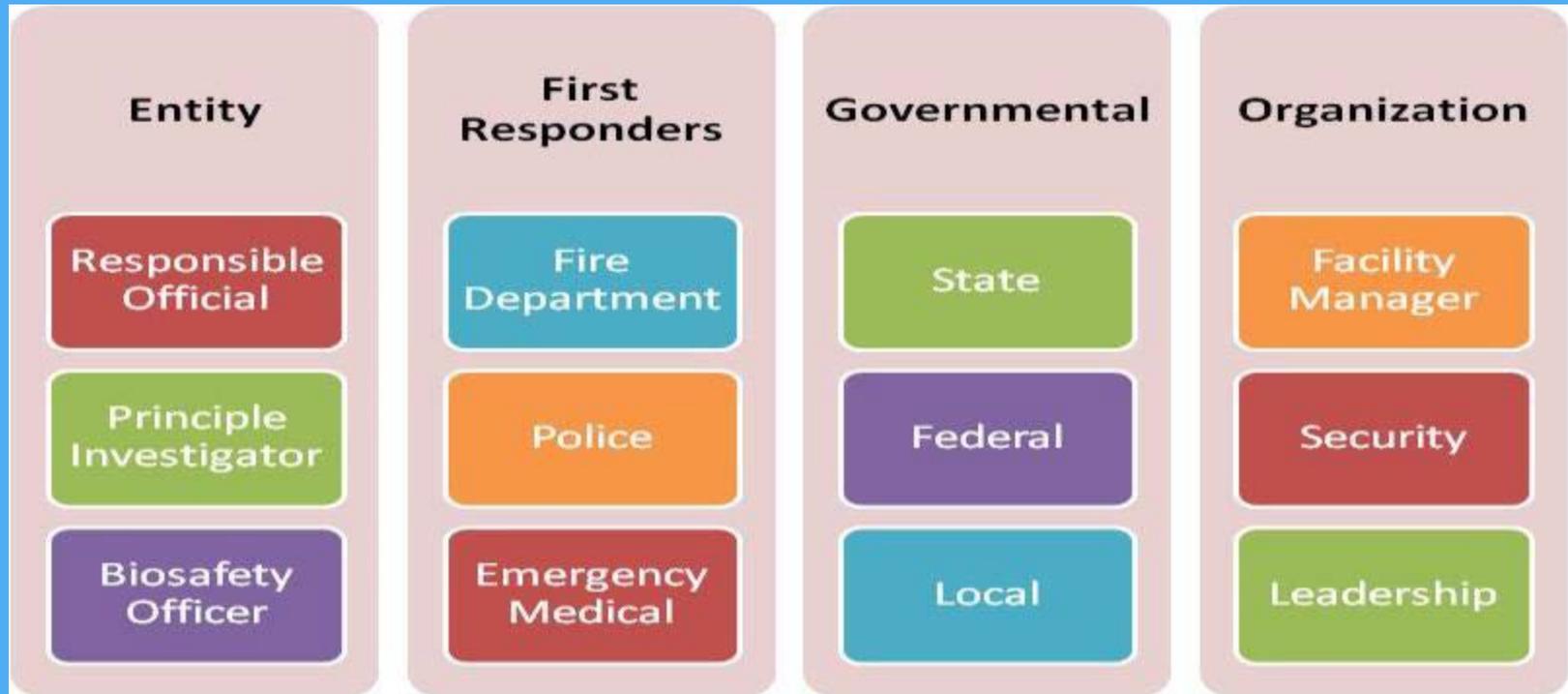
THINGS TO CONSIDER



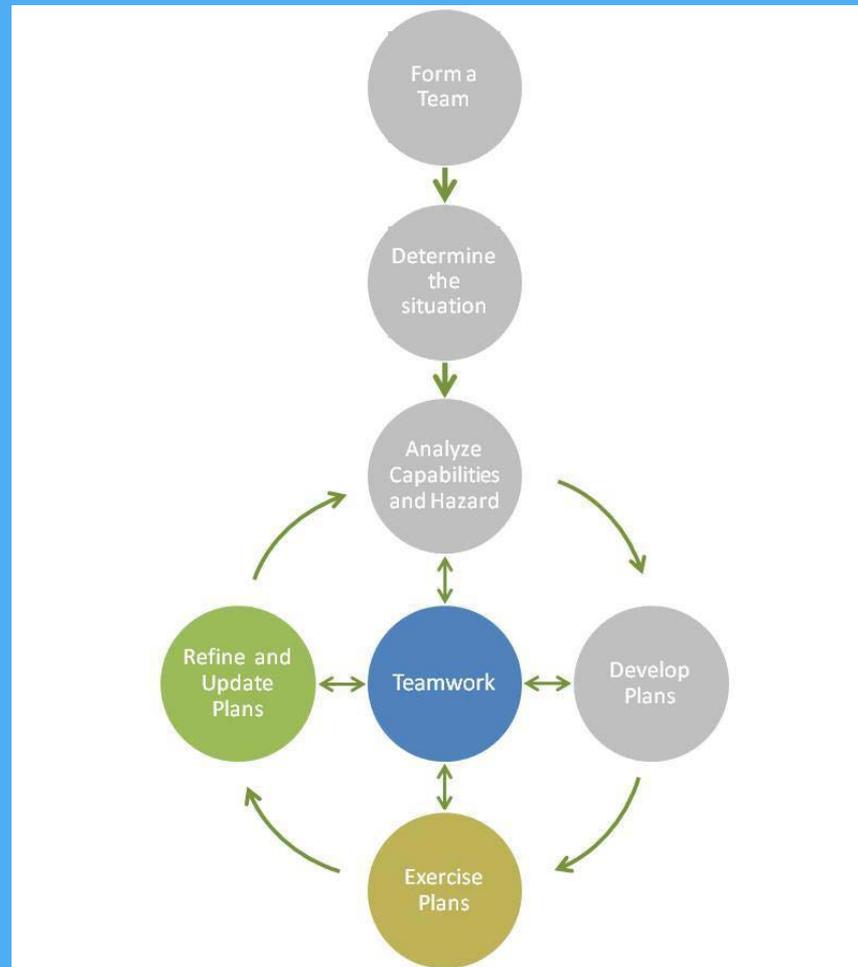
SITE-SPECIFIC RISK ASSESSMENT (Section 14 (a))

- ❑ Describe who was involved in the risk assessment process.
- ❑ Describe the natural and man-made disasters and all possible threats to select agents or toxins and how they were determined.
- ❑ Describe how the disaster could affect the security and state of the select agents or toxins (e.g., power outage could defrost freezers)
- ❑ Describe the consequence of the agent following an incident (e.g., mortality, morbidity, or other measures).
 - Entities are strongly encouraged to use the Risk Assessment Tool <http://www.biosecurity.sandia.gov/BioRAM/>.

TEAMWORK MAKES THE TEAM WORK (5)

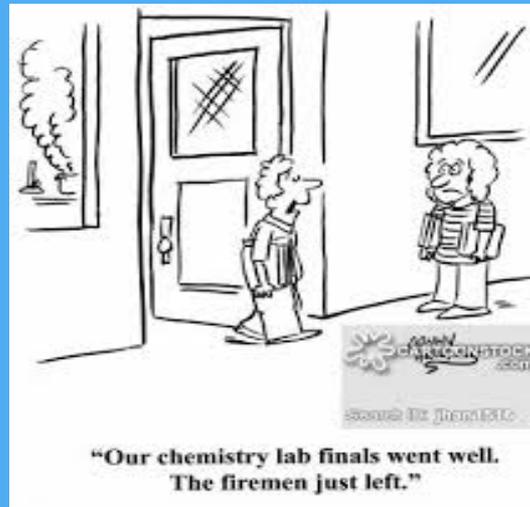


TEAMWORK MAKES THE TEAM WORK (6)



DRILLS AND EXERCISES

- **Drills, Exercise and Annual Review. (Section 14 (f))**
 - The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.



LOW PROBABILITY/HIGH CONSEQUENCE EVENTS



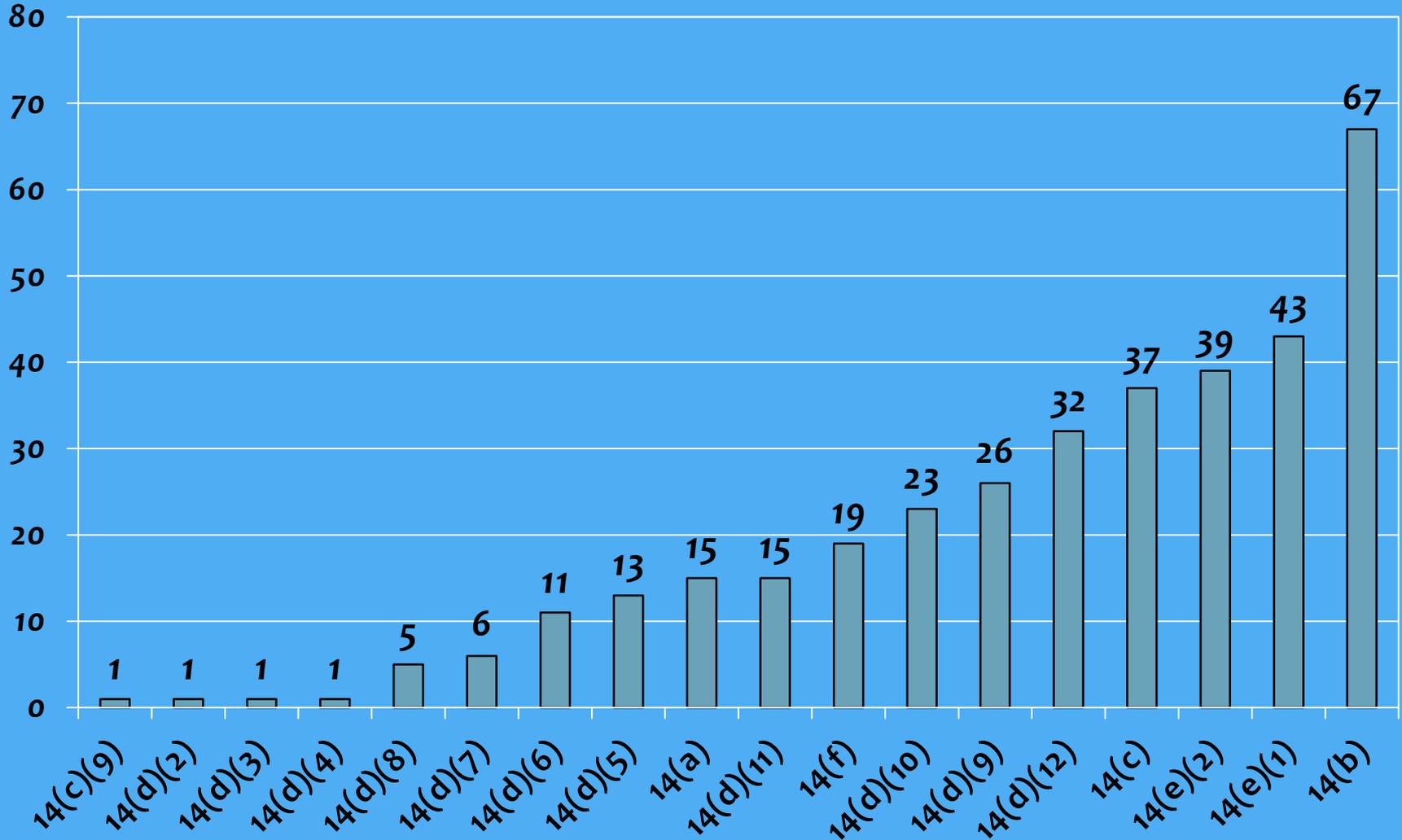
Fertilizer Plant Explosion in Waco, TX

DRILLS AND EXERCISES (2)

Updating Plan:

- ❑ Results of training (what went well, what can be improved, changes made)
- ❑ 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

INCIDENT RESPONSE CITATIONS



42 CFR 73.14(b)

9 CFR 121.14(b)

7 CFR 331.14(b)

- The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, and other natural and man-made events.

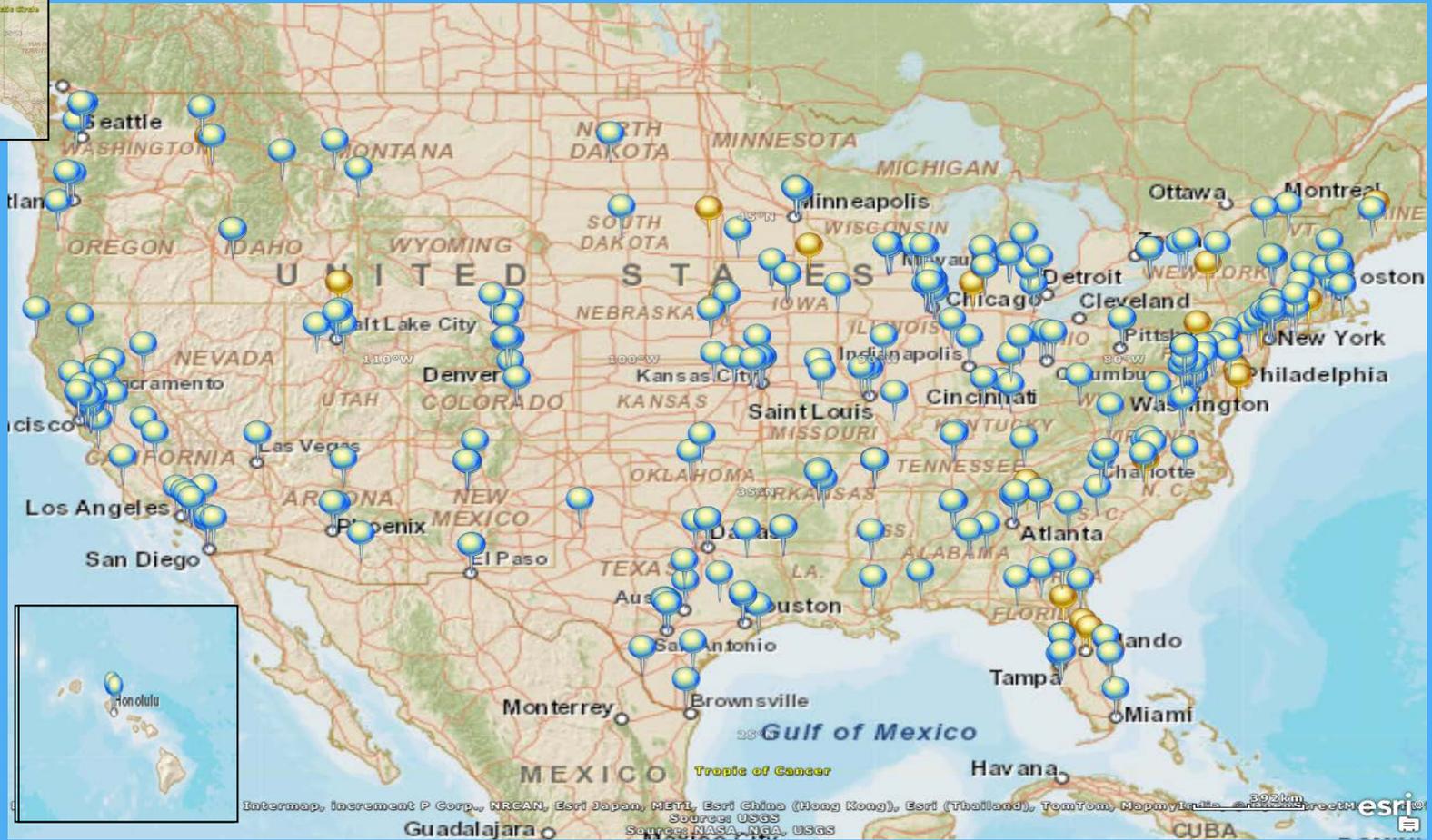
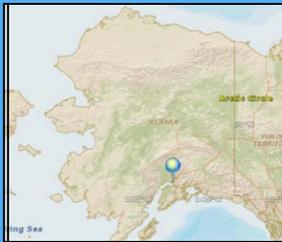
TORNADO (EXAMPLE)

□ **Example of Response Actions:**

- PI/RO and Lab staff will monitor weather.
- When Tornado warning is issued all select agent work stops and select agents are secured and stored safely in registered space.
- All entity staff will remove PPE if in laboratory, and go to nearest shelter in place area.
- When 'all clear' is given entity staff will return to normal operations, noting any damage to the laboratory.
- Entity staff (RO, PI and ARO) will ensure all select agents are safe and secure and have not been compromised.

