

How to Succeed as a Responsible Official

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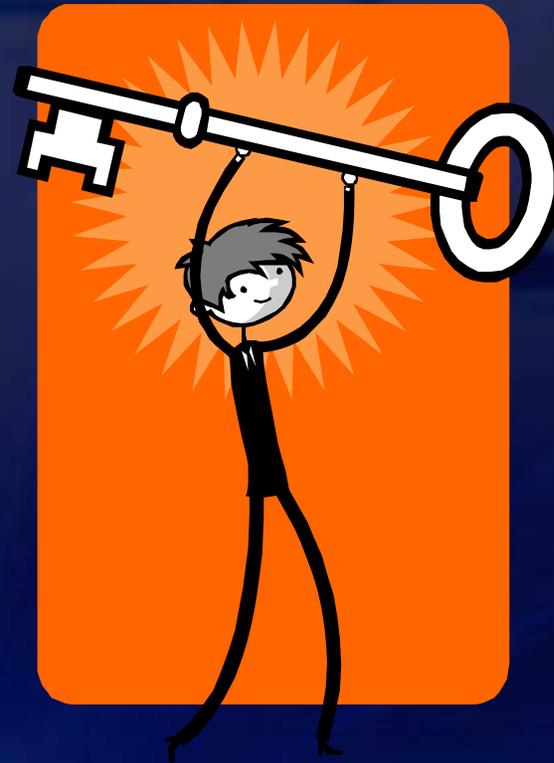


**Select Agent Program
Workshop Series**



Keys to Success

- Knowledge
- Communication
- Authority
- Monitoring
- Documentation
- Coverage



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42 CFR 73.9 Requirements

- Be approved for access to select agents & toxins
- Be familiar with the regulations
- Have authority and responsibility
- Ensure compliance with regulations
- Ensure annual inspections are conducted
- Report identification of select agents & toxins



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Knowledge

- Regulations – 42 CFR 73.9 “Responsible Official”
- Laboratories – What, Where
- Work conducted – Who, What, Where, How
- Agents – What, Where, How
- Safety – National biosafety standards (BMBL)
- Security – Security risk
- Facilities – How are they maintained



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Communication

- Management
- Investigators/Laboratorians
- Engineers/Maintenance
- Security personnel
- Emergency response
- Select Agent Program
- Public



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Authority/Control

- Lack of authority/control is a significant risk factor for entity compliance
- Must be engaged daily
- Position in the organization
- Must have direct access to decision makers
- Must be involved in activities that involve SA

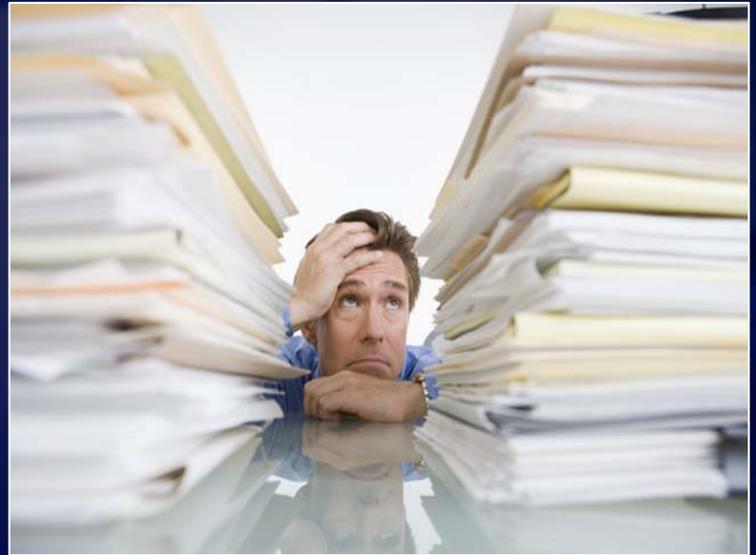


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Documentation

- Inventory
- Internal Audits
- Access Records
- Training Records
- Incidents
- Drills or Exercises
- Transfers
- Theft/Loss/Release Reports
- Isolation/Identification of Select Agent & Toxins



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Monitoring

- Access to Select Agents
- Inventories
- Personnel Access Approvals (SRA)
- Facilities and equipment
- Projects
- Records
- Training
- Security



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Coverage

(b) An entity may designate one or more individuals to be an Alternate Responsible Official in his/her absence.

These individuals must have the authority and control to ensure compliance with the regulations when acting as the Responsible Official.

[42 CFR 73.9 (b)]



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Building a Program



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Program Needs Work



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Lost in the Fog



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You Are Not Alone



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We are Here to Help



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Resources

- **www.selectagent.gov**
 - Forms
 - Templates
 - Standards, Regulations, FAQ, Updates
- **LRSAT@cdc.gov**
 - Questions
 - Notices
- **File Manager**
 - Status of amendments
 - Questions about your entity
 - Inspections



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Thank you



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