

STANDARD DEVIATIONS: Watching Out

Greetings,

Do CAP inspections make you nervous? Maybe CLIA or JCAHO are the reason for your short fingernails. Well, just be grateful that the **Federal Select Agent Program** (FSAP) isn't looking over your shoulder. A couple days with these guys is enough to make waterboarding seem like Lagoon Day. They dot "i"s and cross "t"s with a jeweler's loupe.

The Federal Select Agent Program is jointly comprised of CDC/DSAT and APHIS/DASAT. FSAP oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products (BSAT).

Alphabet soup! Let's clear up some of the acronyms that are slung around:

BSAT. Biological select agents and toxins are pathogens or toxins that have been determined to have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products.

DSAT. The Division of Select Agents and Toxins regulates the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to *human* health.

DASAT. The Division of Agricultural Select Agents and Toxins regulates the possession, use, and transfer of biological select agents and toxins which may pose a severe threat to *animal or plant* health, or to animal or plant products.

APHIS. The Animal and Plant Health Inspection Service protects U.S. agricultural health, regulates genetically engineered organisms, administers the Animal Welfare Act and manages wildlife damage activities.

HHS. The U.S. Department of Health and Human Services is a cabinet-level agency whose mission is to enhance the health of all Americans by providing effective health and human services

HHS OIG. HHS Office of Inspector General is an independent office within HHS dedicated to oversight, combating fraud, waste and abuse and to improving the efficiency of HHS programs.

RO. The Responsible Official is the individual designated by a registered entity with the authority and responsibility to act on behalf of the entity to ensure compliance with the select agent regulations.

ARO. An Alternate Responsible Official is an individual that is appointed and approved to assume the Responsible Official's duties in their absence.



The program evolved in the aftermath of September 11, 2001. It comes out of the USA PATRIOT Act and the Public Health Security and Bioterrorism Preparedness and Response Act, two measures that responded to the 9/11 terrorism and [2001 anthrax attacks](#).

HHS and the USDA have a [list of agents](#) that are regarded as threat-worthy. They include bacteria, viruses, fungi, and toxins. Some are affecting humans, some plants and animals, and some are threats to both groups. Periodically the list is revised/updated to add or remove agents.

Within the select agents are a select group of really bad-ass bugs and toxins characterized as “presenting the greatest risk of deliberate misuse with most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence.” Handling agents of this subset (called [Tier 1](#)) requires escalated biosafety above and beyond the typical clinical capacity (e.g. BSL-3, or 4).

So, laboratories that have BSL3 and BSL-4 capacity for Tier 1 agents are regulated by the Fed. The facilities and the staff who have access are scrutinized and inspected for compliance in their biosafety and biosecurity. Fingerprinting and FBI background checks are *de rigueur* hoops to jump through. Annual inspections raise the hair on arms and necks.

FSAP inspections focus on the lab’s ability to safely and securely perform testing on select agents. Inspectors drill down into the entity’s biosafety and containment plans, security, incident response, and appropriate training.

Deficiencies, or departures from regulation, are closely monitored. When any findings warrant, labs can voluntarily implement a corrective action plan. Yay!

Or,

- Suspension of (in part or in whole) the entity’s registration to possess, use, or transfer biological select agents and toxins.
- Revocation of the entity’s registration.
- Referral of the entity to the Health and Human Services Office of Inspector General for further investigation and possible civil monetary penalties.
- Notification to the **Federal Bureau of Investigation** of inspection findings that identify potential violation of criminal law.

Yikes.

When you throw in the caveat that these inspections may be unannounced, the value of good practices becomes apparent.

The Federal Select Agent Program inspections are daunting because the work with these agents is pretty sensitive. Tier 1 testing capability is important to protecting the clinical laboratorians who may encounter these agents in disease diagnosis and the general population in biothreat situations.



But inspections are inspections. They all have value and promote good science. Maintaining secure inventory documentation, adhering to structured routines, ensuring instrumentation performance, and following best practices for safety and security are fundamental to *any* successful inspection.

Next week I'll break down the forms we are required to submit for this testing. Meh. But to understand what we do inside the biosafety cabinet, we have to talk about all the things we do on the outside, too.

Have a great week and be safe,

Bryan