* The entity should also consider response actions if the building housing select agents is compromised or damaged

FEDERAL SELECT AGENT PROGRAM'S RESPONSE PROCEDURES FOR REGISTERED ENTITIES



Intermap, Increment P Corp., NRCAN, Esri Japan, METI, Esri China (Hong Kong), Esri (Thailand), TomTom, MapmyIndia, © 2013 Esri, All rights reserved. Source: USGS, NOAA, NGA, USGS

NOTIFICATION

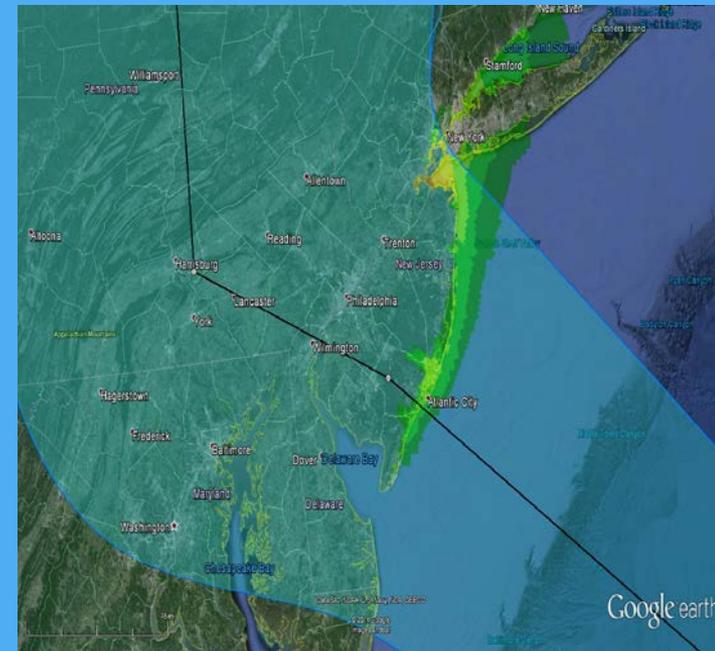
- ❑ **Helps with risk assessment**
- ❑ **Goes to all RO and AROs**
- ❑ **Pre and Post event**
- ❑ **Pre event**
 - Hurricanes, winter storms, sometimes severe weather and fires
 - Lets you know what questions we'll ask after the event
- ❑ **Post event**
 - Lets us know your status
 - Helps us assess risk for surrounding entities

1 YEARS WORTH OF CONTACTS



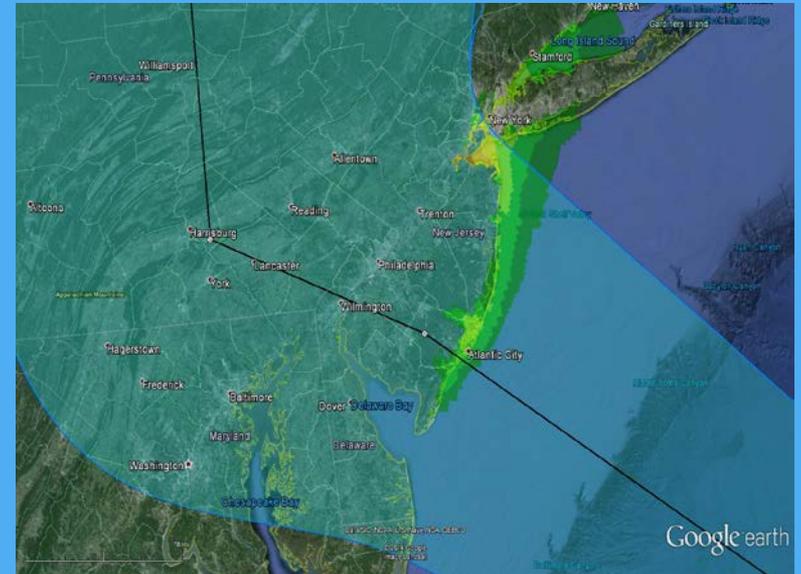
CASE STUDY- HURRICANE SANDY

- ❑ **Pre-storm notification sent out 3 days before landfall.**
- ❑ **We were aware storm surge may impact New York City @ 5pm Sunday, 36 hrs before the storm hit. Directors notified.**
- ❑ **24 hrs before impact, we reviewed the Entity IRPs and began looking for ‘similar’ entities in DE, NJ and NY for possible transfer.**
- ❑ **Also monitoring potential Nor’easter**



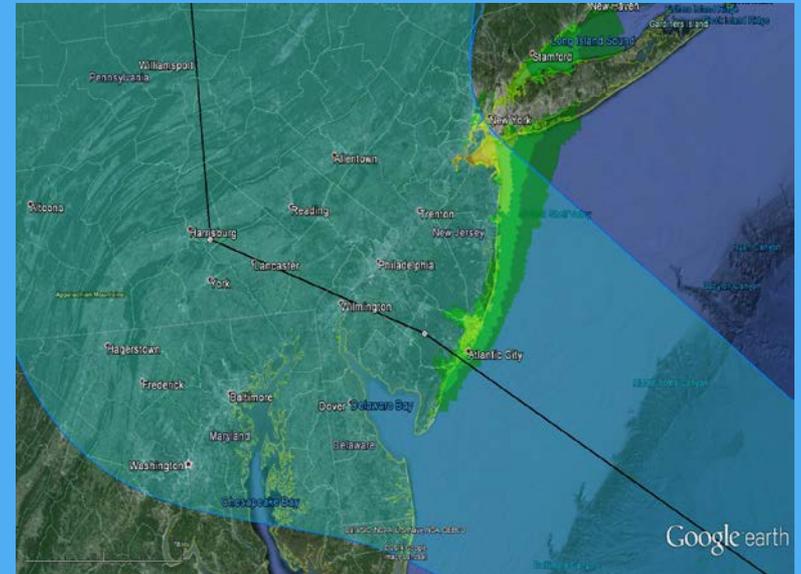
HURRICANE SANDY

- ❑ Began post-storm contacts the day after land fall.
- ❑ Could NOT contact 2 entities in NYC and 1 in NJ.
- ❑ Conducted impact assessments (2 were in the surge zone, 1 was in a power outage).
- ❑ Continued to refine peer entities.



HURRICANE SANDY (2)

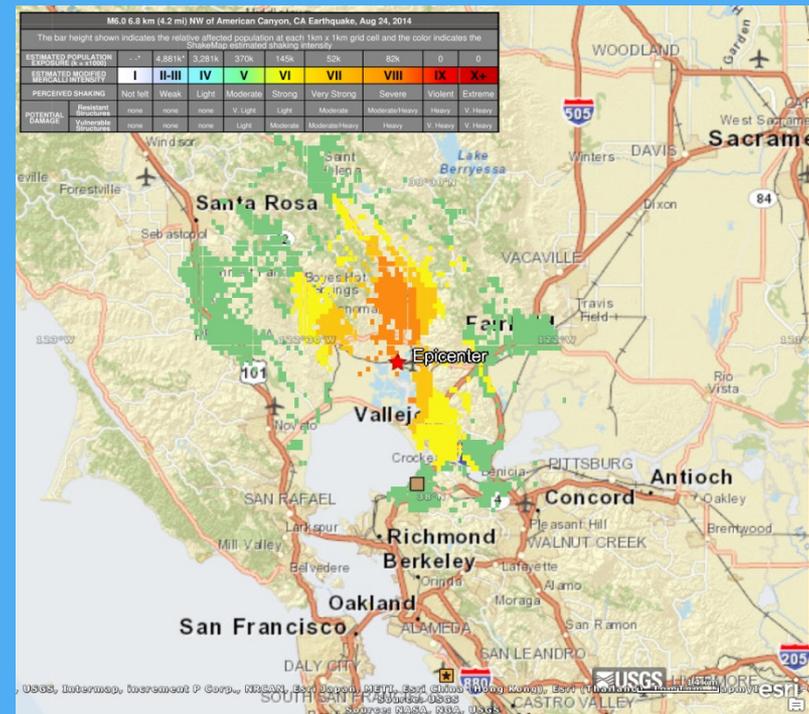
- ~48 hours after storm, contacted the 3 entities, 1 had 'serious' issues.
- Began Nor'easter contacts
- Coordinated with similar entity for the 1 with issues.
- 96 hours after landfall, entity with issues elected not to transfer agents.



CASE STUDY- NAPA EARTHQUAKE

- Sunday, 24 August 7:20 am Eastern: Earthquake
- 8am: USGS notification
- 8:15 am: Modeled damage assessment from USGS- no entities in the “Strong” area. No entities with active work in “moderate” area.
- 8:40 am: Email to directors, recommending monitoring but no contacts.

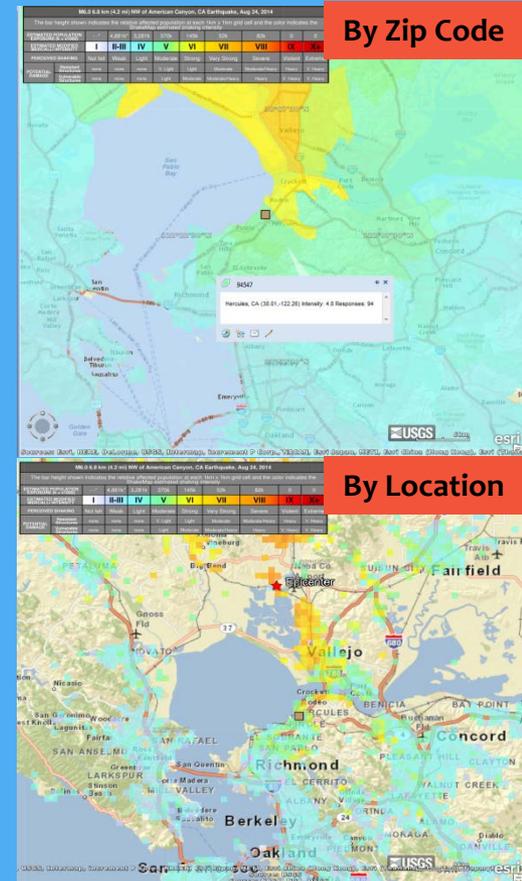
USGS Modelled Damage Assessment



NAPA EARTHQUAKE

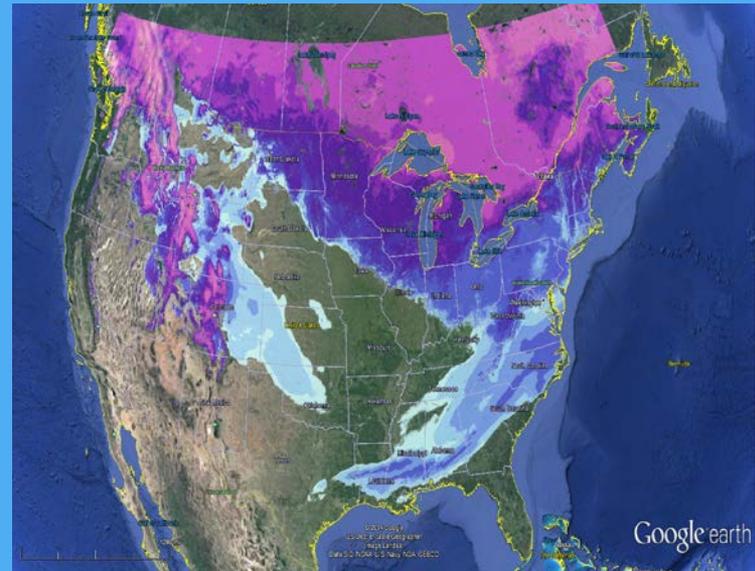
- Periodically: Checked damage reports. No indications warranting contacts.
- Tuesday: Final damage reports in, contacted 2 entities

Actual Damage Reports



CASE STUDY- SNOWMAGEDON 2014 RESPONSE

- ❑ Snow from Texas to Maine
- ❑ Snow is a 'rare' event for some locations- 97th percentile for Atlanta.
- ❑ CDC and AgSAS closed for 3 days
- ❑ Many Entities in the SE closed as well



SNOWMAGEDON 2014 RESPONSE

- ❑ **Monitored from home.**
- ❑ **Rolling responses as the storm moved north based on modeled US Weather Service data.**
- ❑ **Ready to support transfers if needed.**
- ❑ **SA-Grams produced from home.**
- ❑ **Response procedures went as normal- business as usual, though not from the office.**

EXAMPLE STORM DAMAGE

The image is a screenshot of the Google Earth desktop application. The main map area shows a satellite view of Michigan and the surrounding Great Lakes region. A yellow line traces a path across the state, indicating the path of a storm. Several locations are marked with red pins and labels: "Heavy Rain" near Saginaw Bay, "Thunderstorm Wind Damage" near Lansing, "Thunderstorm Wind Gust" near Battle Creek, and "Tornado" near Troy. Other cities visible include Grand Rapids, Holland, Ann Arbor, Detroit, Toledo, Cleveland, and Elyria. A white popup window is centered over the "Tornado" location, containing the following text:

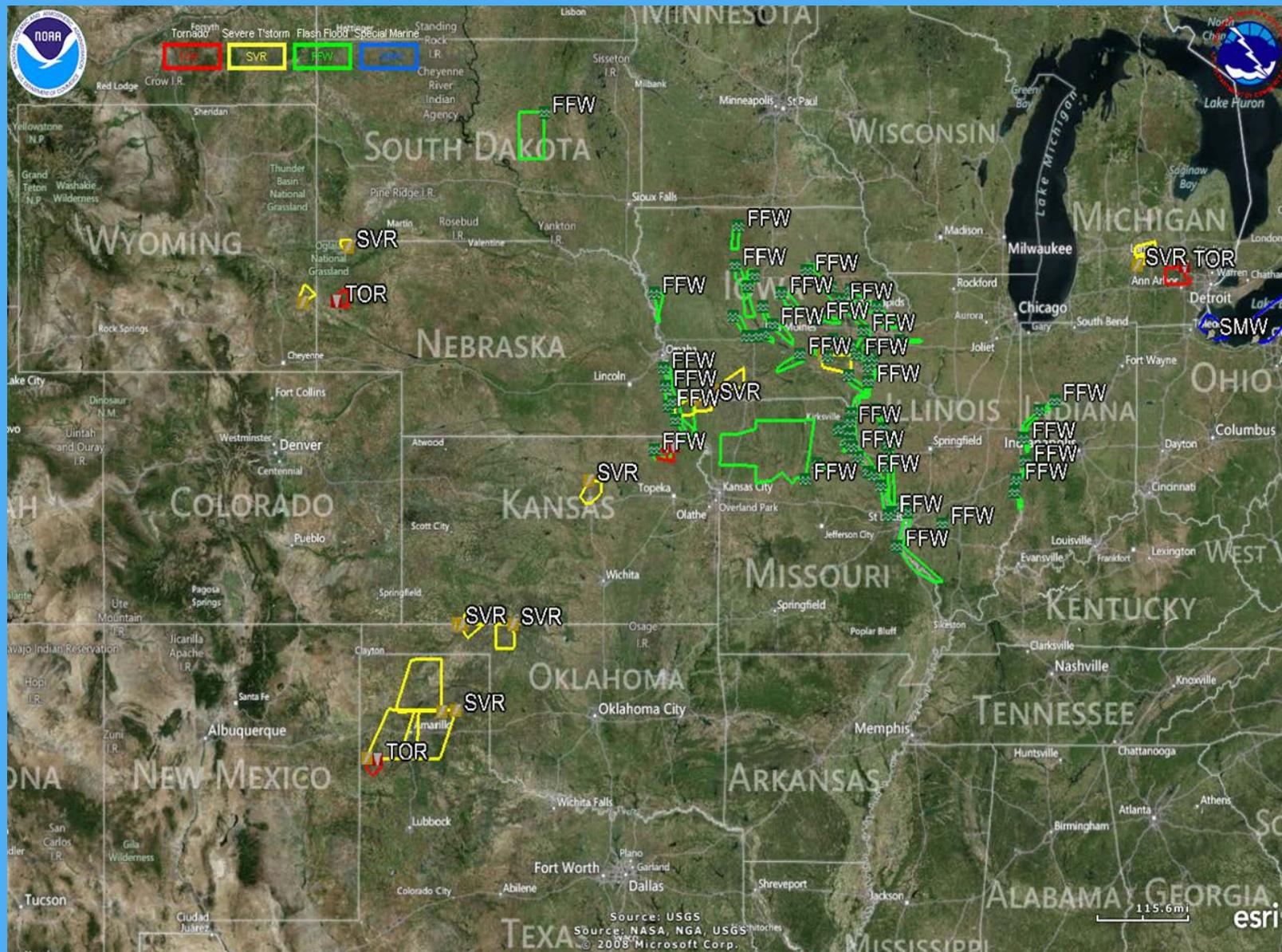
Tornado
Local Time: 5:57 AM EDT (21 Sep 2014)
UTC Time: 0957Z (21 Sep 2014)
Place: 3 WNW ROCHESTER
County: OAKLAND
State: MI
Source: NWS STORM SURVEY
Magnitude:

THE TORNADO STARTED NEAR LAMBETH PARK AND NEW KENT ROAD AND TRACKED EAST-NORTHEAST, ENDING NEAR WEST RIDGE DRIVE AND SPRING CREEK ROAD. THE TORNADO IS RATED EF-1 WITH MAXIMUM WIND GUSTS OF 90 MPH. MAXIMUM PATH WIDTH WAS 150 YARDS AND PATH LENGTH WAS 1 1/4 MILES. STRONGEST DAMAGE WAS BETWEEN GRANDVIEW AND FAIRLANE DRIVES WITH PARTIAL ROOF TORN OFF OF HOUSE AND SEVERAL TREES WERE DOWNED ALONG THE PATH. THE TORNADO LIFTED AT 559 AM.

