



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



Importance of a Personnel Reliability Program as Part of a Culture of Responsibility

FESAP Perspective

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FESAP



- Federal Experts Security Advisory Panel
 - 15 Departments and Agencies represented
 - Chaired by HHS and USDA
- Asked to make recommendations on:
 - Tiering of the list and removal of agents/toxins
 - Physical security for Tier 1 Biological Select Agents and Toxins (BSAT)
 - **Security requirements for personnel with access to Tier 1 agents and toxins**
 - **Provided advice for regulations and guidance**



Outline

- Exercise
- Highlights of Latest Select Agent Program Revision
 - Suitability Assessment
 - Pre-access
 - On-going
- Supporting a Culture of Responsibility

The concepts in this presentation are those of the presenter and not necessarily those of the Federal Government.



Exercise



- Professor X would like to bring on A. Goode Scientist, Ph.D. to contribute to her lab's research, which involved Tier 1 BSAT.
- Dr. Scientist has provided a resume, an FD-961 form, and fingerprint forms.
- Professor X has requested an expedited review from you, the institution's RO, because of the critical nature of this project.
- How do you decide whether or not to allow access to BSAT in this case.
 - How do you assess trustworthiness or reliability when you don't know someone?



A. Goode Scientist, Ph.D.



Accomplished scientist seeks position in infectious disease laboratory.

Experience

Research Associate, Uniformed Services University of the Health Sciences
Student Researcher, University of Cincinnati
Laboratory Technician, University of Miami

Experience

Education

Ph.D. Biology, University of Cincinnati

Education!

Publications

Journal of Infectious Disease
Journal of Medical Laboratory Science
American Journal of Tropical Medicine and Hygiene

Peer-Reviewed Work!

- A. Goode Scientist filled out an FD-961 form and fingerprint cards, which are submitted to FBI for a **Security Risk Assessment**



- A. Goode Scientist has a favorable SRA
What to do?



Executive Action



- In 2005, President Bush ordered a review of the existing Select Agent Program and other aspects of pathogen security in the U.S.
 - Gaps were identified in the assessment of individuals
 - Some ROs lacked clarity in understanding what a favorable FBI SRA meant
 - Some ROs did not feel empowered to deviate from the SRA decision



SRA is a specific database check



An individual with a favorable SRA:

- Is not under indictment for nor has been convicted of a crime punishable by imprisonment for a term exceeding 1 year
- Is not a fugitive from justice
- Is not on record as being an unlawful user of any controlled substance
- Is not an illegal alien
- Hasn't been adjudicated as a "mental defective" and hasn't been committed to any mental institution
- Isn't from a country that has repeatedly sponsored terrorism
- Hasn't been dishonorably discharged from the Armed Services
- As far as we can tell, isn't a member of a known terrorist organization
- Hasn't committed an act of terrorism transcending national boundaries
- Doesn't knowingly involve themselves with terrorist organizations
- Isn't a known agent of a foreign power.



Where does that leave us?

- Do we have a complete picture of our candidate?
- Are we empowered to ask for more information?
- There's pressure to hire this individual– we're standing in the way?
- Who are we to question the FBI's assessment?
- What to do?



Executive Action



- In 2009, President Obama ordered action to address gaps identified by Federal and non-Federal advisory panels
 - Created FESAP
 - Required Select Agent Rules to be updated



New Select Agent Regulations

- Section 11(f) (1) of the select agent regulations (Part 331 of Title 7, Part 121 of Title 9, and Part 73 of Title 42 of the Code of Federal Regulations) provides that the security plan for an entity possessing Tier 1 biological select agents and toxins (Tier 1 BSAT) must describe procedures for conducting a **pre-access suitability assessment** of persons who will have access to Tier 1 BSAT.
- Section 11 (f)(4)(i) provides that an entity with Tier 1 BSAT must prescribe procedures that will limit access to Tier 1 BSAT only to those individuals who are approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General, have had an **entity-conducted pre-access suitability assessment**, and are subject to the **entity's procedures for ongoing suitability assessment**.



What is a suitability assessment?



- From SAP Guidance:

“Suitability Assessment Program: A combination of pre-access and on-going suitability practices, in conjunction with comprehensive and consistent review mechanisms, determining the reliability of personnel for access to Tier 1 BSAT, and allowing individuals to report risks and threats to safety and security concerning Tier 1 BSAT to entity leadership.”

- “Whole Person” review of an individual before granting unrestricted access to Tier 1 select agents
 - Collection and review of information provided by applicant
 - Education and work history
 - Reference contact information
 - Verification of information provided
 - Verify education when able
 - Review publications listed
 - Assess criminal records, if available
 - Connect with reference
 - Personal interviews





Why go through the extra steps?



- Empower RO to make a more comprehensive determination of the suitability of an individual to have access to BSAT at their institution
 - Assess how the individual has exhibited trustworthiness and reliability in the past
- Encourage a dialogue between ROs, PIs, and researchers on aspects of suitability and risk assessments



Why not have FBI run clearances?



- Timing
- Purpose of the investigation
- Expertise
- Responsibility of oversight



Skill does not equal character.

Knowledge and abilities do not ensure
trustworthiness.



