

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 (1st interim rule)
November 2003 (2nd 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 1st 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 1st 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

Security Problems

- 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

Key Points

Organize and Prepare

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