[Directions: To here](#) - [From here](#)

The left sidebar shows the "Places" panel with a tree view of saved locations and layers. The "Layers" panel at the bottom left shows various weather-related layers like "Storm Damage", "Thunderstorm Wind Gust", and "Heavy Rain". The bottom status bar displays the "Imagery Date: 4/9/2013" and "Image Landsat © 2014 Google Image NOAA". The system tray at the very bottom shows the time as 11:21 AM on 9/22/2014.

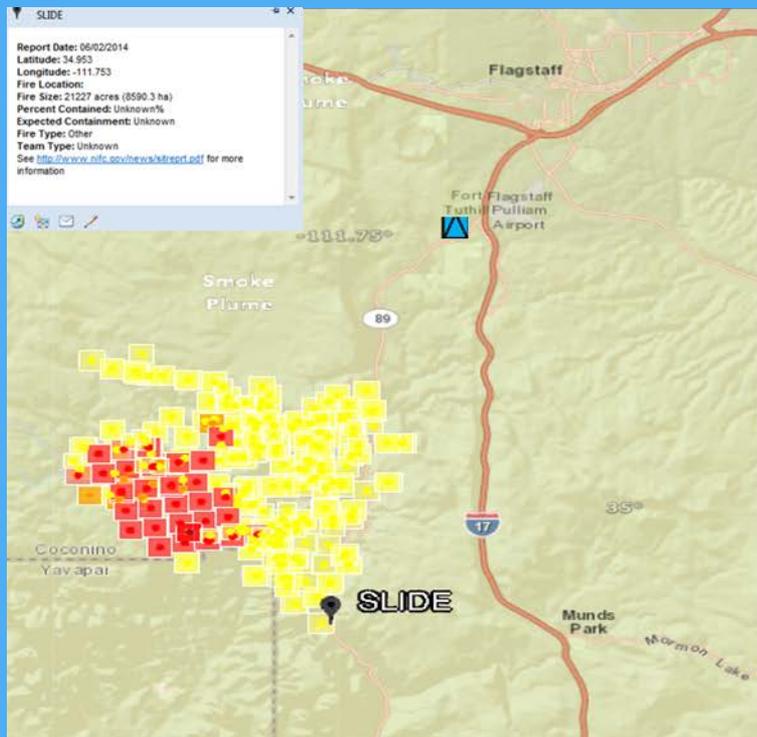
EXAMPLES OF STORM WARNING TYPES



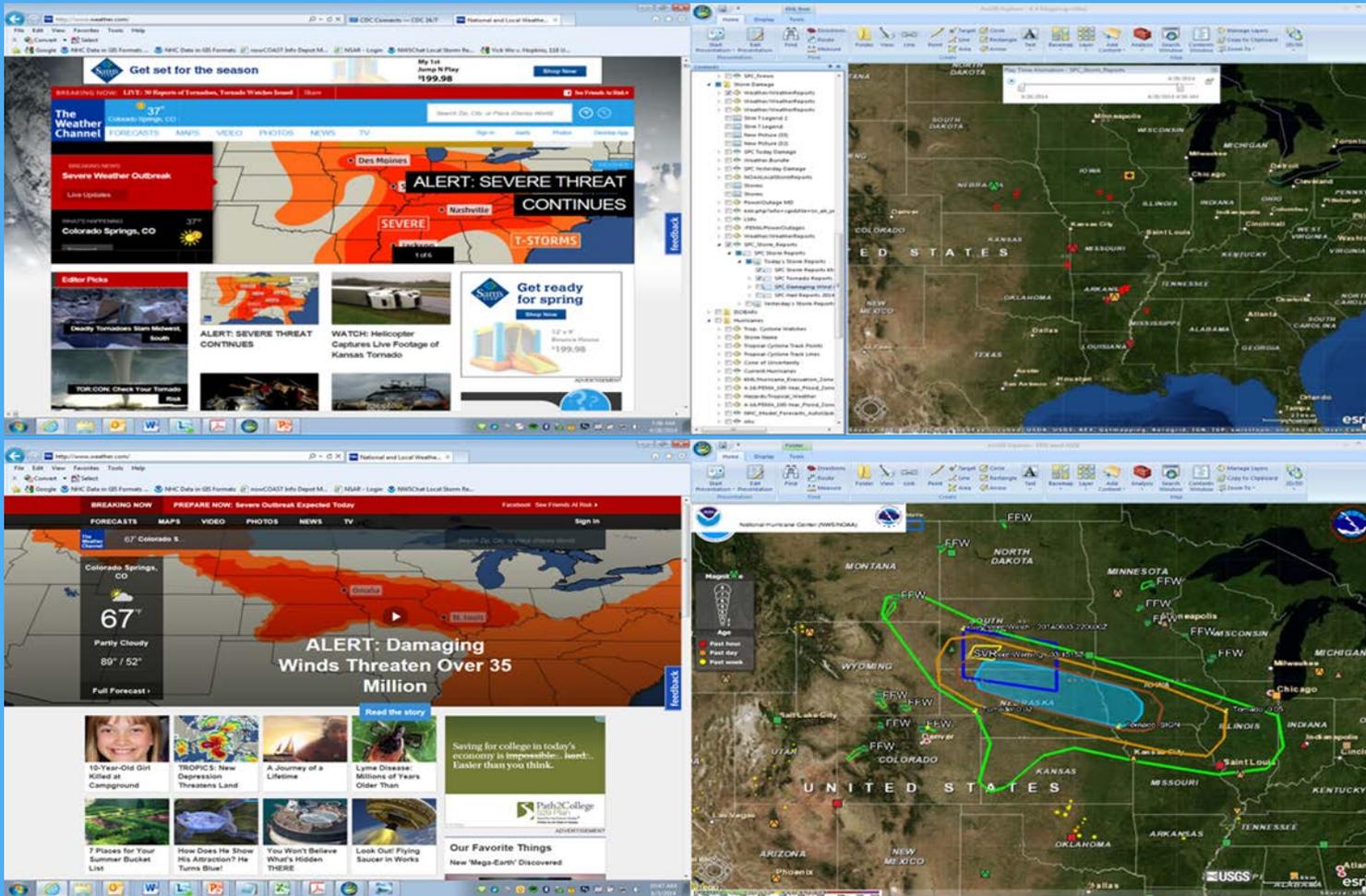
EXAMPLE FIRE

Current Hotspots

Smoke



EXAMPLE TORNADO/SEVERE WEATHER



RESPONSE TAKE-AWAYS

- ❑ **We are proactively managing events to ensure the safe and secure possession of select agents and toxins**
 - You should do the same
- ❑ **We work to minimize burden on you by contacting only when needed.**
 - Information received from sources are fact-based and focused on the area affected.
- ❑ **We are working to assist you before you ask.**
 - Finding peer entities
 - Preparing to support transfers
- ❑ **We use the best data available.**

CFR Section 11(f)(4)(viii)

□ **The entity must:**

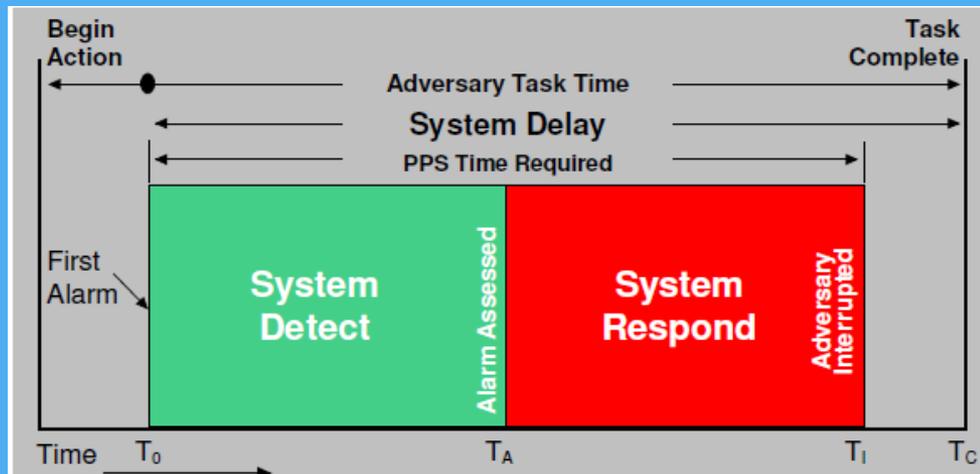
- Determine that the response time for security forces or local police will not exceed 15 minutes or
- Provide security barriers that are sufficient to delay unauthorized access until the response force arrives in order to safeguard the select agents and toxins from theft, intentional release, or unauthorized access.
- The response time is measured from the time of an intrusion alarm, or report of a security incident, to the arrival of the responders at the first security barrier.

CFR Section 11(f)(4)(viii) (cont.)

- ❑ **More and more police departments are NOT reacting to home security alarms at all!**
 - Detroit
 - Las Vegas
 - Indianapolis
 - Orange County CA
- ❑ **Response time for an alarm in Orange County was 24 hours.**
- ❑ **Police do have priority alarms or potentially dangerous alarms**
 - Banks
 - Pharmacies
 - Gun shops

CFR Section 11(f)(4)(viii) DELAY TIME

- ❑ Barriers don't stop anyone, they just slow them down
- ❑ Response force stops (interrupts) a threat
- ❑ Barriers should slow down a threat long enough for a response force to arrive



CFR Section 11(f)(4)(viii) Response Force

- The response force can be:
 - Police
 - Personnel trained to respond
 - Observe/Report to neutralize



QUESTIONS?

REVIEW OF RECENT BIOSAFETY INCIDENTS AND ANALYSIS OF SELECT AGENT EXPOSURE INCIDENTS: 2005-2012

Richard Henkel, PhD, Mark Hemphill, MS, and Robbin
Weyant, PhD

Division of Select Agents and Toxins
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention



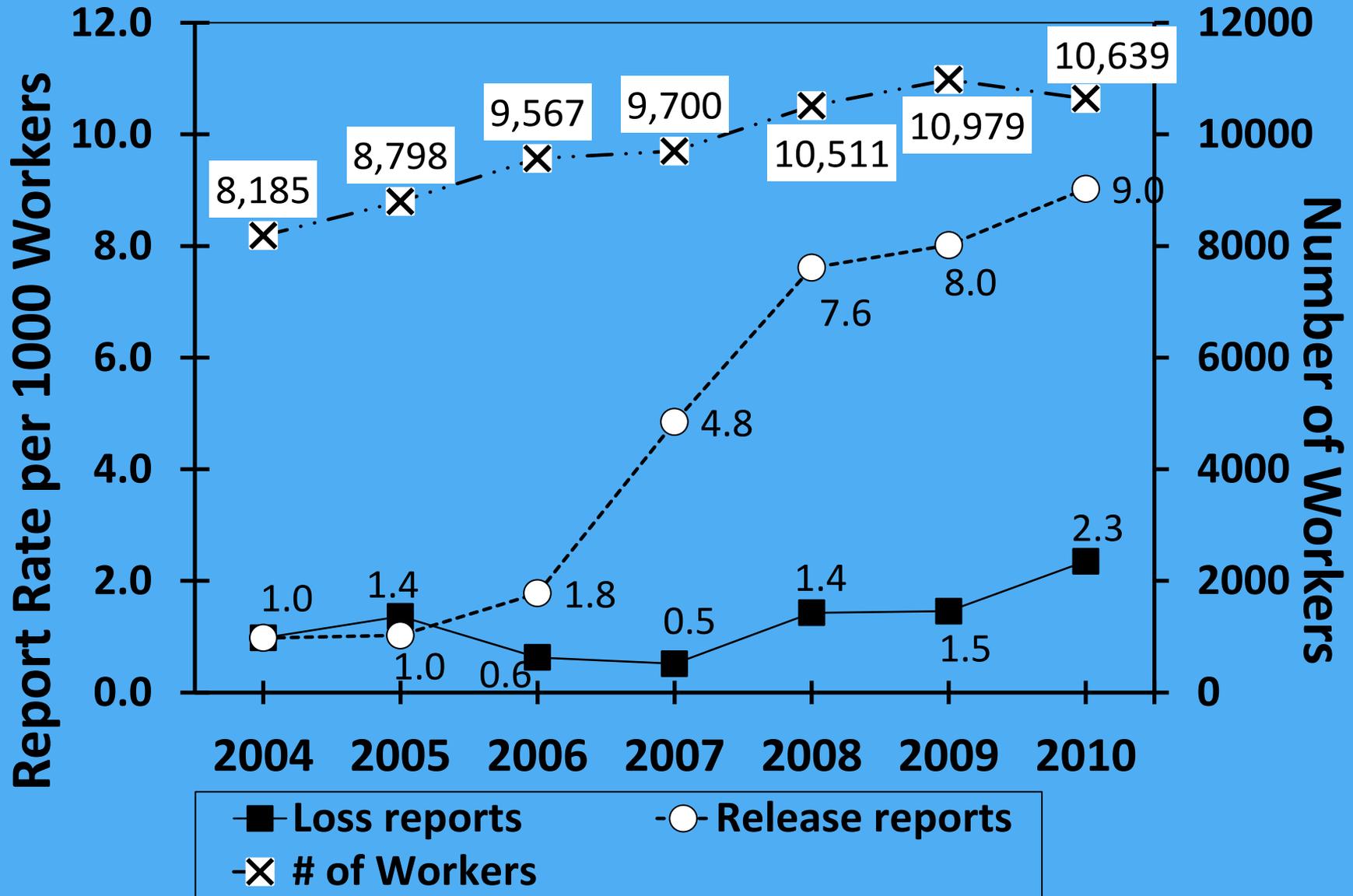
SELECT AGENT REGULATIONS: SECTION 19*

- *(a) Upon the discovery of the theft or loss of a select agent or toxin, an individual or entity must immediately notify CDC or APHIS and the appropriate Federal, State, or local law enforcement agencies. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.*
- *(b) Upon discovery of the release of an agent or toxin causing occupational exposure , or release of the select agent or toxin outside of the primary barriers of the biocontainment area, an individual or entity must immediately notify CDC or APHIS.*

