Case Studies in Suitability and Application to the Research Community

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Select Agent Program

Approval requires two background checks for Tier 1 registered facilities:

SRA approval
Tier 1 Suitability
Suitability Program

**Must include:**

- A “whole person” assessment.
- Mechanisms in place for both self- and peer-reporting.
- Enhanced security.
- Ongoing training, including that for insider threats.
- An Occupational Health Program.
- *Ongoing assessment for continued suitability.*

**Should Include**

- A culture of safety supported at every level of the entity
- Free communication, interdepartmentally, to conduct Suitability Assessments.
- Support from entity leadership to commit to decisions of the RO and, if applicable, the Suitability Panel
Case Study: Personality Conflicts

Scenario: Two individuals, both approved for access to Tier 1 registered spaces, have a volatile relationship. They are required to work together, both inside and outside of registered space. Already, they have several altercations and reported each other to their respective supervisors.

Is this a Suitability Issue?

It Depends.
Case Study: Personality Conflicts

Things to Consider:

- Can this be addressed through the individuals’ supervisors?
- Are these two individuals a threat for theft/loss/release of a Select Agent?
- Are these two individuals a threat to the entity Select Agent program?

Case Study: Personality Conflicts

Potential Outcomes

- (A culture of safety supported at every level of the entity) Concerns can be brought to supervisors, with the expectation that they will support a culture of safety.
  - Can one or both of the individuals be assigned to different locations?
- Should the Suitability Panel be consulted?
Case Study: Personality Conflicts

Additional Considerations

- Does it matter if these individuals do not directly work with Select Agent?
- Has one individual has demonstrated a pattern of aggression?
- Is there a No Contact Order in place?

Case Study: Personality Conflicts

No-Contact orders at Universities

- Do you know what a “No Contact Order” means at your institution?
- Differs from university to university

Months of stalking end with 2 dead at UW
Case Study: Attempts or Threats of Self-harm

Scenario: A graduate student, with approval to work with and access to Select Agent, has been hospitalized because they made a credible threat of self-harm.

Is this a Suitability issue......?

.... or a health issue?

Yes.
Case Study: Attempts or Threats of Self-harm

Acute concerns may require action that can be reversed.

- **Temporary** or permanent suspension of Suitability
- **Temporary** or permanent assignment to non-Select Agent registered spaces

If the suspension is considered temporary, what are the terms for regaining access?

Case Study: Attempts or Threats of Self-harm

Use of Your Occupational Health Program

- Potential in-house evaluation
- Ability to refer the individual to mental health care professionals outside of the university system
- Can speak to mental health care professionals outside of the university system without compromising medical confidentiality
- Can provide recommendations concerning Suitability without compromising medical confidentiality
Case Study: A Principle Investigator’s Suitability is in question

Scenario: A Principal Investigator, who previously was found suitable for work with Select Agents, is demonstrating erratic behavior.

What issues must be considered if a Select Agent PI is found unsuitable?
Case Study: A Principle Investigator’s Suitability is in question

Special Considerations

- Should the PI’s lab personnel continue to have access to Select Agent registered spaces if their PI is found unsuitable?
- Who should communicate with personnel that report to a PI that has been found unsuitable?
- Does the PI have a Select Agent inventory?

Suitability and Wider Application to the Research Community

Tier 1 Suitability exists because of the high impact that misuse of Select Agent can have on the workers, the entity, and the general population.

What other program’s misuse would have a high impact on workers, the entity, or the general population?
Environmental Health & Safety

Suitability and Wider Application to the Research Community

Any BSL-3 Facility

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

CDC Generally Met Its Inspection Goals for the Federal Select Agent Program; However, Opportunities Exist To Strengthen Oversight

University of Pittsburgh

Environmental Health & Safety

Suitability and Wider Application to the Research Community

Animal Care Groups
Suitability and Wider Application to the Research Community

Individuals ordering large amounts of specific chemical agents

- Nicotine
- Dimethylmercury
- Ethylene Glycol
- Arsenic
- Sodium Cyanide
- Ethylene Glycol
- Sodium Cyanide

In Conclusion

- Suitability Assessments are a powerful tool in maintaining a culture of safety.
- Case studies in Suitability illustrate that there are multiple approaches to answering personnel concerns.
- The application of portions of the Suitability Assessment to sensitive departments and programs may enhance overall safety and security.
Thank you!

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