Assessing Ongoing Reliability



- Don't lose contact with staff!
- Annual performance evaluations:
 - communicate expectations for safety and security, address potential problems, and coordinate with occupational health requirements.
- Robust self and peer reporting system



Reporting Systems



- Provide a consistent, safe mechanism for employees to report when they have a safety or security concern about themselves or a fellow employee.
- In this mechanism,
 - all concerns would be taken seriously by leadership,
 - responses would be proportional to risk,
 - the reporter would be protected, and
 - where necessary, assistance would be provided to ameliorate concerns.

Importance of Leadership

“We hear little of the value of “leadership” as a measure of safety and security in our select agent labs. Successful, enlightened leaders **lead** with quality science, an emphasis on safety, vision, education, responsibility, accountability, honesty, transparency, and ethics. From this, a culture of trust and accountability virtually always results.

Quotes from “Balancing Our Approach to the Insider Threat”
-- David Franz and James Leduc



Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. September 2011, 9(3): 205-206.



Vision

- Everyone at an entity is empowered to support
 - the development of norms;
 - the safety and security of materials, laboratory animals, facilities, plants, public health; and
 - their own well-being and that of their colleagues.

Threats to Laboratories Exist



James Holmes

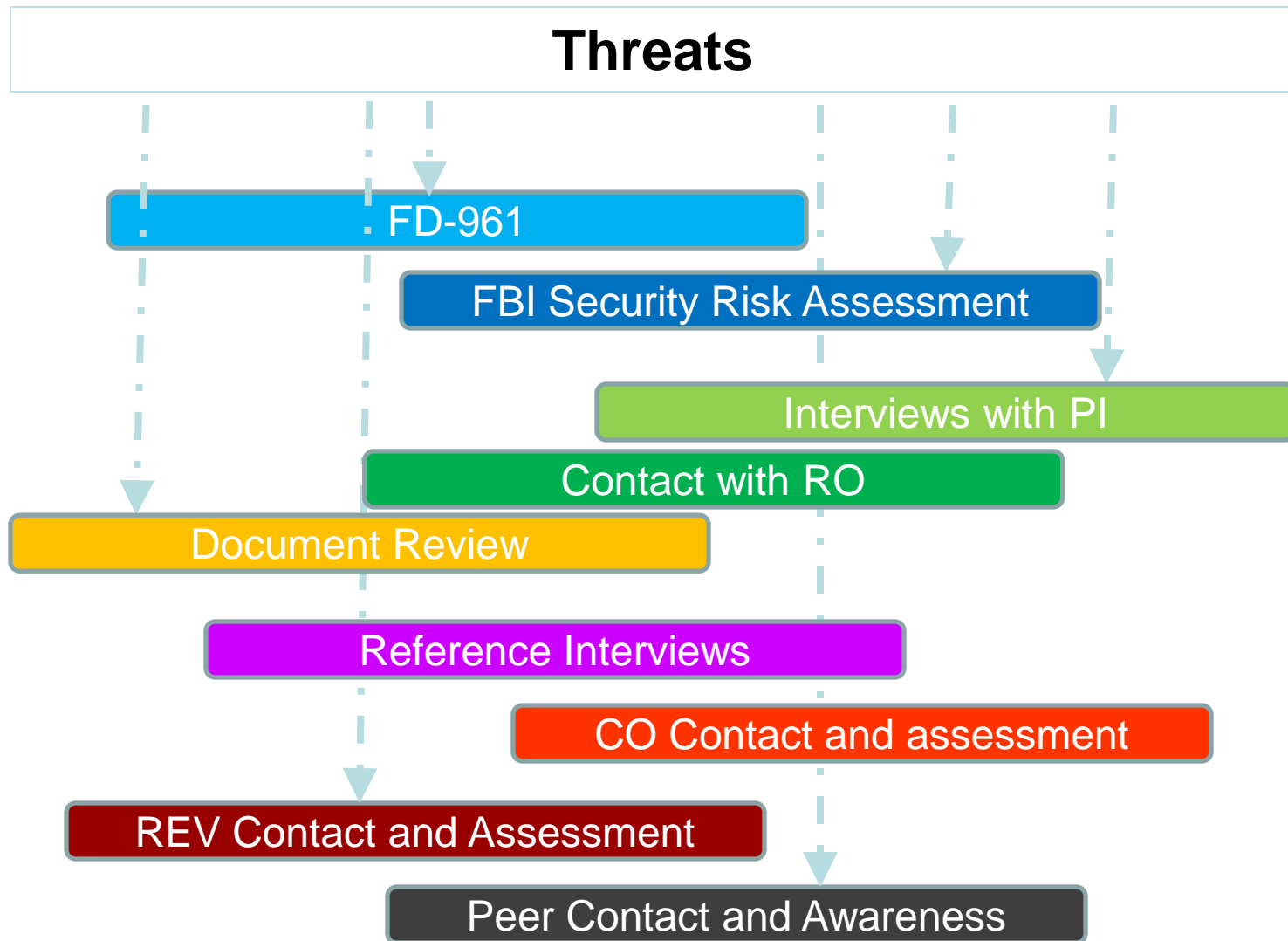
Amy Bishop



Raymond J. Clark, III



Personnel Security Layers: Select Agent Program





Conclusions



- Balancing security with scientific progress
- Continuing to identify best practices for personnel security
- Leveraging federal resources to improve security of BSAT

http://www.selectagents.gov/Guidance_Documents.html

- Living Document! Please provide feedback to DSAT on what does and does not work.



<http://phe.gov/s3>



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