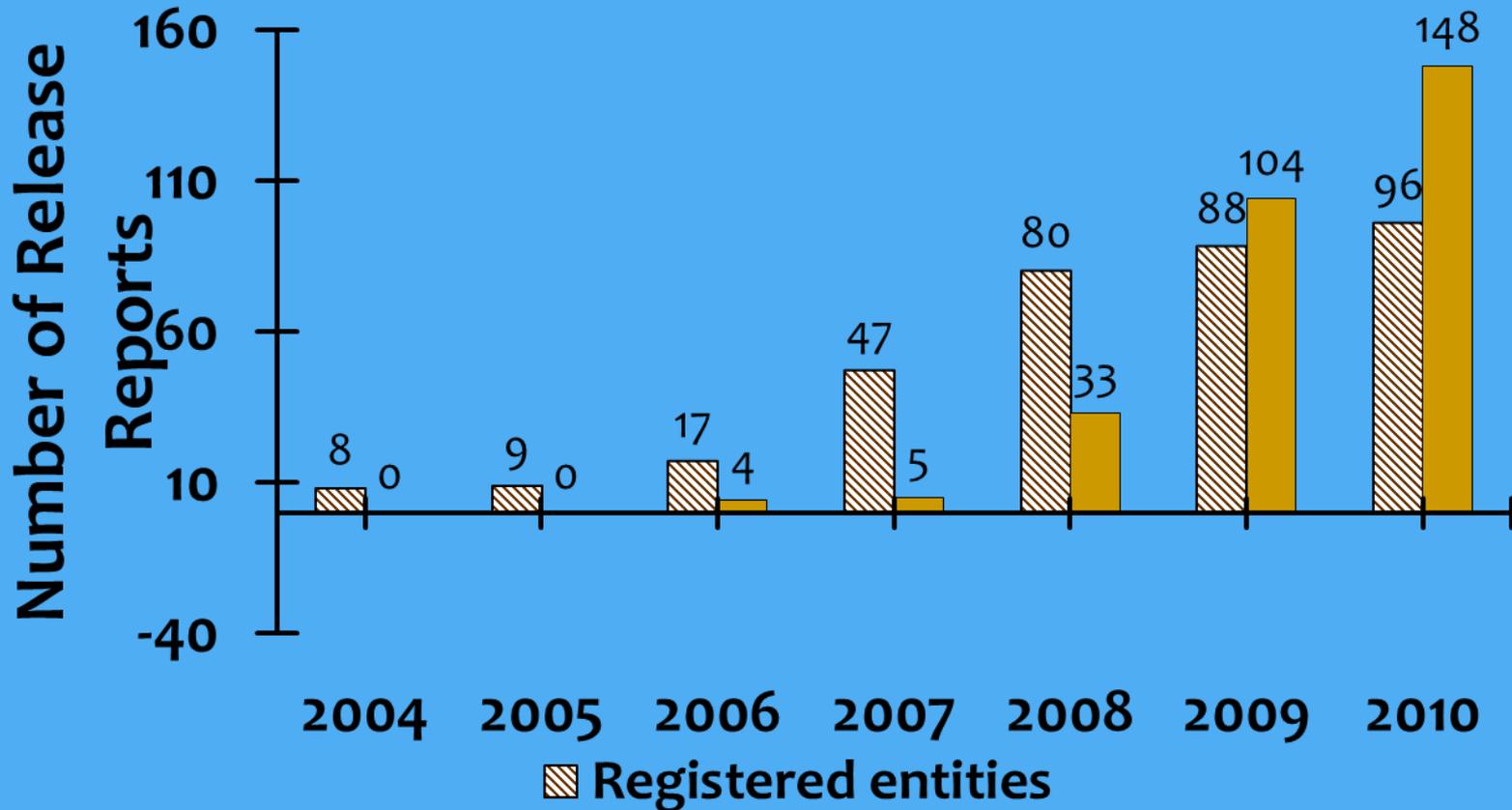
*42 CFR Part 73

ANNUAL RATES OF FORM 3 SUBMISSIONS TO CDC PER 1000 WORKERS

(HENKEL ET AL. APPL. BIOSAFETY 2012)



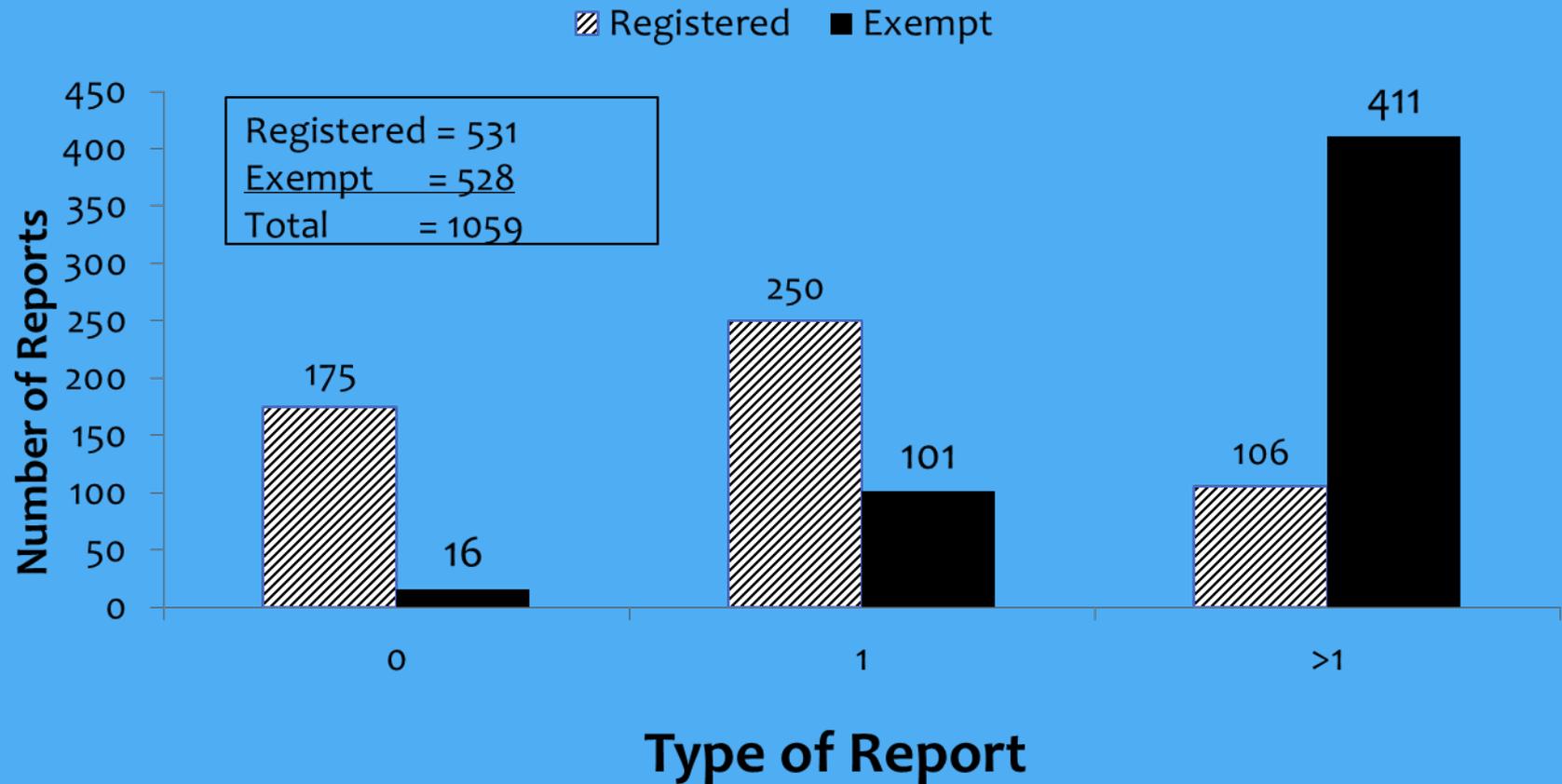
RELEASE REPORTS SUBMITTED TO CDC 2004-2010 (HENKEL ET AL., APP BIOSAFETY 2012)



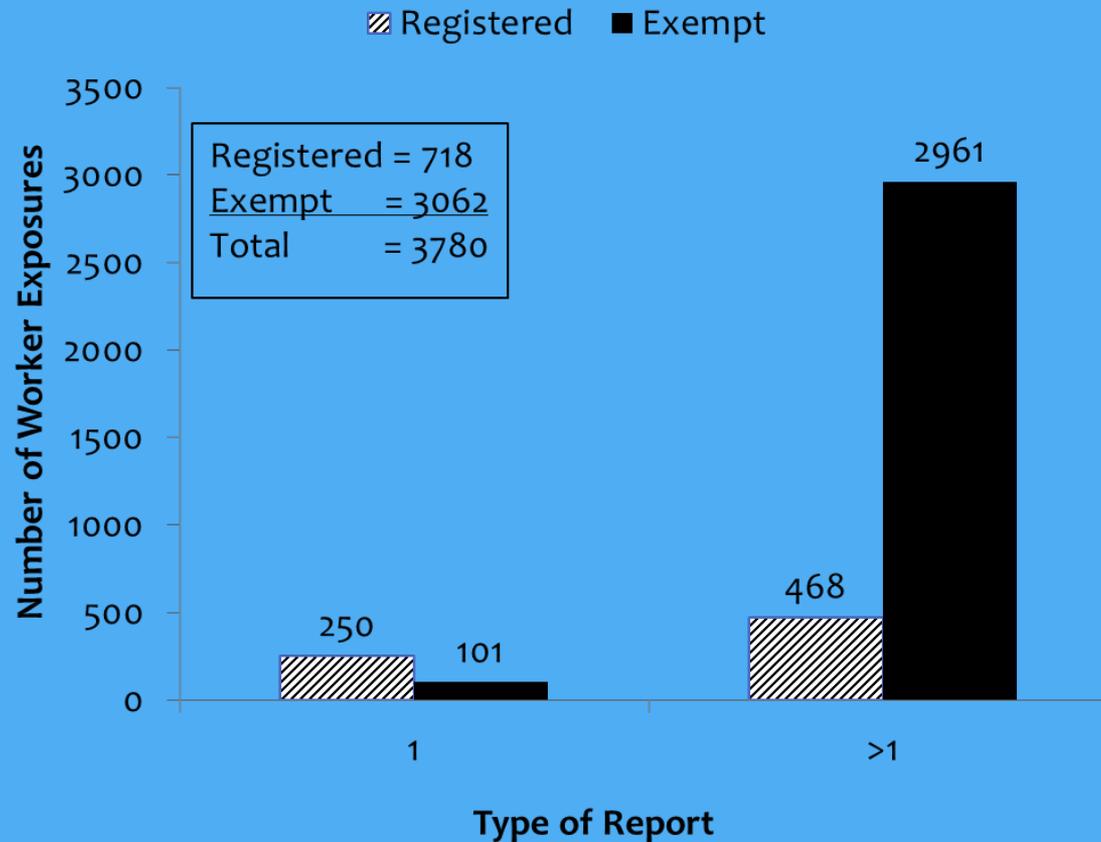
BSAT FORM 3 RELEASE REPORTS SUBMITTED TO CDC 2005-2012

- **1059 reports**
 - **531 from registered entities**
 - **528 from exempt entities**
- **3780 potential worker exposures**
- **10 Laboratory acquired infections (LAIs)**

NUMBER OF RELEASE REPORTS SUBMITTED TO CDC 2005-2012



POTENTIAL WORKER EXPOSURES IN FORM 3 RELEASE REPORTS SUBMITTED TO CDC 2005-2012



BIOCONTAINMENT LEVELS FOR INCIDENTS INVOLVING SINGLE (1) AND MULTIPLE (>1) INDIVIDUALS AT RISK FOR EXPOSURE: REGISTERED ENTITIES 2005-2012

Laboratory Type	1	>1		Total (1, >1)	
	Reports/exposures	Reports	Exposures	Reports	Exposures
BSL 1	0	0	0	0	0
BSL 2	32	42	255	74	287
BSL 3	97	48	150	145	247
BSL 4	20	0	0	20	20
ABSL1	0	2	7	2	7
ABSL 2	6	1	2	7	8
ABSL 3	87	12	52	99	139
ABSL 4	6	0	0	6	6
BSL 3 Ag	2	1	2	3	4
Total	250	106	468	356	718

BIOCONTAINMENT LEVELS FOR INCIDENTS INVOLVING SINGLE (1) AND MULTIPLE (>1) INDIVIDUALS AT RISK FOR EXPOSURE: EXEMPT ENTITIES 2005-2012

Laboratory Type	1	>1		Total (1, >1)	
	Reports/exposures	Reports	Exposures	Reports	Exposures
BSL 1	0	4	21	4	21
BSL 2	95	382	2797	477	2892
BSL 3	5	20	122	25	127
BSL 4	0	0	0	0	0
ABSL1	0	1	5	1	5
ABSL 2	1	4	16	5	17
ABSL 3	0	0	0	0	0
ABSL 4	0	0	0	0	0
BSL 3 Ag	0	0	0	0	0
Total	101	411	2961	512	3062

ACTIVITIES ASSOCIATED WITH INCIDENTS INVOLVING SINGLE (1) AND MULTIPLE (>1) INDIVIDUALS AT RISK FOR EXPOSURE: REGISTERED ENTITIES 2005-2012

Activity	1	>1		Total (1, >1)	
	Reports/exposures	Reports	Exposures	Reports	Exposures
LOC*	47	49	278	96	325
Procedural Failure	22	13	58	35	80
Spill	35	27	71	62	106
Needle/Sharp Injury	80	2	8 ^b	82	88
Equipment Failure	14	14	51	28	65
Personal Protective Equipment (PPE) Failure	28	1	2	29	30
Animal Injury	24	0	0	24	24
Total	250	106	468	356	718

*LOC = Loss of containment

ACTIVITIES ASSOCIATED WITH INCIDENTS INVOLVING SINGLE (1) AND MULTIPLE (>1) INDIVIDUALS AT RISK FOR EXPOSURE: EXEMPT ENTITIES

Activity	1	>1		Total (1, >1)	
	Reports/exposures	Reports	Exposures	Reports	Exposures
LOC*	93	404	2905	497	2998
Procedural Failure	1	4	44	5	45
Spill	2	3	12	5	14
Needle/Sharp Injury	2	0	0	2	2
Equipment Failure	0	0	0	0	0
PPE Failure	0	0	0	0	0
Animal Injury	3	0	0	3	3
Total	101	411	2961	512	3062

*LOC = Loss of containment

SELECT AGENTS AND TOXINS ASSOCIATED WITH SINGLE (1) AND MULTI-EXPOSURE INCIDENTS (>1): REGISTERED ENTITIES

Select Agents	1	>1		Total (1, >1)	
	Reports/ exposures	Reports	Exposures	Reports	Exposures
<i>Brucella</i> species	37	36	182	73	219
<i>Bacillus anthracis</i>	39	13	69	52	108
<i>Francisella tularensis</i>	37	17	66	54	103
Viral agents	65	11	29	76	94
<i>Yersinia pestis</i>	32	14	56	46	88
<i>Clostridium botulinum</i>	11	6	19	17	30
<i>Coccidioides</i> sp.	8	6	18	14	26
<i>Burkholderia</i> sp.	15	4	10	19	25
Total =	244	107	449	351	693

SELECT AGENTS AND TOXINS ASSOCIATED WITH SINGLE (1) AND MULTI-EXPOSURE INCIDENTS (>1): EXEMPT ENTITIES

BSAT	1	>1		Total (1, >1)	
	reports/ exposures	reports	exposures	reports	exposures
<i>Brucella</i> sp.	28	185	1842	213	1870
<i>F. tularensis</i>	40	119	550	159	590
<i>Coccidioides</i> sp.	26	66	290	92	316
<i>Burkholderia</i> sp.	2	24	121	26	123
<i>Y. pestis</i>	2	6	54	8	56
Viral agents	1	4	32	5	33
<i>C. botulinum</i>	1	1	4	2	5
<i>B. anthracis</i>	0	1	2	1	2
Total =	100	406	2895	506	2995

SUMMARY OF FINDINGS

- *Form 3 reports submitted to CDC from 2005 through 2012 = 1059*
 - *531 from registered entities*
 - *528 from exempt entities*
- *Potential exposures reported = 3780*
 - *81% occurred at exempt entities*
 - *Registered entities: typically single exposure events (70%)*
 - *Exempt entities: typically multiple exposure events (80%)*
- *Bacterial and mycotic select agents and toxins were most commonly involved in exposure incidents*
- *Most common laboratory type involved in an incident: BSL-2 at an exempt entity (77% of potential exposures reported)*
- *Most common activity associated with potential exposures: working outside of containment (45% registered lab incidents; 98% exempt lab incidents)*
- *Laboratory acquired infections with select agents and toxins = 10; 5 in registered entities and 5 in exempt entities. Approximate registered entity annual LAI rate/worker in a registered lab < 0.0005 (5 confirmed LAIs per 10,000 workers over 7 years).*

RECENT BIOSAFETY INCIDENTS AT U.S. GOVERNMENT INSTITUTIONS

2

[HTTP://WWW.CDC.GOV/OD/SCIENCE/INTEGRITY/DOCS/FINAL_ANTHRAX_REPORT.PDF](http://www.cdc.gov/od/science/integrity/docs/final_anthrax_report.pdf)

