

National Select Agent Workshop

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Select Agents and Toxins Regulations

- Public Law 107-188; June 12, 2002 requires the United States to improve its availability to prevent, prepare for and respond to acts of bioterrorism and other public health emergencies that could threaten public health and safety or American agriculture.
- Regulations developed were:
 - HHS: 42 CFR part 73
 - USDA: 9 CFR part 121 and 7 CFR part 331.



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Regulations

7 CFR 331, 9 CFR 121, and 42 CFR 73

- Registrations
 - An individual shall not possess, use, or transfer any select agent or toxin without a certificate of registration
 - As a condition of registration an entity must designate a responsible official (RO).
- Approvals by the APHIS Administrator or HHS Secretary of Security Risk Assessments (SRA) by the U.S. Attorney General of:
 - The entity (or individual)
 - The RO
 - Any individual who owns or controls the entity



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Responsible Official

- Must be approved by the APHIS Administrator or the Secretary of HHS.
- Be familiar with these regulations (7 CFR 331, 9 CFR 121, and 42 CFR 73).
- Have authority and responsibility to act on behalf of the entity.
- Ensure compliance with the requirements of the regulations.
- Ensure annual entity inspections are conducted and deficiencies are corrected.
- Report final dispositions to APHIS or CDC.



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Responsible Official

- May designate one or more individuals to be alternate responsible officials (ARO).
- These designees will only act in the absence of the RO.
- They must have the same authorities as the RO when acting.
- AROs are *not* replacements or assistants to the RO, serving only when the RO is not on-site.
- The RO maintains responsibility for all functions when present.
- The RO is not a high-level figurehead but someone engaged in the managerial function of the entity.



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Regulatory Meaning

7 CFR 331, 9 CFR 121, and 42 CFR 73

- Registrations
 - An individual shall not possess, use, or transfer any select agent or toxin without a certificate of registration
 - As a condition of registration an entity must designate a responsible official (RO).
- Approvals by the APHIS Administrator or HHS Secretary of Security Risk Assessments (SRA) by the U.S. Attorney General of:
 - The entity (or individual)
 - The RO
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Regulatory Meaning

7 CFR 331, 9 CFR 121, and 42 CFR 73

The *Responsible Official* must:

- Have a day-to-day understanding of these regulations.
- Have managerial function and authority to act on the legal behalf of the entity.
- Ensure annual entity inspections are conducted and deficiencies are corrected (COMPLIANCE).
- Report deficiencies found to the Agriculture Select Agent Program or Division of Select Agents and Toxins.



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Regulatory Meaning

7 CFR 331, 9 CFR 121, and 42 CFR 73

The *Responsible Official* must: (continued)

- May designate one or more individuals to be *alternate* responsible officials (ARO), **not** *assistant* responsible officials.
- These AROs will have authority only when the RO is not physically present at the entity.
- These AROs must have the same authorities as the RO when acting.
- The RO maintains responsibility for all functions when present.



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Regulatory Meaning

7 CFR 331, 9 CFR 121, and 42 CFR 73

Entity Compliance Failures are directly correlated to the level of active-participation by the Responsible Official.



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When things go wrong...

Dr. Freeda Isaac

Agriculture Select Agent Program



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“When Things Go Wrong...”

- Reporting – Theft, Loss and Release (TLR), Form 3
 - If not sure whether to report, report it!
 - Reporting in a timely fashion is better!
- Response
 - Containment – C&D of laboratory, secure package, medical monitoring
 - Corrective actions - Short Term, Long Term
- Analysis (Lessons learned)
 - Trends – Same pathogen? Same personnel?
 - Management issues-Turnover, inadequate staffing, training?



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Entity Performance Improvement Program (PIP)

Dr. Rob Weyant

Division of Select Agents and Toxins



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Entity Performance Improvement Program (PIP)

“What is It?”

- Voluntary program to resolve compliance issues and avoid formal compliance actions
- Involves increased interactions with Responsible Officials (ROs) and senior managers or directors of entities with the national select agent program
- Requires the development of improvement plans with defined milestones and verification
- Agreed upon by entity and select agent program management



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When is a “PIP” Considered

- Unresolved issues from multiple inspections at an entity
- An increase in reported incidents at an entity
- Concerns raised by an RO or select agent inspector



Generic “PIP” Protocol

- Conference call or meeting with RO and entity senior management and national select agent program director(s)
- Communication of program concerns
- Establishment of remediation plan
 - May include temporary reduction of activities
 - Defined milestones and program follow-up
- Program verification



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“PIP”s initiated thus far:

- Air handling issues within a BSL-3 facility
- Failure to produce and implement site-specific plans and training
- Cluster of incidents at an entity



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Questions?



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