



Federal Experts Security Advisory Panel Meeting July 21, 2011

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ABSA

American Biological Safety Association

www.absa.org

Thank You to FESAP

- ABSA is pleased to be working with FESAP and the USG to ensure an effective partnership to develop policies based on biorisk assessment and rational biorisk management.
- ABSA is honored to be a partner in this initiative, not only for today's presentation, but in the future development of a rational risk based approach to laboratory biosecurity.

American Biological Safety Association

- History
 - 1955-The 1st Annual Biological Safety Conference
 - 1984-ABSA officially founded/incorporated
- Membership Profile
 - 1,700 members (≈300 international, 37 countries)
 - Life Scientists, Safety and Security Professionals, Veterinarians, Industrial Hygienists, Engineers, Architects, Nurses, MD's
 - Representing academia, government laboratories , private industry

ABSA's Platform for FESAP

- ABSA is generally supportive of the proposed improvements to the Select Agent Regulations from the FESAP report (June 2011)
- ABSA is poised to engage appropriate members to participate with FESAP on personnel reliability, physical and cybersecurity, and tiering issues
 - Biosecurity subject matter experts
 - Biosecurity Task Force
 - ABSA Council

ABSA's Tiering Recommendation

- There needs to be a consistent biosecurity risk assessment methodology to evaluate each of the currently listed Select Agents and Toxins and to tier these agents accordingly
- Without using a rigorous and transparent biosecurity risk assessment methodology, there is likely to be little advantage to the tiering of the list of Select Agents and Toxins

FESAP's Tiering Recommendation

- Tiering Results
 - In general, ABSA supports the proposed tiering of agents and toxins
- Tiering Process
 - All 82 BSAT on the Select Agent list were scored against **20 criteria** by over 60 SMEs representing the federal life sciences, public health, law enforcement, security, and intelligence communities

ABSA's Comments on Tiering

- What were the qualifications of the SMEs?
- What were the 20 criteria used in scoring?
- What process was used to assess the 20 criteria?
 - Qualitative?
 - Quantitative?
 - Repeatable?
 - Published?

Assessment methodology must be rigorous AND transparent

ABSA's Personnel Reliability Recommendation

- Current Select Agent Regulations (SAR) only require FBI's Security Risk Assessment (SRA)
 - Assumes criminal background is indicator of potential misuse
 - Tends to absolve institutions of this responsibility
- Pros and cons of traditional PRP's
- Institutional management of personnel is ideal

FESAP's Personnel Reliability Recommendations

- Personnel Reliability Results
 - In general, ABSA supports proposed improvements to the Security Risk Assessment (SRA) process
 - Require pre-access suitability assessment be required in entity security plans
 - Explore the utility of behavioral assessments prior to implementation
 - Ongoing monitoring of an employee's reliability
 - Utilize reports from the biosecurity community to promote a culture of responsibility among their employees
 - Self- and Peer-Reporting

ABSA's Comments on Personnel Reliability

- The ideal program should focus on ensuring honesty, integrity and reliability among personnel
 - Locally developed and maintained
 - Comprehensive
 - A true commitment by and for the institution
- What is the difference between entities with and without Tier 1 agents?
- Use caution on how credit reports are utilized

Institutional management of personnel is key and contributes to creating a culture of responsibility

ABSA's Recommendation on Physical and Cyber Security

- Without substantive guidance biosecurity risk assessments generally are ad hoc and do not directly link to implemented risk mitigation measures
 - Inspectors and entities alike do not seem to understand the connection between risk assessment and mitigation measures

FESAP's Recommendation on Physical and Cyber Security

- Physical and Cyber Security Results
 - In general, ABSA supports proposed improvements to Physical and Cyber Security
 - Federal partners involved in BSAT security should develop a government-furnished risk management tool for Site Specific Risk Assessment to ensure:
 - Consistent evaluation of Facilities for vulnerability to particular threats
 - Implementation of security measures appropriate to the level of risk
 - Consistent inspections of activities across multiple regulatory and oversight agencies

FESAP's Recommendation on Physical and Cyber Security

- Is this adequate guidance?
- How will this be universally interpreted and implemented (by entities) and assessed (by HHS/USDA)?

Security Barriers	The entity has a robust security and monitoring system that enables the facility to thwart adversary penetrations.
Intrusion Detection and Monitoring	The entity can demonstrate a reasonable probability that unauthorized adversary actions would be detected and access would be denied, and that unauthorized actions by individuals with authorized access would be detected.
Delay/ Response Force	The entity is able to detect and initiate a response to intruders resulting in the intruders being interdicted before they reach a restricted area.
Access Control	The entity can demonstrate a reasonable probability of detecting and preventing fraudulent entry and has a system for the timely reporting of such attempts to law enforcement.
Cybersecurity	The entity provide backup power and energy sources to power lighting, networks and integrated access controls during emergencies.

ABSA's Comments on Physical and Cyber Security

- Permit individual laboratories to implement different security measures based on site-specific risk assessments
- Consider potential cost/logistical impacts
- Proposed stratification of security requirements should be rigorously reviewed by subject matter experts in the fields of biosecurity, the biosciences, and risk assessment

Security requirements should be coordinated, but not overly prescriptive

Follow-on Activities

- Proactive education and awareness to scientific community
 - Example: Dual Use Research: A Dialog video produced by NIH (<http://oba.od.nih.gov/biosecurity/biosecurity.html>)
- Investigate and identify possible funding mechanisms to help defray the costs associated with potential increased security requirements
- Future FESAP and ABSA collaborations to provide training and guidance on implementation of the new regulations
 - Written summaries
 - Informational webinars
 - Training courses or seminars

Summary

- Personnel reliability and security measures can reduce but will never eliminate the threat
- We must balance the need for security with the need for continued scientific progress
- Strategic and transparent rationale for SAR requirements will foster acceptance and compliance
- ABSA's members represent those impacted by new regulations, as well as experts in biosecurity and risk assessment, and will serve as a bridge to interpreting and implementing new biosecurity rules and approaches



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