□ ***Centers for Disease Control and Prevention***

- *June 6-13 Bacillus anthracis*
- *March - July 9 Avian influenza H5N1*

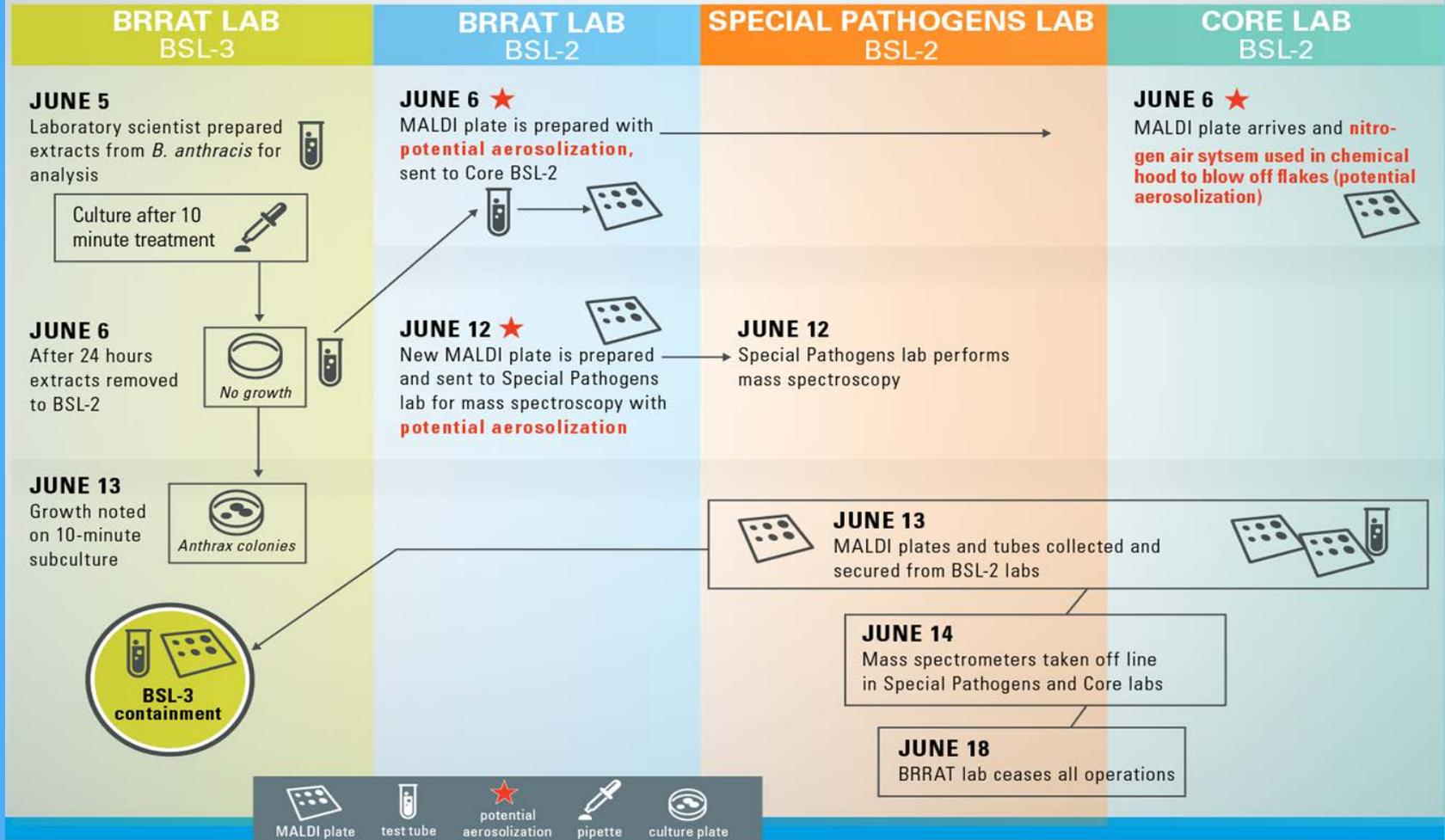
□ ***Food and Drug Administration***

- *July 2 discovery of Variola virus at FDA facility on National Institute of Health campus*

RECENT CDC LABORATORY INCIDENT

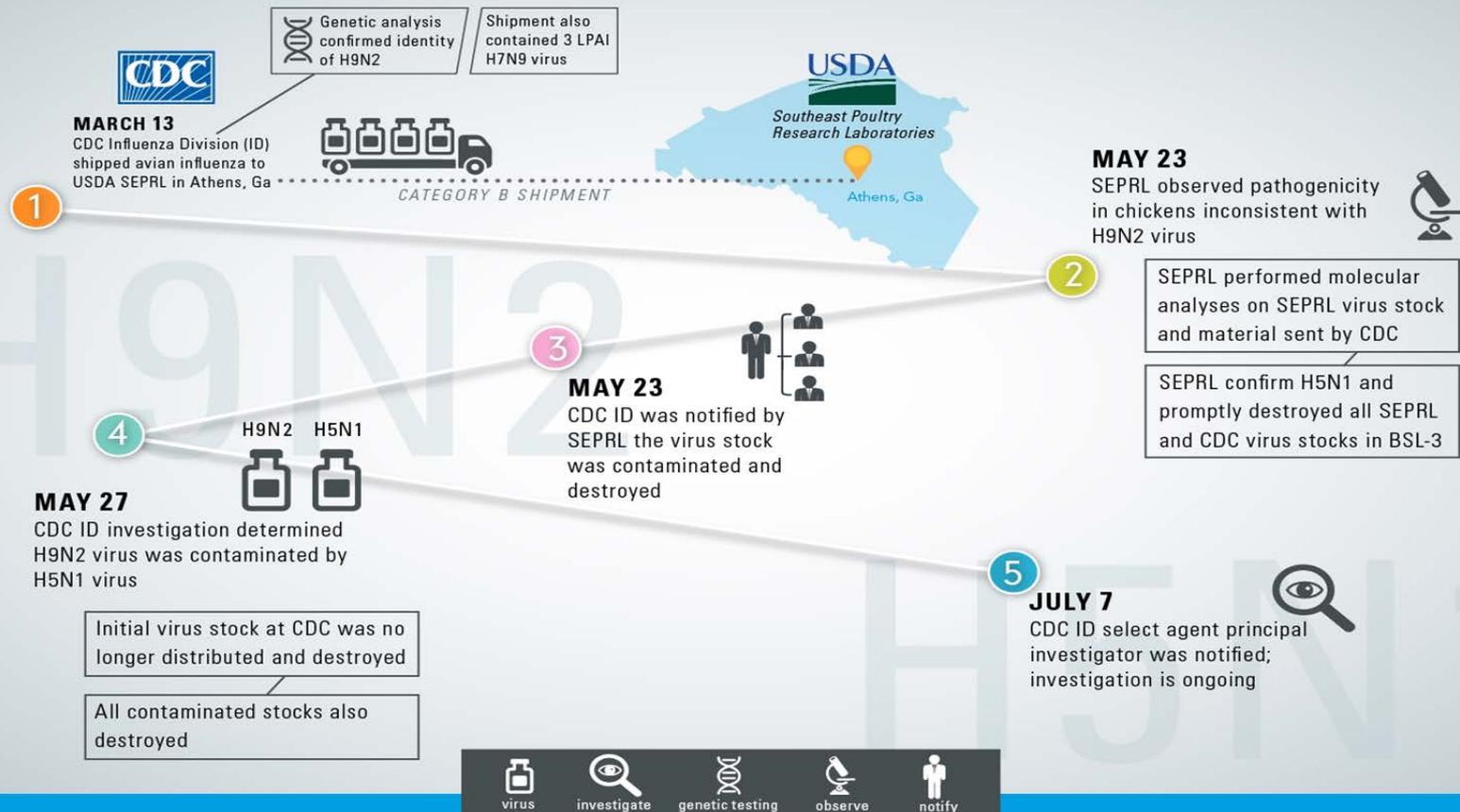
CDC LABORATORY INCIDENT

TIMELINE OF MAJOR EVENTS



TIMELINE OF CDC CONTAMINATED SAMPLE SHIPMENT INCIDENT

CDC SHIPMENT TO USDA LABORATORIES CONTAMINATED



U.S.G. RESPONSES TO 2014 LABORATORY BIOSAFETY INCIDENTS

□ CDC

- *Closure of laboratories involved in influenza and anthrax incidents*
- *Moratorium on distribution of infectious materials from CDC high and maximum containment laboratories*
- *Establishment of senior single point of contact for lab safety*
- *Establishment of external advisory committee for lab safety*
- *Review of inactivation procedures*
- *Use of CDC Incident Command System for future lab incidents*

□ NIH and FDA

- *Clean sweep of all storage spaces for dangerous pathogens*
- *Internal review of biosafety policies*

QUESTIONS???

45 MINUTE LUNCH
BREAK
PROGRAM WILL
RESUME AT 1:00 PM
EST

FEDERAL SAFETY STAND DOWN

Freeda E. Isaac, DVM
Director
Animal Plant Health Inspection Agency
Agriculture Select Agent Services



WHITE HOUSE TASKING

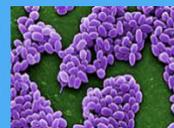
Holdren-Monaco Memo

- **Lisa Monaco: Assistant to the President for Homeland Security and Counterterrorism, National Security Council**
- **John Holdren: Assistant to the President for Science and Technology, Office Science & Technology Policy**
- **Response to incidents at CDC and NIH**
- **Meaningful measures to address underlying causes**
- **Reduce risk so incidents would not re-occur**
- **Memo issued August 19, 2014 to all Federal Departments and Agencies**



HOLDREN-MONACO MEMO

- **Contains several actions**
- **Immediate First Steps**
- **Longer Term Efforts**
 - **Federal Experts Security Advisory Panel**
 - **Broad Stakeholder Engagement**



IMMEDIATE FIRST STEPS

Safety Stand Down Activities:

- **Inventory Sweep**
 - All areas searched for BSAT's
 - Report findings to FSAP
 - Completed by October 1, 2014
- **Sustained Inventory Monitoring**
 - Review plans for all biological agents
 - Revise plans as needed
 - Includes SA and non-SA



IMMEDIATE FIRST STEPS CONT.

- **Review laboratory biosafety and biosecurity procedures**
 - **Review protocols and procedures**
 - **Training for all employees who work with biological agents**
 - **Drills and exercises**
- **Encourage extramural facilities to participate**
- **Report on activities by October 15, 2014**



FEDERAL EXPERTS SECURITY ADVISORY PANEL (FESAP)

**Interagency Committee composed of all Federal Departments
and Agencies**

Recommendations provided in 90 days.

Three Issues reviewed:

- **Needs and gaps to optimize biosafety, biosecurity, oversight and inventory management and control**
- **Regulatory changes necessary to improve biosafety and biosecurity**
- **Identify approach to determine appropriate number of high containment US laboratories to possess, use, and transfer BSAT's.**



BROAD STAKEHOLDER ENGAGEMENT

Interagency group:

- Review impact of SAR on science, technology, and national security
- Analysis of benefits, costs, and limitations of the SAR
- Recommendations to address any challenges and gaps
- National Science Advisory Board for Biosecurity and Institute of Medicine
- Public meeting
- Recommendations by 180 days after group formed



WHAT TO DO IF ENCOUNTER A SELECT AGENT OR TOXIN

- **Immediately contain the select agent safely and securely**
- **Immediately contact the Federal Select Agent Program**
- **Secure the location. If suspicious activity, contact your local WMD coordinator or local law enforcement**
- **If the material is tested, submit appropriate documentation. Form 4 or Form 3.**
- **FSAP will provide appropriate guidance.**



ADVANCE NOTICE OF PROPOSED RULE MAKING (ANPRM)

- **Method to obtain public interest, information, and opinion**
- **Government can indicate what they are thinking**
- **Obtain public input**
- **Opportunity to provide input**
- **Select Agent Biennial Rule**
- **Changes to list of select agent and toxins**



QUESTIONS??

INSPECTIONS UNDER THE REVISED REGULATIONS

Lyla Lipscomb Ph.D.
Microbiologist/Inspector

Centers for Disease Control and Prevention
Office of Public Health Preparedness and Response
Division of Select Agents and Toxins

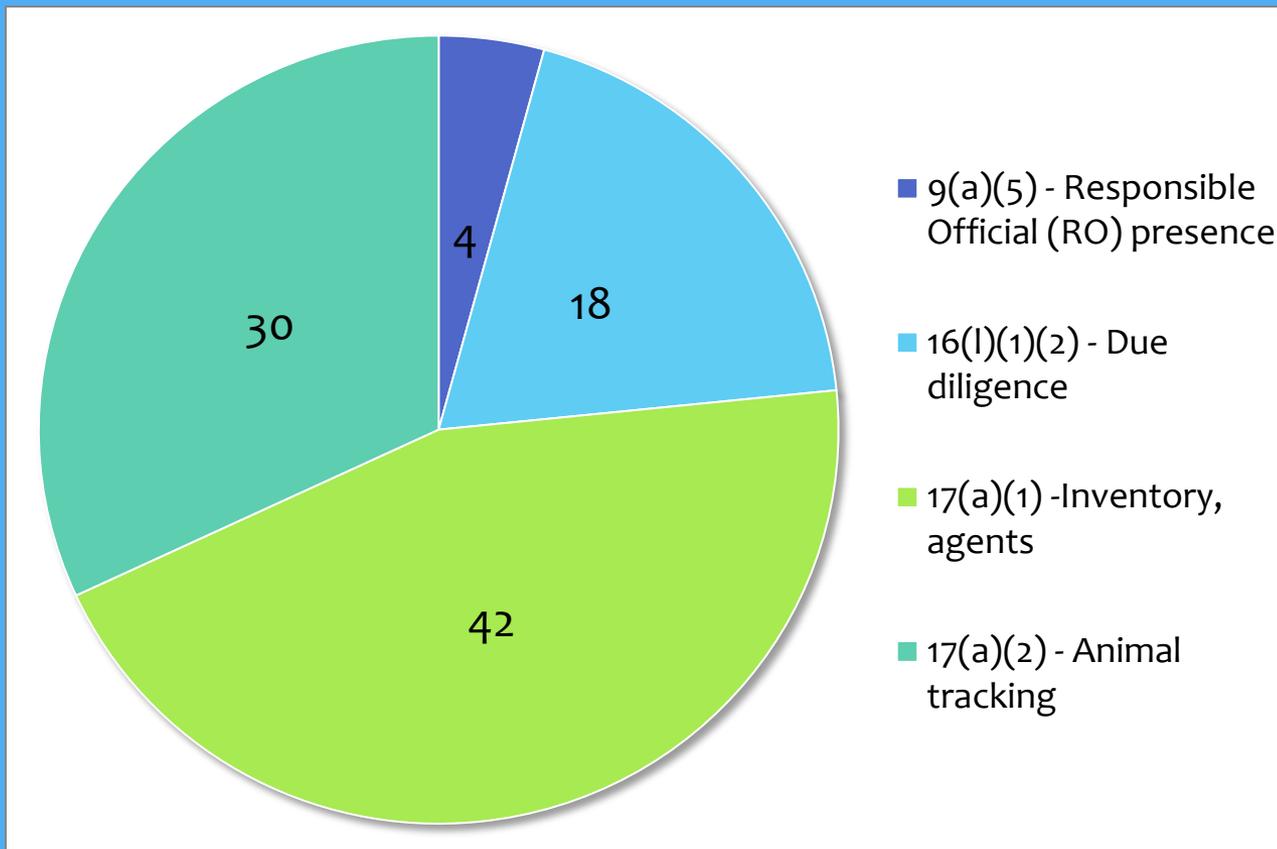


OBJECTIVES

- 1. Compliance with Amended Select Agent Regulations (effective December 4, 2012)**
 - Reasons for departures
- 2. Compliance with Amended Select Agent Regulations (effective April 3, 2013)**
 - Reasons for departures
- 3. Compliance with Tier 1 Requirements (effective April 3, 2013)**
 - Reasons for departures
- 4. Preparing for your next inspection**



AMENDED REGULATIONS, RESPONSIBLE OFFICIAL, DUE DILIGENCE, RECORDS DECEMBER 2012 – SEPTEMBER 2014 (N = 234)



REASONS FOR NON-COMPLIANCE RO, DUE DILIGENCE

- 9(a)(5) – (4/234) RO Presence
- 16(I)(1)(2) – (18/234) Due Diligence - If transferring an amount of a select toxin otherwise excluded under section 73.3(d):
 - Failure to document legitimate need prior to transfer



REASONS FOR NON-COMPLIANCE RECORDS

- 17(a)(1) – (42/234) Accurate and current inventory
 - Record does not include all required select agents (e.g., SARS-CoV genomic material)
 - All elements not captured (17(a)(1)(i-v))
 - All material meeting the criteria for long-term storage not included in long-term storage record (refer to Guidance on the Inventory Requirements for Select Agents and Toxins, <http://www.selectagents.gov/guidance-storage.html>).
 - Material in long-term storage does not match information in the record
 - Animal tissues held in long-term not included in inventory
 - Failure to enter material received by APHIS/CDC Form 2 (Request to Transfer Select Agents And Toxins) into inventory record

