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Biosurety Update

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CDC, Army, and DoD Regulations

- **42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121**
 - The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules for the possession, use, and transfer of select agents and toxins in the Federal Register on March 18, 2005. All provisions of these final rules supersede those contained in the interim final rules and became effective on April 18, 2005.
- **Draft Army Regulation 50-X, Biological Surety (Status?)**
 - Implemented as interim policy effective 5 May 2005, per directive DAMO-SSD Memorandum dated 7 January 2005
- **DoDD 5210.88 – Safeguarding Biological Select Agents and Toxins (11 Feb 2004)**
- **DoDI 5210.89 – Minimum Security Standards for Safeguarding Biological Select Agents and Toxins (18 April 2006)**
- **Army Regulation 190-17 – Biological Select Agents and Toxins Security Program (6 September 2006)**

The Issue – Biological is Not Chemical

- Chemical Surety relies on a balance of physical security, material safety, inventory and access control, and personal reliability
- Biological Surety *cannot* rely on inventory controls
 - All of the BSAT used in the DoD Biological Defense Research Program are available from other sources (academic institutions and laboratories, NIAID Repository, American Type Culture Collection (ATCC))
 - Laboratory activities require growth and propagation of BSAT stocks, NOT use from a single container
 - Access continues long after BSAT stocks are back in the refrigerator / freezer

The Issues facing JPEO-CBD

- Applicability of Regulations to Contractor Facilities?
- Definition of “DoD Source Biological Select Agents and Toxins (BSAT)”?
- Definition of Access to BSAT – DoD 5210.89?
 - “Access – The freedom or ability to obtain and/or make use of biological select agents and toxins (BSAT) by any individual”
 - “The number of people authorized access to BSAT shall be kept to the minimum consistent with operational, safety, and security requirements”
- DOJ/FBI versus DoD Background Investigations?

Army Regulation 190-17

- The latest voice on the subject; well written, but clearly from an MP's perspective.
 - “its provisions should be incorporated into all Army contracts that involve biological select agents and toxins” for “Army contractors that are provided BSAT by the Department of the Army”
 - 2-8. b. “Biological select agents and toxins are designated as inherently dangerous to others. The **use of deadly force is authorized** in accordance with AR 190-14”
 - 5-10. c. “The two-person concept applies to keys allowing access to BSAT reference stocks...”

Recommendations

- Applicability – appears to be a “given” contractually
- DoD Source Material – need to distinguish between ‘source’ and lineage (e.g. the difference between a bottle of anthrax spores from USAMRIID versus spores grown from an agar slant of Ames *B. anthracis* from USAMRIID)
- Access – Should be limited to primary containers of reference stocks; in concert with “DoD Source” definition
- Background Checks – DoD/Army should accept DOJ/FBI adjudicated CDC Unique Identifier