

TO BE OR NOT TO BE: THE NEW SELECT AGENT REGULATIONS

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History of 42 C.F.R. Part 73



- **Version 1.0: Interim Final Rule February 7, 2003**
- **Version 2.0: Final Rule March 18, 2005**
- **Version 3.0: Proposed Rules October 3, 2011**

What to expect:



← Then

Now→



Change 1: Tier 1 Agents

HHS

- Ebola virus • Francisella tularensis
- Marburg virus • Variola major virus
- Variola minor virus • Yersinia pestis
- Botulinum neurotoxin
- Toxin-producing strains of Clostridium botulinum

OVERLAP

- Bacillus anthracis
- Burkholderia mallei
- Burkholderia pseudomallei

Tier 1:

Security: People & Places.

Biosafety: Occupational Health Program.

Training: Insider Threat Awareness.

Special Security for Variola Major and Variola Minor.

Incident Response: Notification of FBI.

Tier 1: *People* Security



Security Plan must describe *procedures* for conducting a:

pre-access suitability assessment of **persons** who will have *access* to a Tier 1 agent or toxin.

Security Plan must Describe *procedures* for the:

ongoing assessment of the *suitability* of **personnel** with *access* to a Tier 1 agent or toxin.

Tier 1: Who is Suitable?

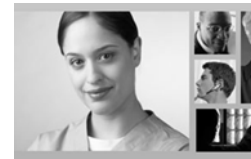


“Suitability” is NOT defined.

Section 73.11 describes minimum **procedures** for the ongoing assessment of the suitability of personnel with *access* to Tier 1 agents.

- ❶ Self- and peer-reporting of incidents or conditions that could affect an individual’s ability to safely have access to or work with select agents and toxins, or to safeguard select agents and toxins from theft, loss, or release;
- ❷ The training of all entity employees on entity policies and procedures for reporting, evaluation, and corrective actions concerning the assessment of personnel suitability to access Tier 1 select agents and toxins; and
- ❸ The ongoing suitability monitoring of individuals with access to Tier 1 select agents and toxins.

Tier 1: Who is Trustworthy?



Not only must personnel be suitable . . .

Section 73.11(e)(4)(i) “individuals with *access*” must be:

- “trustworthy” and,
- “behaving in a manner that upholds public health and safety, security, and the integrity of the scientific enterprise.”

The above terms are NOT defined.

Tier 1: Who is Suitable, Trustworthy *and* BMUP?

- CDC may publish guidance documents.
- Borrow from other entities/ fields/ industries?
 - NASA
 - CIA
- Vague standard:
 - Pro: Entities will choose their own “procedures?”
 - Con: Will CDC Inspectors agree on the “procedures?”

Tier 1: Facility Security



- Who can access *registered space*?
 - Only those with SRAs and are trustworthy and BMUP.
- Who can access *laboratory* and *storage facilities outside of normal business hours*?

Only those specifically approved by the RO .

- Minimum security required for Tier 1 Agents?

Three barriers where each subsequent barrier is different and adds to the delay in reaching secured areas where select agents and toxins are used or stored. Barriers must be monitored in such way as to detect and assess intentional and unintentional circumventing of established access control measures under all conditions (day/night, severe weather, etc.)

Tier 1: Facility Security



- All registered space or areas that reasonably afford access to the registered space must be protected by an intrusion detection system (IDS) unless physically occupied;
- Personnel monitoring the IDS must be capable of evaluating and interpreting the alarm and alerting the designated security response force or law enforcement;
- Response time for security forces or local police must not exceed 15 minutes from the time of an intrusion alarm or report of a security incident.

Tier 1: Facility Security



Mandatory inventory audits of all Tier 1 select agents and toxins in long-term storage when any of the following occur:

- (A) Upon the physical relocation of a collection or inventory of select agents or toxins for those Tier 1 select agents or toxins in the collection or inventory;
- (B) Upon the departure or arrival of a principal investigator for those Tier 1 select agents and toxins under the control of that principal investigator; or
- (C) In the event of a theft or loss of a Tier 1 select agent or toxin.