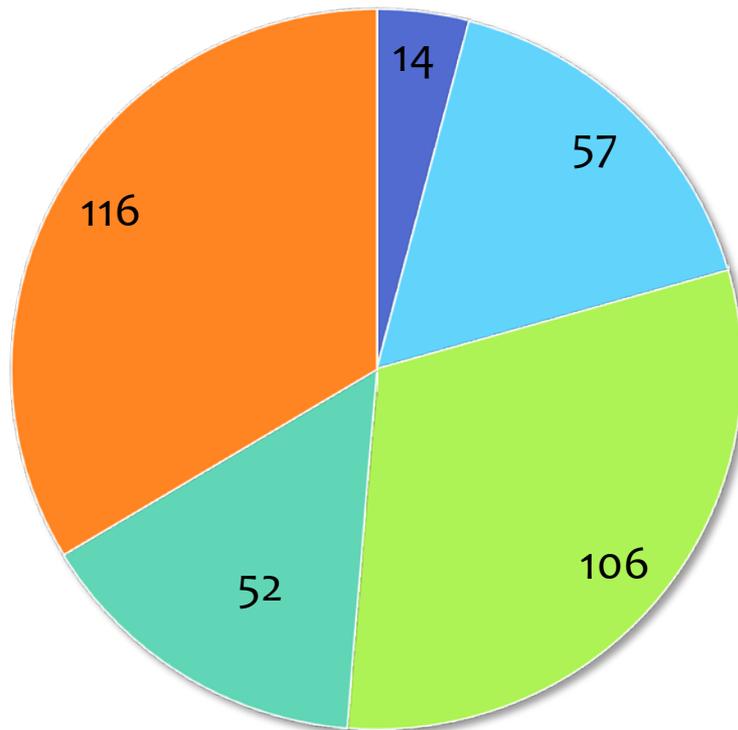


REASONS FOR NON-COMPLIANCE RECORDS CONT

- **17(a)(2) – (30/234) Accounting of animals or plants**
 - Failure to have any accounting system in place for animals or plants intentionally or accidentally exposed to or infected with a select agent
 - Failure to include the number and species, location, and appropriate disposition (e.g., autoclaved, incinerated)
 - Accounting system in place but not current or accurate



AMENDED REGULATIONS, SECURITY APRIL 2013 - SEPTEMBER 2014 (N = 214)



- 11(b) - Risk assessment
- 11(c)(2) - Access control, including animals, arthropods, plants
- 11(c)(8) - RO informed suspicious activity, criminal in nature
- 11(c)(9)(i-v) - Information security (average)
- 11(c)(10) - Shipping/receiving



REASONS FOR NON-COMPLIANCE SECURITY

- **11(b) – (14/214) Risk Assessment**
 - Site-specific risk assessment not performed or not adequate
 - Security plan did not provide **graded protection** (e.g., hidden but not secured keys)
- **11(c)(2) – (57/214) Access Control**
 - Inadequate or lack of procedures for safeguarding of animals, arthropods, or plants intentionally **or accidentally exposed** or infected
 - Access control points not defined
 - Consider circumstances, as relevant (e.g., lab occupied or not)
 - Consider if IT/Security staff can program access to registered space; are there controls in place to prevent access to select agents and toxin, or are these authorized individuals?



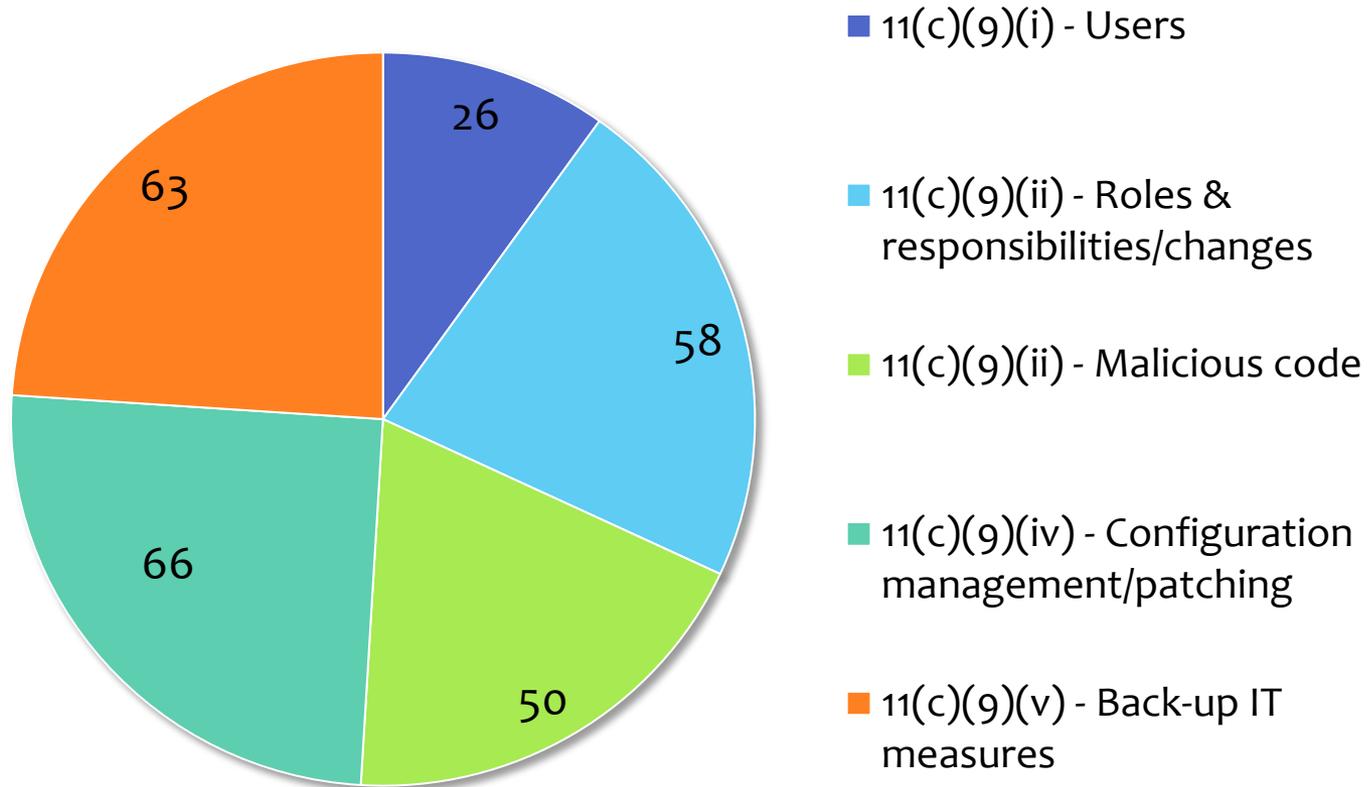
REASONS FOR NON-COMPLIANCE SECURITY (CONT)

- 11(c)(8) – (106/214) RO informed of suspicious activity that may be criminal in nature
 - No process for how the RO will be informed of suspicious activity that may be criminal in nature
 - Lack of description of activity that is “criminal in nature”
 - Example: Person hovering by fence may be suspicious; person who jumps the fence may be **criminal in nature**
- 11(c)(10) – (116/214) Shipping/receiving
 - Inadequate or lack of provisions for shipping/receiving
 - “Lost in the crowd” versus registration of shipping/receiving area with only authorized individuals with access
 - Where are select agents and/or toxins packaged for shipment?
 - How are select agents and/or toxins **monitored** during shipment?
 - Lack of provisions for **unexpected shipments**



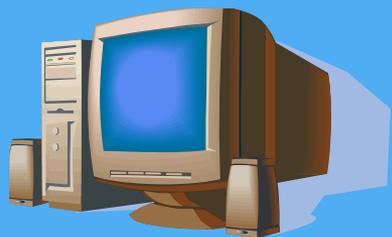
AMENDED REGULATIONS, INFORMATION SECURITY

APRIL 2013 – SEPTEMBER 2014 (N = 214)

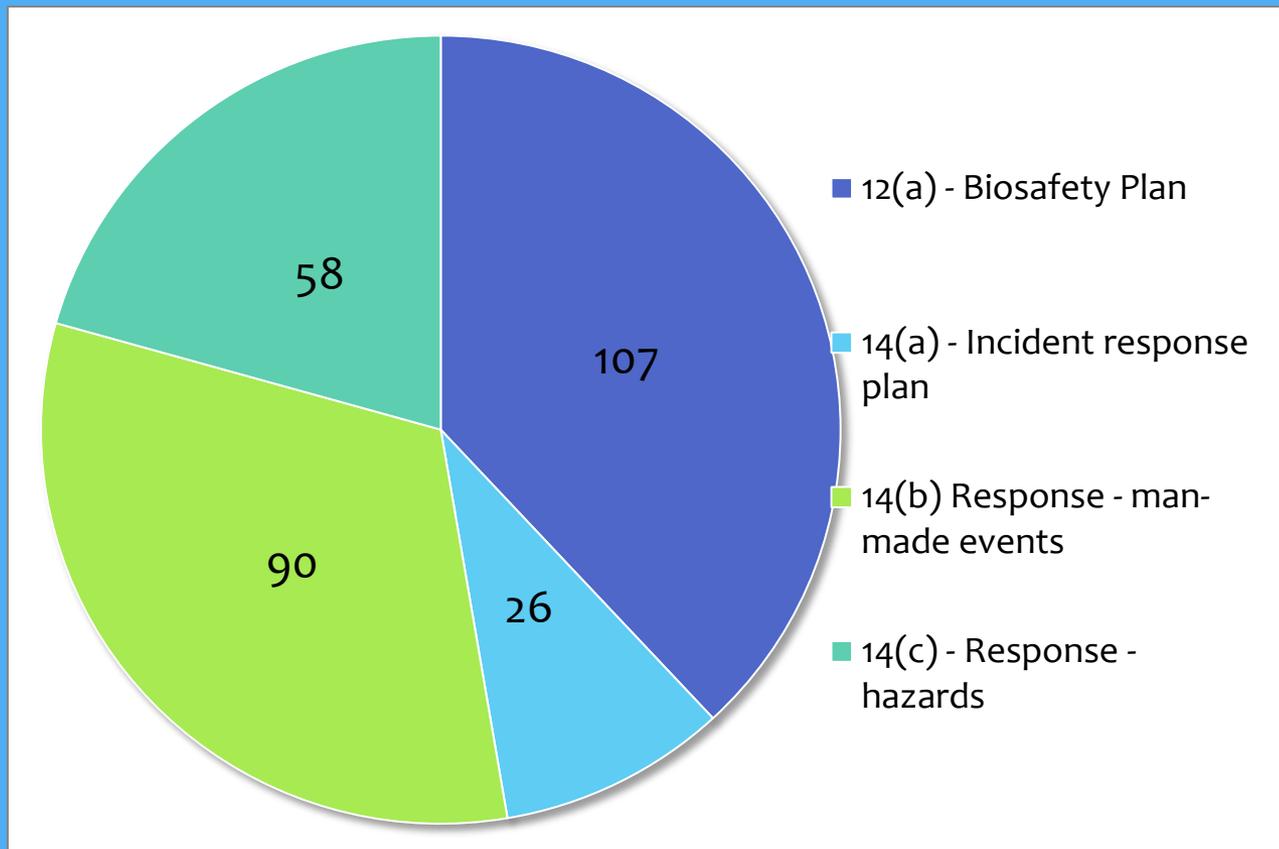


REASONS FOR NON-COMPLIANCE INFORMATION SECURITY

- **11(c)(9)(i-v): Provisions for information security**
 - Entity has measures in place; however, provisions for information security are not in the security plan or provisions included in other documents are **not referenced** in the security plan for:
 - Authorized and authenticated users (26/214)
 - User's roles and changes in responsibilities (58/214)
 - Controls to prevent malicious code (50/214)
 - Regular patching and updates to operating systems (66/214)
 - Back-up IT security measures (63/214)
 - Rare but more serious: Entity does not have measures in place that address any or all of the requirements in 11(c)(9)(i-v):
 - Required systems must be installed and security plan updated



AMENDED REGULATIONS, BIOSAFETY AND INCIDENT RESPONSE APRIL 2013 – SEPTEMBER 2014 (N = 214)



REASONS FOR NON-COMPLIANCE BIOSAFETY/BIOCONTAINMENT PLAN

- **12(a) – (107/214) Biosafety/biocontainment plan**
 - Not commensurate with the risk of the select agent or toxin, **given its intended use** –
 - Does the plan describe the work that will be done for each registered select agent or toxin, and how it will be done safely?
 - Are the procedures specific for the entity?
 - Can be supplemented with Standard Operating Procedures (SOPs), but must be included or referenced in the plan?



REASONS FOR NON-COMPLIANCE BIOSAFETY/BIOCONTAINMENT PLAN (CONT)

- **12(a) – (107/214) Biosafety/biocontainment plan**
 - Does not contain biosafety and containment procedures for animals, arthropods, or plants as required
 - Intentionally or **accidentally** exposed or infected with a select agent
 - Consider shared areas (e.g., suites, corridors) that may contain select agents, non-select agents, uninfected animals
 - Consider movement of workers or equipment from select agent area to non-select agent area
 - Did not contain information used to render select agents non-viable and select toxins nonfunctional prior to removal from registered areas.
 - Plan contains adequate procedures, but they **have not been implemented**



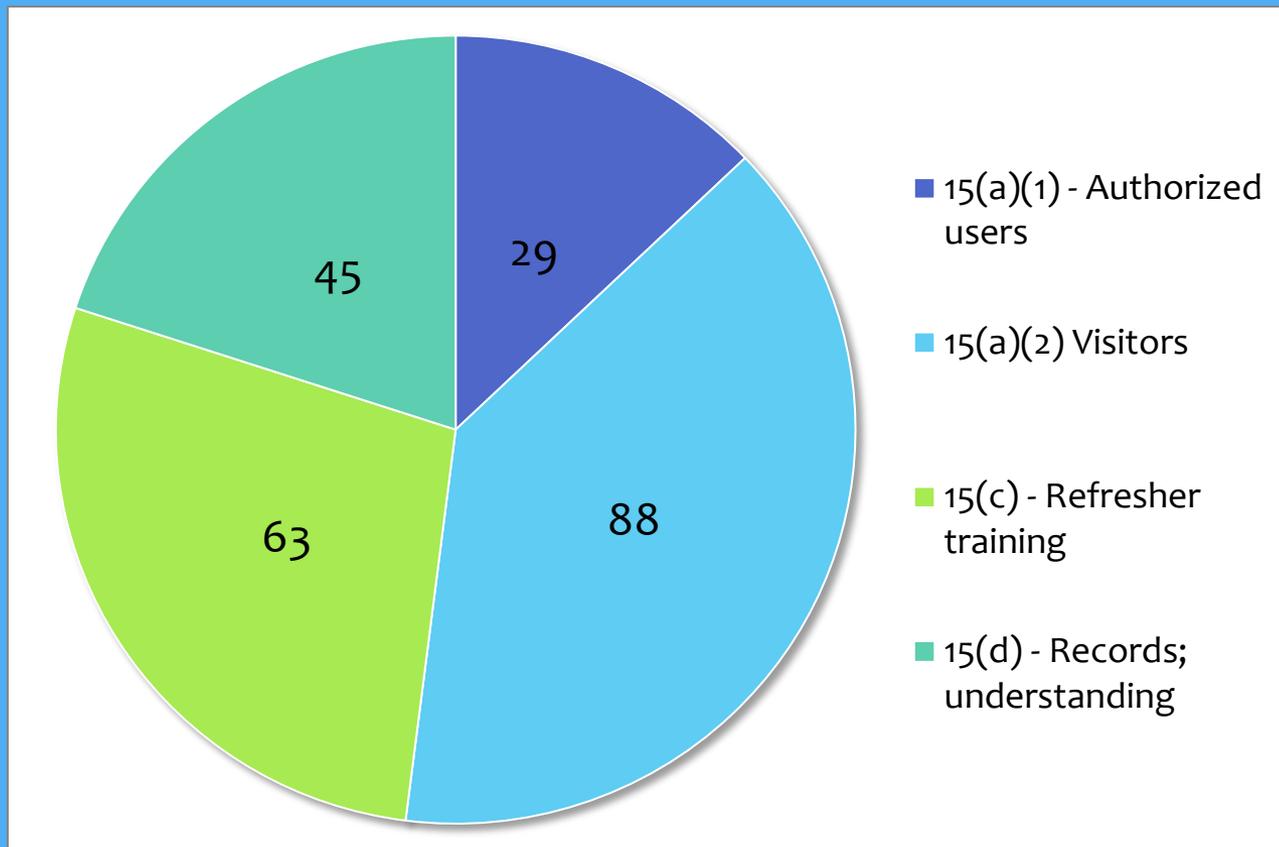
REASONS FOR NON-COMPLIANCE INCIDENT RESPONSE PLAN



- **Section 14 Incident Response Plan**
 - **14(a) – (26/214) Not based upon a site specific risk assessment**
 - Example, if tornadoes are common in the area, are there response procedures for these events?
 - **14(b) – (90/214) Multiple events, including natural or man-made events, not included**
 - Example, if entity has an animal facility, does the plan include response procedures for animal activists?
 - **14 (c) – (58/214) Hazards of the select agent or toxin, including any animals, arthropods, or plants intentionally or accidentally exposed, not considered**



