STANDARD DEVIATIONS: Form(s) and Function

Greetings,

What's government regulation without a bunch of paperwork? Non-existent, that's what.

The Federal Select Agent Program (FSAP) regulates 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. That entails having a system to track the users, handling the agents, problems with agents, and identifying select agents through testing. Forms, forms, forms, and more forms; 5 forms to rule them all (apologies to J.R.R. Tolkien).

Here they are:

Form 1: Registration and Amendments.

An individual or entity that intends to possess, use, or transfer any select agent or toxin must register with Department of Health and Human Services (HHS)/Centers for Disease Control and Prevention (CDC)/Division of Select Agents and Toxins (DSAT).

Approval is granted when a "certificate of registration" is issued. The certificate must be reauthorized every three years.

Need to make a change? Back to square one and an amended Form 1. Prior to *any* change (e.g., personnel, space, work, animal species or agents), the Responsible Official (RO) must apply for an amendment to the entity's certificate of registration. The amendment must be approved before the requested changes can be implemented.

Form 2: Transfer Requests.

Form 2, Request to Transfer Select Agents and Toxins, is used by entities to request prior authorization of a transfer of select agent(s) or toxin(s). Sounds pretty straight forward? Listen up.

To move a SA, Form 2 requires the sender identify:

- Recipient information
- Sender Information
- Agent or toxin, and how it came to be (e.g. a clinical sample or experiment product)
- Contact Information for Individual Notified of Expected Shipment
- Packaging and Shipping Information
- And a signature

But that ain't all. The form must be completed by the recipient, too. They need to include:

- Shipment Receipt and Condition

- Signature
- And the *transfer must occur within 48 hours*. If not, the recipient must also complete Form 3.

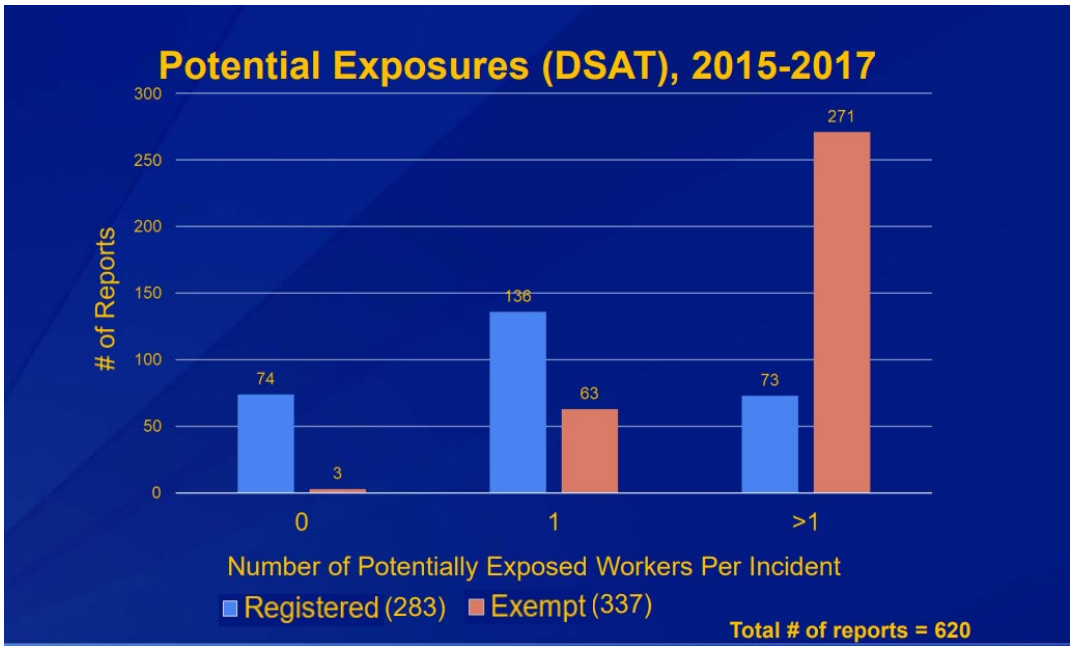
Form 3: Report of Theft, Loss, or Release.

Form 3, Report of a Release/Loss/Theft, is used by entities to report a theft, loss, or release of a select agent or toxin. Discovery of a theft, loss, or a release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent or toxin is required to be immediately reported.

This is the one you never want to fill out. This is how we report any accidental exposures with SA, or "Why MALDI-TOF may not be the best choice for every sample". Loss of containment is the leading reported release and bacteria are the most common agents.

To be fair, PPE failure and spills account for exposure, too, and lab acquired disease is extremely rare.

But, this graph illustrates how a release can affect staff:



Need to report loss or theft? You'll become familiar with an FBI agent (probably not on a first name basis).

Form 3 is a nightmare for clinical labs; this is one reason why we preach **Rule Out & Refer**, and offer training for recognizing these bugs using ASM sentinel lab protocols.

Form 4: Report of Identification.

Form 4, Report of the Identification of a Select Agent or Toxin, is used to notify the Federal Select Agent Program of the identification of a select agent or toxin as the result of diagnosis, verification, or proficiency testing and of the final disposition of that identified agent or toxin.

When the system works, we love to find these guys in tissues, slants, and plates (and PT) that are sent our way. Successful recovery of an agent makes our work useful and rewarding. The pain of filling a Form 4 is offset by the validation of our practices and protocols.

When an agent *is* identified, there is an immediacy to reporting and disposing the entire contents. We're also reaching out to our partners to report the finding and trace any other samples that may be around as well as determining any need for the dreaded Form 3.

Form 5: Request for Exemption

Form 5, Request for Exemption, is used by an entity to request an exemption from the select agent regulations for an investigational product. This is not a common event, and is used for research purposes where investigation warrants using the agent. We've *occasionally* transferred (Form 2) agents to universities for research.

Robust records are important to any lab's success. Regulation of Select Agents imposes a burden with the required forms. We keep records that require a lot of detail but it protects the population and the workers. The FSAP helps to ensure the safety of clinical laboratorians and the accurate diagnosis of disease caused by agents that pose a risk to all.

Have a great week and be safe,

Bryan

p.s. I know that you're dying to see the forms (or from boredom reading this), so here are some print-only files:

APHIS/CDC FORM 1

APHIS/CDC FORM2

APHIS/CDC FORM 3

APHIS/CDC FORM 4A (This is the form we use for *clinical samples*; Proficiency Tests and criminal seizures need Form 4B or 4C.)

APHIS/CDC FORM 5