Tier 1: Biosafety- Occupational Health Program

- Biosafety Plan must include an Occupational Health Program for Individuals with access to Tier 1 agents.

- No opt out. Individuals w/ "access" must enroll.
- The occupational health program *may* be made available to individuals without access to Tier 1 agents.
- The term "Occupational Health Program" is NOT defined.

"We believe aspects of an individual's health may be relevant to their suitability to access biological select agents and toxins; identification of potential health problems and review of medication or treatment that may affect security and safety is paramount; and, occupational health programs should inform scientists of the types of medications and treatments that might have a potential deleterious effect on working safely and securely with select agents and toxins."

Tier 1: Training

Annual insider threat awareness training on how to identify and report suspicious behaviors.

Tier 1: Special Security Provisions- Variola major and minor

→ See, 42 C.F.R §73.11(e)(5).

Tier 1: Incident Response Plan

- Describe procedures for failure of IDS alarm.
- Describe notification procedures for the FBI in the event of a theft or suspicious activity that may be criminal in nature involving a Tier 1 agent or toxin.

Change 2: All Tiers Written Security Plans



1) Must be submitted for: 1) initial registration, 2) renewal of registration, or 3) when requested.

Versus old rule: when requested.

2) Must provide for control of access to animals and plants intentionally or accidentally exposed to or infected with a select agent against unauthorized access, theft, loss or release.

Versus old rule: access to agents and toxins only .

3) Must have procedures for how the RO will be informed of *suspicious activity that may be criminal in nature* and related to the entity, its personnel, or its select agents and toxins and how the RO will NOTIFY THE FBI.

Versus old rule: no similar provision.

Change 2: All Tiers Written Security Plans



4) Information Security : limits outside access, limits internal access depending on user's role, prevents outside malicious code, provides backup access in case of main system inoperability, etc.....

5) Written procedures for receiving and shipping agents and toxins and Written Contingency Plan for Unexpected Shipments.

Change 3: All Tiers Written Biosafety Plan



The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for . . . any animals or plants intentionally or accidentally exposed to or infected with a select agent (not a toxin).

Change 4: All Tiers- Transfers



→ The individual packaging a select agent or toxin for transfer must be approved for access and possess a SRA.
→ Transportation in commerce starts when the agent or toxin is packaged for shipment and is ready for receipt by a courier . . . and ends when the package is received by the intended recipient . . .

Change 5: All Tiers Restricted Persons



- **Existing Rule 73.10: Restricting access to select agents and toxins; security risk assessments.**
 - Does not use terminology “Restricted Person.” It cites 18 U.S.C. 175b.
- **Proposed Rule:** An individual’s access approval will be denied or revoked if the individual is a “*restricted person*.” A person is a restricted person if he or she:
 - Is under indictment or has been convicted of a crime punishable by imprisonment for a term exceeding one year.
 - Is an unlawful user of any controlled substance.
 - Has been adjudicated as a mental defective or has been committed to any mental institution.
 - Etc. . .

Change 6: All Tiers Responsible Officials



- Must have the appropriate training and expertise to completely implement and manage the requirements of this part.
 - No more VPs or Regulatory Compliance Officers as RO.
- Must have their “principal duty station” at the physical location of the entity.
 - No remote ROs?
 - Entities with more than one location- RO fore each location?

Various and Sundry

- Have we settled on a definition of “Access?”
 - 73.10(b) (past and present): “An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g. ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin.”
 - Consider the phrase “limit access to registered space” for Tier 1 agents in 73.11(e)(4).
 - Consider the term “limit access to laboratory and storage facilities” outside of normal business hours for Tier 1 agents in 73.11(e)(4).

Proposed Rules: 42 C.F.R. Part 73

- Published in the Federal Register on October 3, 2011.
- Comments due by December 2, 2011.
 - To view ABSA's comments go to:
<http://www.absa.org/aiarevcom.html>.
- Promulgation Date????????????????????

Conclusion & Legal Disclaimer

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