AMENDED REGULATIONS, TRAINING APRIL 2013 - SEPTEMBER 2014 (N = 214)



REASONS FOR NON-COMPLIANCE TRAINING

- 15(a)(1) – (29/214) Individuals with access approval
 - Training did not include biosafety, security (including security awareness), and **incident response**
 - Training did not address the **risks of select agents and toxins**
 - Training did not address the **work done**
 - All required individuals did not receive training
- Section 15(a)(2) – (88/214) Visitors
 - Training did not include biosafety, security (including security awareness), and **incident response**
 - Training did not address the **risks** of entering areas where select agents or toxins are handled or stored
 - All visitors not trained
 - Entity did not follow their procedures for frequency of visitor training



REASONS FOR NON-COMPLIANCE TRAINING (CONTINUED)

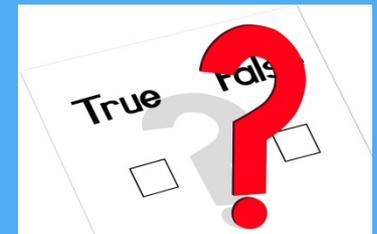
- 15(c) – (63/214) Refresher training
 - Gaps in training
 - All required individuals did not receive refresher training within a given year (people missed training)
 - Required individuals did not receive training each year (years missed)
 - All individuals with access approval did not receive training **when the plan(s) were significantly amended**
 - New space, new agent added
 - Change in procedures (e.g., donning and doffing, additional animal models, routes of inoculation)

Note: once initial training is provided, refresher training must be provided each year, regardless of access

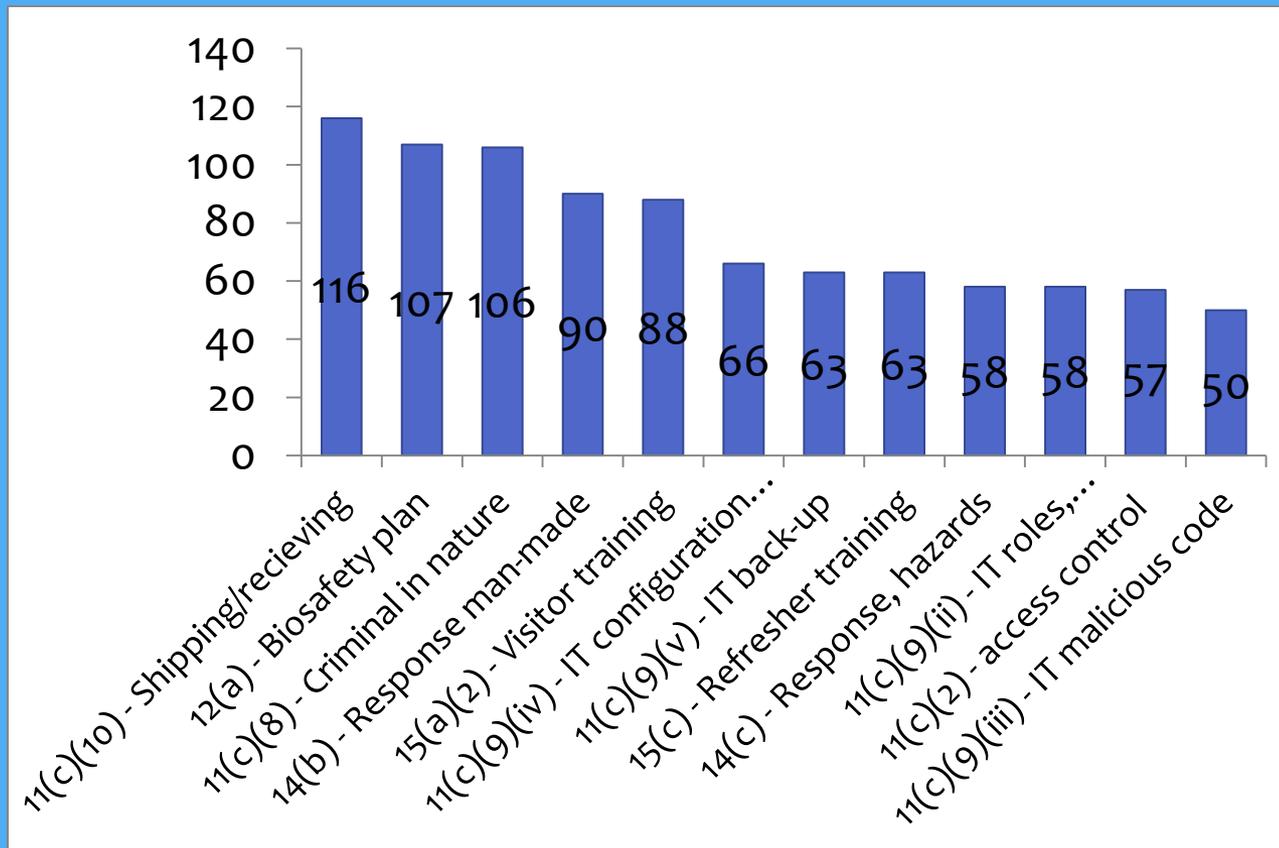


REASONS FOR NON-COMPLIANCE TRAINING (CONT)

- **15(d) – (45/214) RO is required to maintain training record**
 - **Records of training not maintained (entity states that training was done but cannot produce the record)**
 - **Interviews indicated that training was not understood**
 - **Record does not include**
 - **Name of individual**
 - **Date of training**
 - **Description of training**
 - **Means of understanding (quiz, attestation, etc.)**

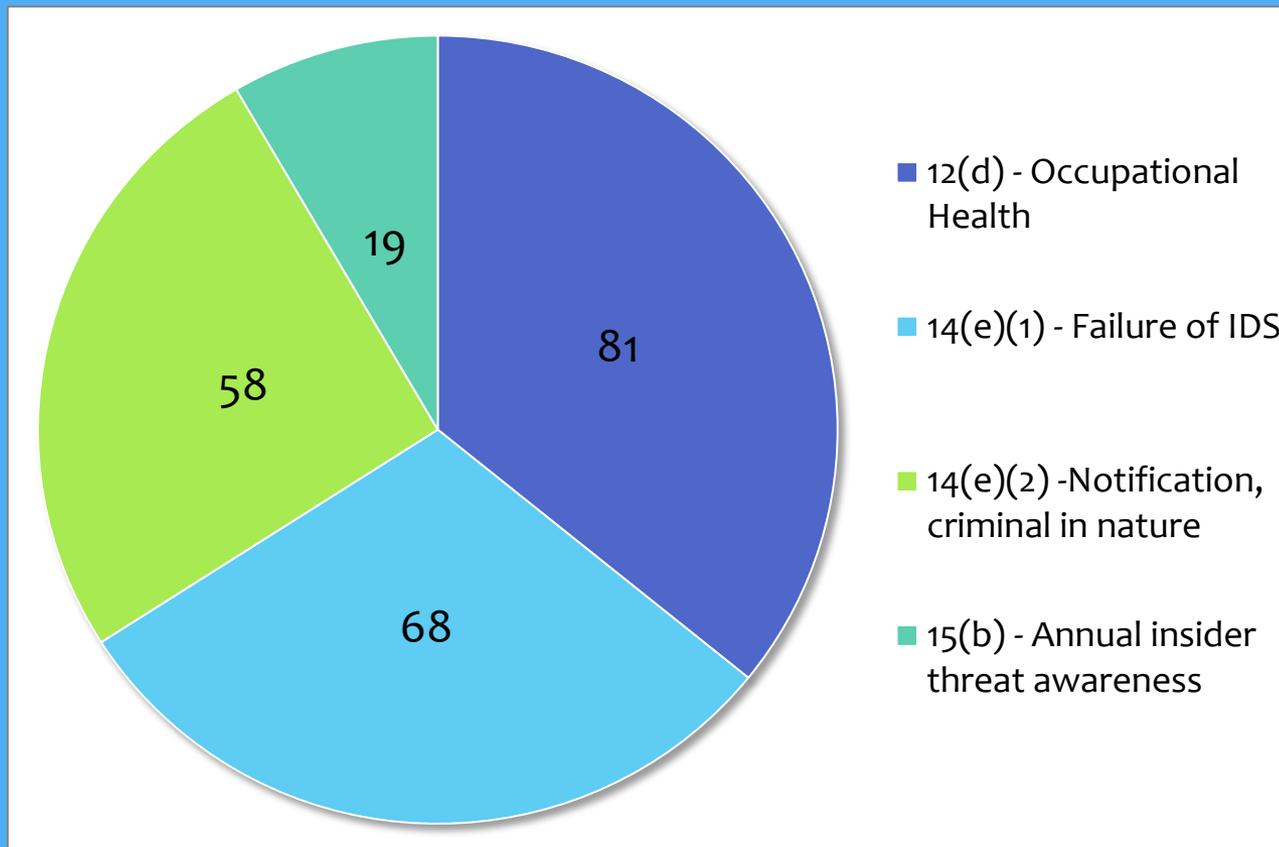


SUMMARY, NON-TIER 1 TOP 12 DEPARTURES



TIER 1 REQUIREMENTS

AMENDED REGULATIONS, TIER 1 BIOSAFETY, INCIDENT RESPONSE, TRAINING APRIL 2013 – SEPTEMBER 2014 (N = 134)



REASONS FOR TIER 1 NON-COMPLIANCE OCCUPATIONAL HEALTH

- 12(d) – (81/134) Occupational Health Program
 - Program does not include, or inadequate for:
 - **Pre-placement evaluations** of workers fitness for duty
 - **Preventive measures** used to reduce risk of occupational infections (e.g., vaccines, respiratory protection, or other medical countermeasures)
 - **Post-exposure management strategies** (e.g., emergency medical evaluations and first-aid, patient isolation and support, and treatment options available)
 - Program described, but individuals with access to Tier 1 agents not enrolled
 - Occupational Health Program Provider not aware of registered select agents or toxins



REASONS FOR TIER 1 NON-COMPLIANCE INCIDENT RESPONSE

- 14(e)(1) – (68/134) Plan does not include procedures for **failure** of intrusion detection or alarm system
 - For example, response force treats the failure as an alarm, back up system for IDS
- 14(e)(2) – (58/134) Plan does not include procedures for notification to appropriate federal, state, or local law enforcement agencies of suspicious activity that may be criminal in nature (entity, its personnel, or its agents or toxins):
 - Communication lines
 - Who decides to report to law enforcement?
 - What activities will prompt contacting law enforcement (and which agency)?



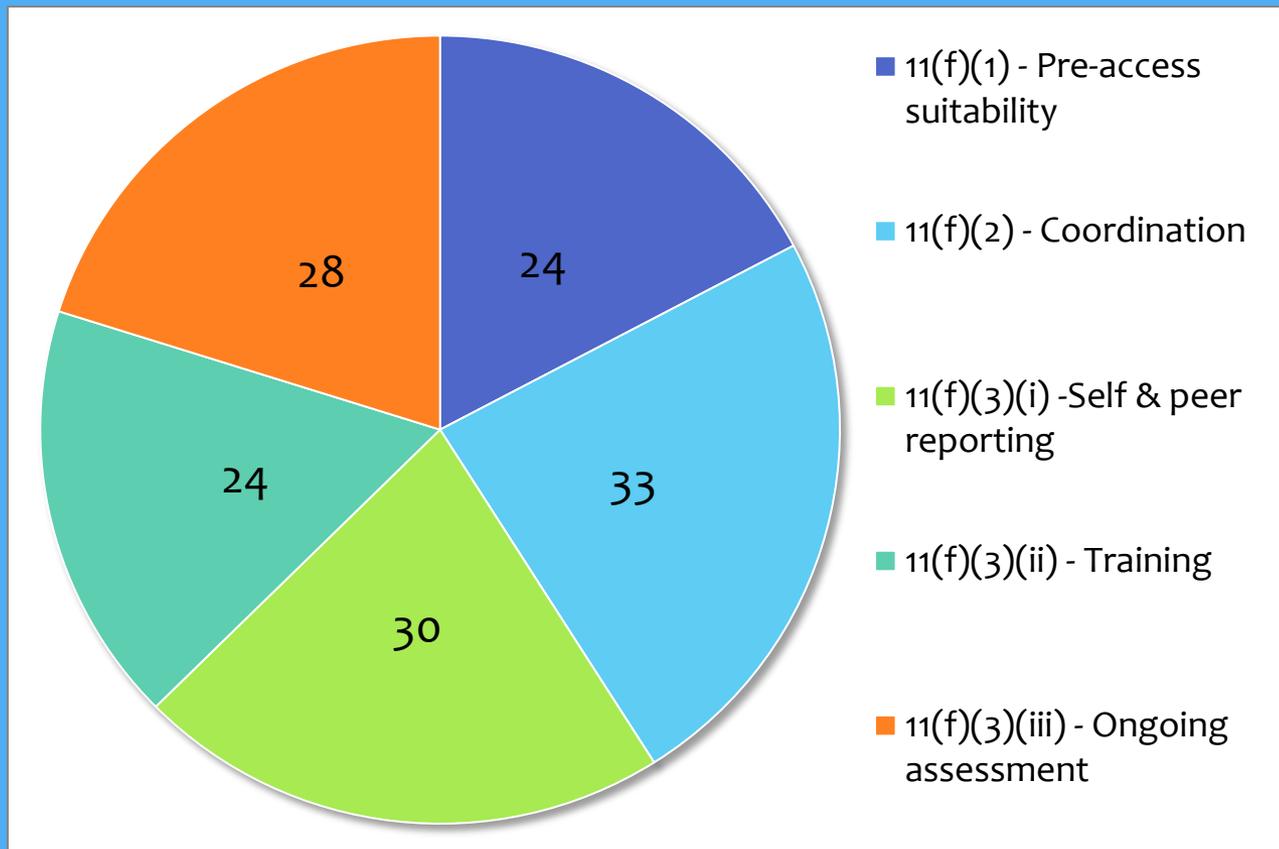
REASONS FOR TIER 1 NON-COMPLIANCE TRAINING

- **15(b) – (19/134) Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behavior.**
 - **Briefing must be provided to all individuals with access approval, not just those with access to Tier 1 agents**



AMENDED REGULATIONS, TIER 1 SECURITY

APRIL 2013 – SEPTEMBER 2014 (N = 134)



REASONS FOR TIER 1 NON-COMPLIANCE SECURITY

- **11(f)(1) – (24/134) Pre-access suitability**
 - Procedures not described/developed
 - Pre-access suitability program not implemented
 - Required individuals not enrolled
 - Required individuals not aware
- **11(f)(2) – (33/134) Coordination with safety and security professionals**
 - Procedures not described
 - Coordination has not occurred
 - Safety and security staff not aware

