# High Containment Facility Security and Audits

It simply doesn't end

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# **Our World Has Changed**

- The Patriot Act 2001 and
- Public Health Security and Bioterrorism Preparedness Act of 2002

Set forth the following Interim rules:

Department of Agriculture 7 CFR Part 331 and 9 CFR Part 121 (USDA, APHIS)

 Department of Health and Human Services 42 CFR Parts 72 and 73 (CDC, OIG and HHS)

December 2002 (1<sup>st</sup> interim rule) November 2003 (2<sup>nd</sup> interim rule)

## Federal Register The Final Rule

March 18,2005

**Select Agents and Toxins Regulations finalized** 

(HHS) (USDA) published final rules for the Possession, Use, and Transfer of Select Agents and Toxins **effective on April 18, 2005** 

# **Restricting Access 42 CFR Part** 73.10

- FBI background checks must be performed on all employees with access to agents or toxins
- Security risk assessment applications are made to the Attorney General
- Approved granted by HHS Secretary or Administrator

# Security 42 CFR Part 73.11

- Security Plan is designed in accordance with the site-specific risk assessment
- Incident response plan must be developed and implemented
- Procedures must be written, implemented and adhered to

# Security 42 CFR Part 73.11

- Training programs for RO thru municipal 1<sup>st</sup> line responders must be established, implemented, and documented
- Security system costs can vary due to size, existing security and specific needs of the entity

# **Who Is Effected**

- Academic Institutions
- Biomedical Centers
- Commercial Manufacturing Facilities
- Clinical and Diagnostic Laboratories
- Research Facilities

#### Now What Do You Have To Do ?

- Aside from reading and writing
- What bells and whistles are needed
- Get security, the RO, and administrators on the same page and informed
- Get everyone to agree on what is needed
- GET ORGANIZED

#### **Security Do's**

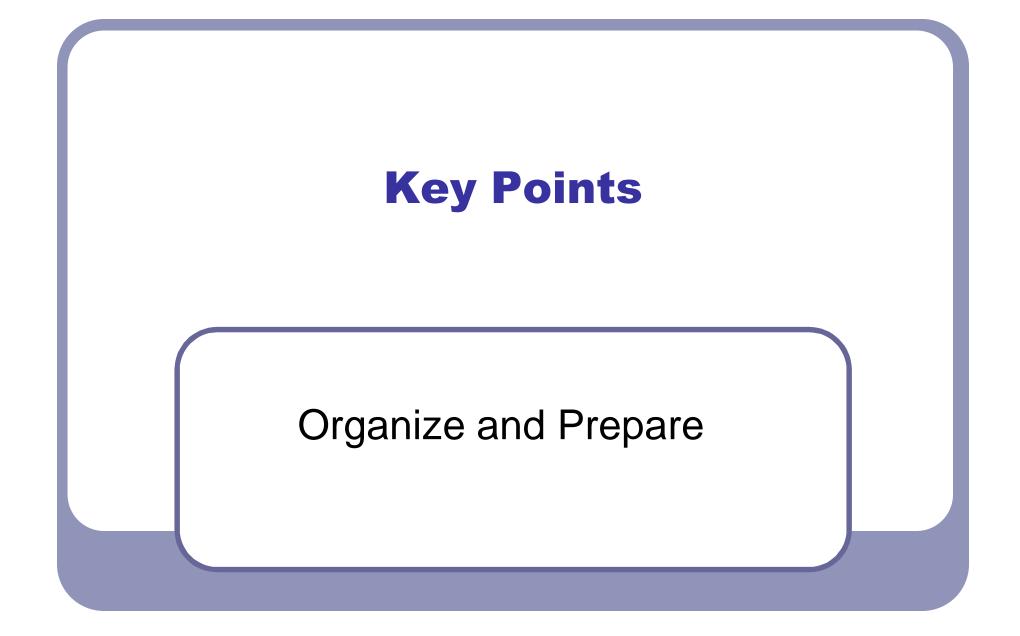
- Do: Employ a knowledgeable security firm that understands lab settings and requirements to install systems
- Do: Install what you think you need the 1<sup>st</sup> time add ons get costly and complicated
- Do: Make sure people overseeing the security systems understand the importance of following procedures, alarms can't just be turned off or ignored



- Someone gets locked in or out
- Emergency buttons and violations
- More paperwork
- Firing, hiring and background checks
- People ignore alarms

# **And Then There Are The Audits**

- The USDA, CDC, APHIS, IG, ORO not to mention NIH, AAALAC, IACUC, sponsors etc.
- Each governing body may want information presented differently
- Key Point: **Be prepared**
- It will take more than one person, It takes a team
- Assign tasks



## **Check Lists**

- Get the Audit check lists from each agency
- Work from those lists
- Document each when completed
- Questions? Call the agency

# **Select Agent Program Manual**

## Compile ALL info in one manual

- Regulations
- Permits
- Inspection reports
- Approvals
- Training
- ETC.

#### Resources

- Chabsa.org
- Aphis.usda.gov/programs/ag\_selectagent
- Cdc.gov/od/sap/
- Biosci.ohio-state.edu/~jsmith/TextSafetyPage.htm