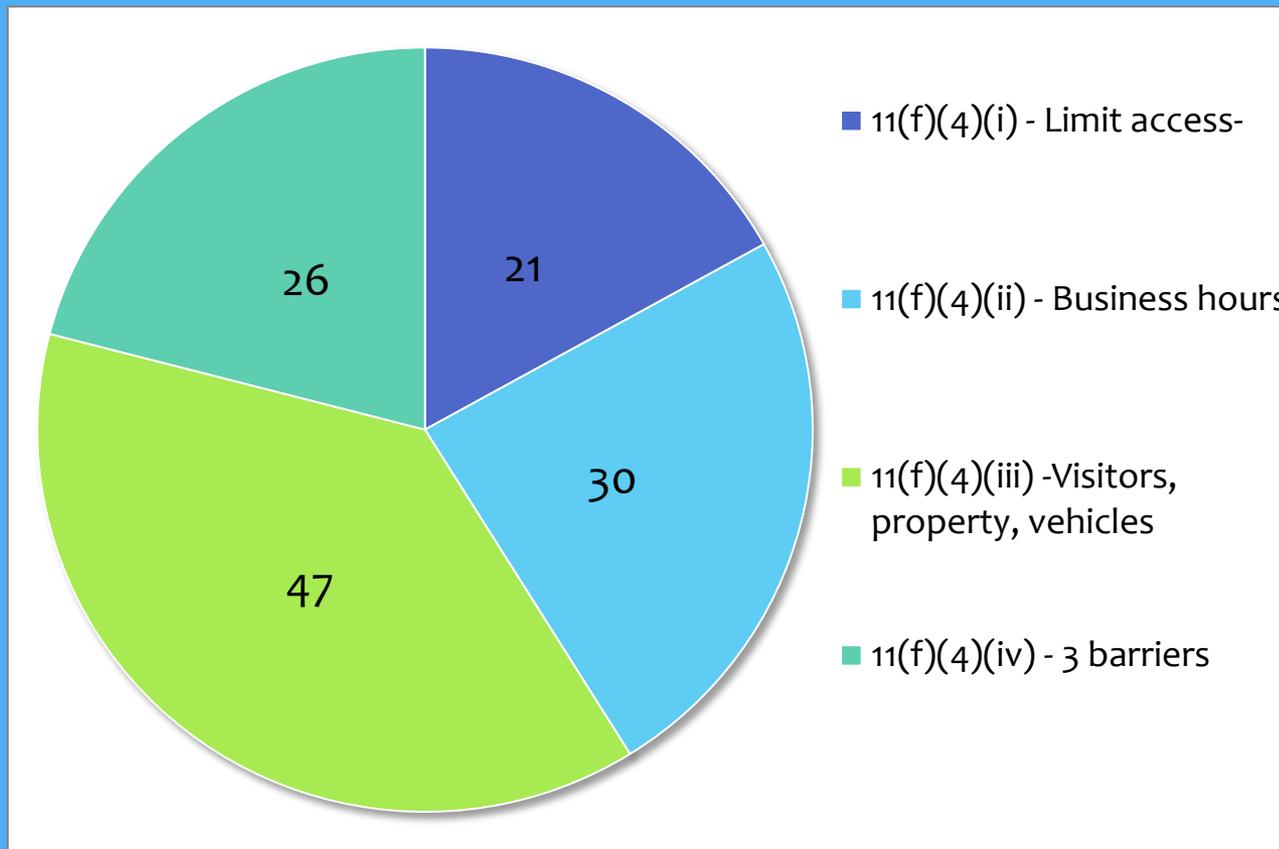


REASONS FOR TIER 1 NON-COMPLIANCE SECURITY (2)

- 11(f)(3)(i) – (30/134) Self and peer reporting and 11(f)(3)(iii) – (28/134) Ongoing assessment
 - Procedures not described/developed
 - Reporting structure not defined or not appropriate (e.g., RO reporting to Principal Investigator)
 - Program not implemented
 - Required individuals not **aware**
 - All required individuals are not evaluated
- 11(f)(3)(ii) – (24/134) Training on suitability reporting, evaluation, and corrective action
 - Procedures not described
 - Failure to conduct training will be cited under section 15



AMENDED REGULATIONS, TIER 1 SECURITY APRIL 2013 – SEPTEMBER 2014 (N = 134) (2)



REASONS FOR TIER 1 NON-COMPLIANCE SECURITY (3)

- 11(f)(4)(i) – (21/134) Limit access to approved individuals + those enrolled in pre-access or ongoing suitability program, as required
 - Procedures not described/developed
 - Program not implemented
 - Access not limited as required
 - Considered **a serious violation**
- 11(f)(4)(ii) – (30/134) RO approves outside normal business hours
 - Procedures not described
 - Normal business hours not defined
 - Circumstances for after hours not defined
 - RO or employees not aware of procedures



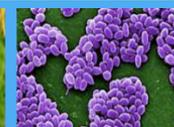
REASONS FOR TIER 1 NON-COMPLIANCE SECURITY (4)

- 11(f)(4)(iii) – (47/134) Visitors, property, vehicles
 - Procedures not described/developed for all 3, especially property vehicles
 - All entry and exit points not considered
 - **Most common** departure of Tier 1 security requirements



REASONS FOR TIER 1 NON-COMPLIANCE SECURITY (5)

- 11(f)(4)(iv) – (21/134) 3 barriers
 - Final barrier does not limit access to select agents and toxins
 - Consider multiple factors
 - Waste stream
 - Multiple entry points to building or room
 - Person serving as barrier
 - Dropped ceilings affording access
 - Barriers not described in plan
 - Barrier not implemented (e.g., Door not locked or propped open)
 - Considered **a serious departure** if 3 barriers not available



GRADED PROTECTION

- **Assess each security barrier**
 - Can it be overcome without special tools or skills?
 - Can you climb over or under without a shovel or ladder?
 - Does it meet a security standard?
 - American Society for Testing and Materials (ASTM), sets height @ 7ft and outrider, 2" height off ground
 - Department of Defense's Unified Facilities Criteria (UFC) sets at 8ft without outrider
 - Department of Energy's @ 7ft with outrider
- **If barrier can be overcome and does not meet a security standard, then it will fail graded protection.**
- **To meet compliance**
 - Most 7' fences will provide graded protection
 - Provide a security standard that supports your barrier, but ensure it's at the applicable standard (don't use 'pool fence' for 'security fence')
 - Determine if you have other barriers that may be used

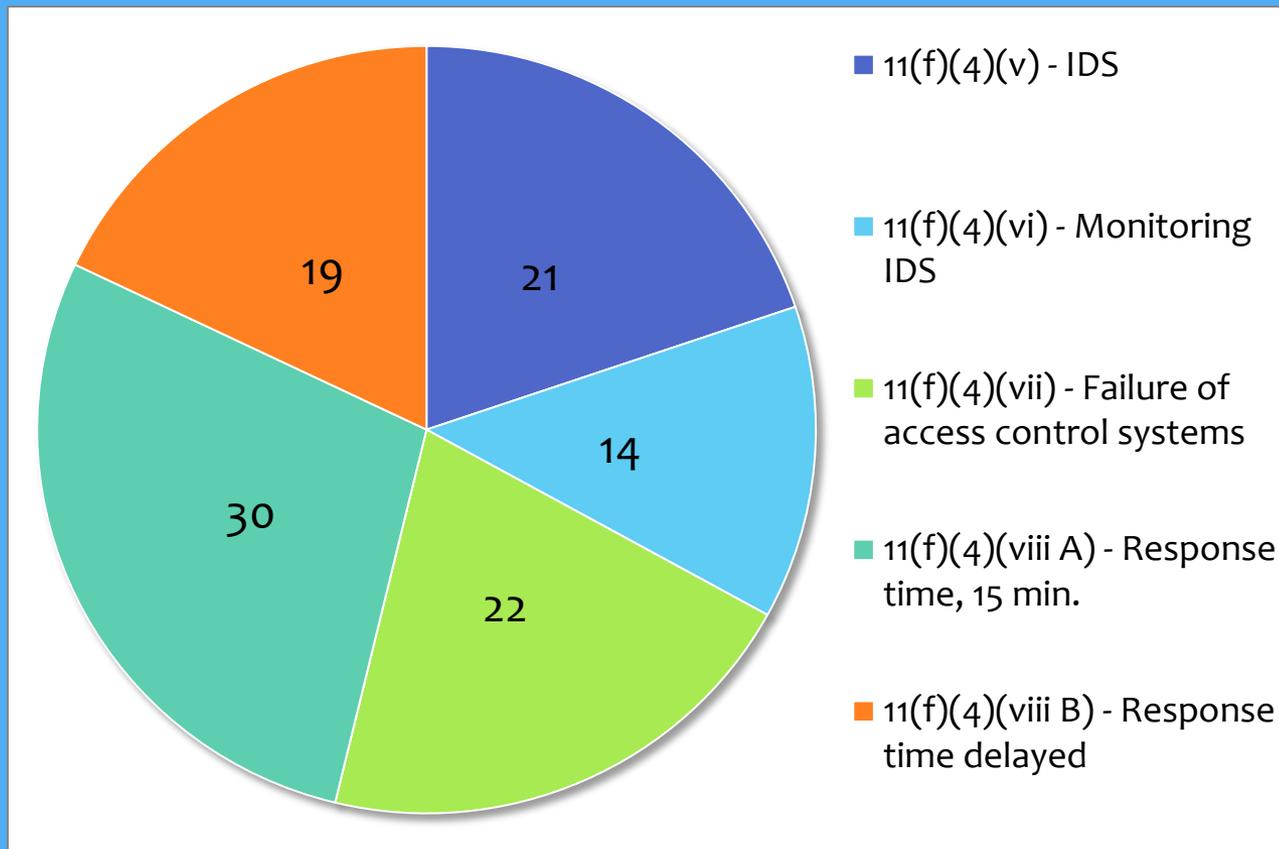
Note: Video cameras are not a barrier (see SA Gram)



Barriers do not provide graded protection



AMENDED REGULATIONS, TIER 1 SECURITY APRIL 2013 – SEPTEMBER 2014 (N = 134) (3)



REASONS FOR TIER 1 NON-COMPLIANCE SECURITY (6)

- 11(f)(4)(v) – (21/134) IDS
 - Registered space not protected by IDS or not physically occupied – **a serious observation**
 - IDS not armed appropriately
 - Procedures not described
 - IDS or physical occupation in absence of IDS – how managed
- 11(f)(4)(vi) – (14/134) Monitoring IDS
 - IDS not monitored
 - Personnel monitoring not capable of evaluating and interpreting alarm
 - No procedure for alerting security response force or law enforcement

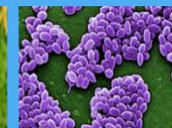
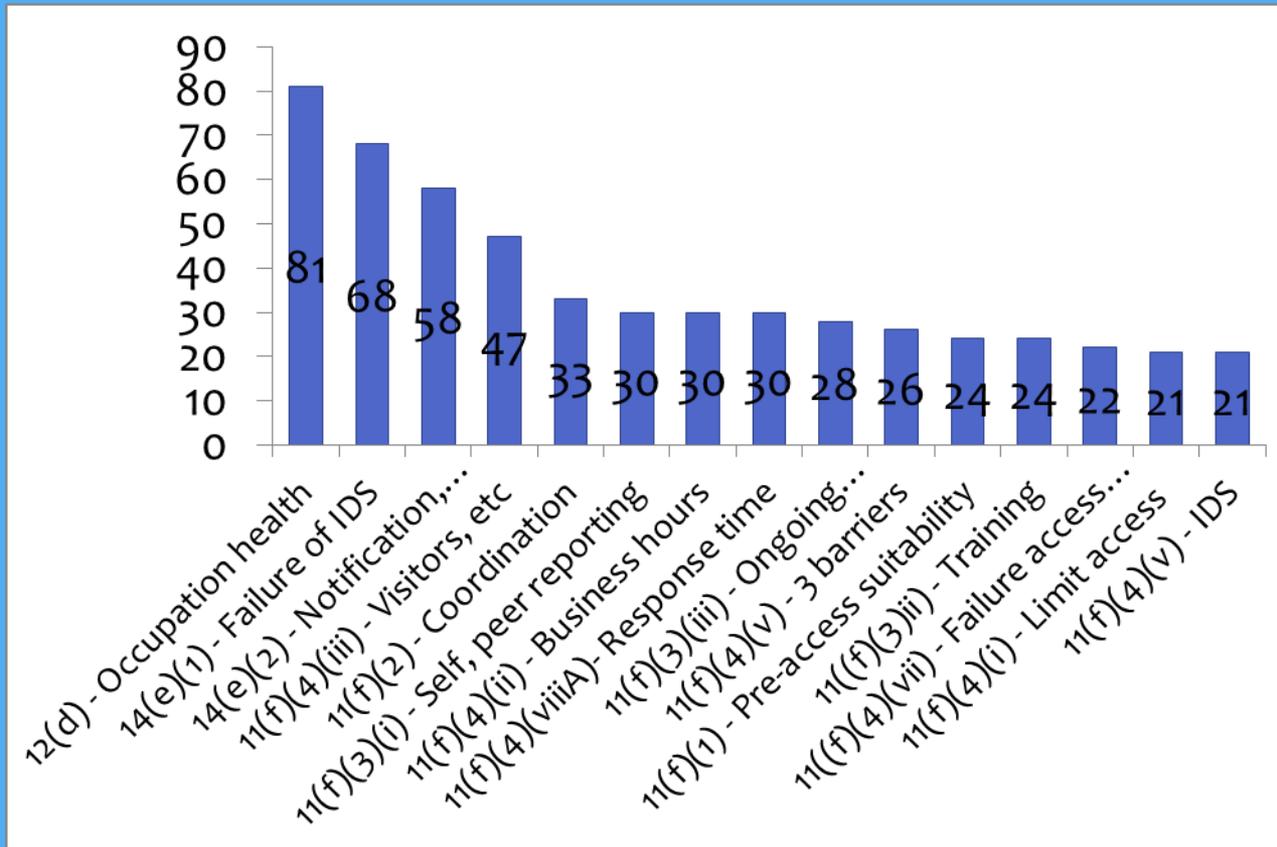


REASONS FOR TIER 1 NON-COMPLIANCE SECURITY (CONT)

- **11(f)(4)(vii) – (22/134) Failure of powered access control systems**
 - Procedures not described
 - How will security be maintained: fail secure/fail safe
 - Power disruption
- **11(f)(4)(viii A) – (30/134) Response time 15 minutes; (viii B) – (11/134) Response time provides delay**
 - Response time not defined
 - Response time exceeds 15 minutes; barriers insufficient to delay unauthorized access
 - Procedures not described



SUMMARY, TIER 1 TOP 15 DEPARTURES



CONSEQUENCES OF NON-COMPLIANCE

- **Suspension or revocation of registration**
 - **Opportunity to participate in corrective action plan**
 - **Opportunity to participate in performance improvement plan**
- **Referral to Department of Health & Human Services' Office of Inspector General or Animal and Plant Health Inspection Service's Investigative and Enforcement Services**
 - **Civil money penalties**
- **Referral to Federal Bureau of Investigation**
 - **Potential violations of criminal law**



NEXT INSPECTION

NEXT INSPECTION (1)

- Prepare throughout the year, not just before the next inspection
- Ensure that all corrective actions from previous inspections have been completed and **implemented**
- Have all plans (and supporting SOPs) been **implemented** (i.e., are staff following the plans)?
- Ensure inventory audits are performed when the situations in 11(e)(1),(2), and/or (3) occur.



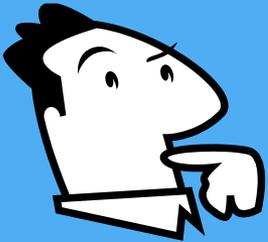
NEXT INSPECTION (2)

- Perform annual requirements
 - Training
 - All required training is conducted for all required individuals each year
 - Training is performed after significant changes to plan
 - BSL3/ABSL3 verification, see <http://www.selectagents.gov/guidance-containment.html>
 - Certifications for biosafety cabinets, fume hoods, HEPA filters (laboratory exhaust, ventilated enclosures)
 - Internal inspections – cover all parts of select agent regulations
 - Drills and exercises to test and evaluate **each** plan
 - Plan reviews (also after drills or exercises, if necessary)



NEXT INSPECTION (3)

- Ensure inventory records capture all items required by 17(a)(1)- select agents, and 17(a)(3)-select toxins
 - Remember, all toxin (if registered) must be inventoried (i.e., no working stock for toxin)
- An accurate and current accounting for animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent (e.g., Cage cards, census records, autoclave records)
- Are select agent and toxin records and databases accurate and can their authenticity be verified for:
 - Inventory? Area access records?
- Additional considerations
 - Registered areas that are activated and inactivated for select agent and/or toxin use or storage
 - Agent specific enhancements/requirements
 - Verify the path of the select agents or toxins (e.g., waste stream, shipping, storage)



NEXT INSPECTION (TIER 1)

- **All Tier 1 requirements must also be in place**
 - Verify the path of the select agents or toxin (e.g., waste stream, shipping, storage)
 - Occupational Health Program
 - Update if changes (e.g., addition of Tier 1 select agent or toxin)
 - Continue to ensure enrollment of staff
 - Verify Tier 1 requirements are in their respective plans and implemented
 - 3 barriers are in place and employed
 - IDS is in place and employed
 - Access permissions to Tier 1 select agents and/or toxin match suitability enrollment





Federal Select Agent Program Training

For more information, please contact the Federal Select Agent Program

Telephone: 301-851-3300 Option 3 (USDA) or 404-718-2000 (CDC)

E-mail: AgSAS@aphis.usda.gov (USDA) or lrsat@cdc.gov (CDC)

Web: www.selectagents.gov



ASK THE
DIRECTORS!!!

CLOSING REMARKS

THANK YOU FOR ATTENDING THE
FEDERAL SELECT AGENT WEBCAST

PLEASE TAKE A MOMENT TO
RESPOND TO OUR E-MAILED SURVEY
WE VALUE YOUR INPUT!