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## Putting more “Sure” in Biosurety

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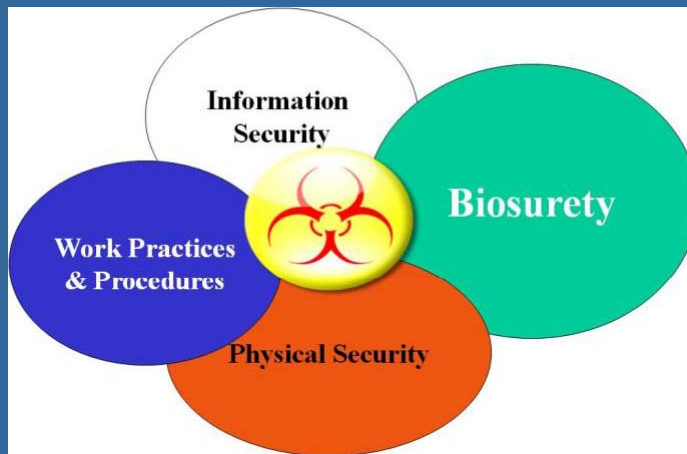
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## Integration of Biosurety





## Why Should You Care?

- Any facility that accepts DoD funding for select agent research must comply with DoD Biosurety regulations
- Impacts training which in turn impacts cost and schedule
- Impacts biosafety program.
- DoD program is most defined and stringent, there may be a government tendency to push it to other federal and state agencies
- There are better ways of improving/monitoring personnel reliability



## Current DoD Biosurety Program

- 1) Compliance with mandated and approved safety, environmental, occupational health, operational and technical procedures
- 2) Physical security measures
- 3) Procedures to assess the reliability of personnel designated for, or assigned to Biological Personnel Reliability Program (BPRP) duties
- 4) Training and/or experience applicable to the position assigned and verification that each individual is proficient in the duties to be performed
- 5) Safe and secure acquisition, storage, handling, maintenance, transportation, inventory management, and disposal of BSAT
- 6) Emergency response to biological mishaps and incidents
- 7) Assessment of organizations that possess, use or transfer BSAT



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## Philosophical Underpinnings of DoD Biosurety

- 1) Program is modeled after DoD Nuclear and Chemical Surety Programs.
- 2) Harmonization of BSAT agents is implicit and follows DHHS guidelines. Access to these materials becomes the primary driver for defining a staff position as a BPRP duty position.
- 3) Reliability of persons in DoD BPRP positions is more rigorous than other federal select agent jobs.
- 4) "Trustworthiness" is an important criteria for enrollment/continuation in a BPRP position.
- 5) Medical and mental health issues are considered important criteria for enrollment and continuation of employees in the BPRP.
- 6) Responsibility for enrollment, suspension and or disenrollment and continuing evaluation is assigned to an individual designated Certifying Official (CO) for all employees at DoD facilities and to a Contract Officers Representative for contract organizations performing DoD work.



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## Recent Biosurety Recommendations

- Defense Science Board (May 2009):
  - Monitoring: "Make changes to monitoring activities to improve effectiveness without introducing overly intrusive measures."  
"Review the usefulness of the two-person rule in preventing insider threats"
  - Scientific Enterprise: "Balance risk of a malevolent insider against detriment to the laboratory mission."
  - Compliance inspections: "provide resources for a single independent inspection team comprised of authoritative individuals".

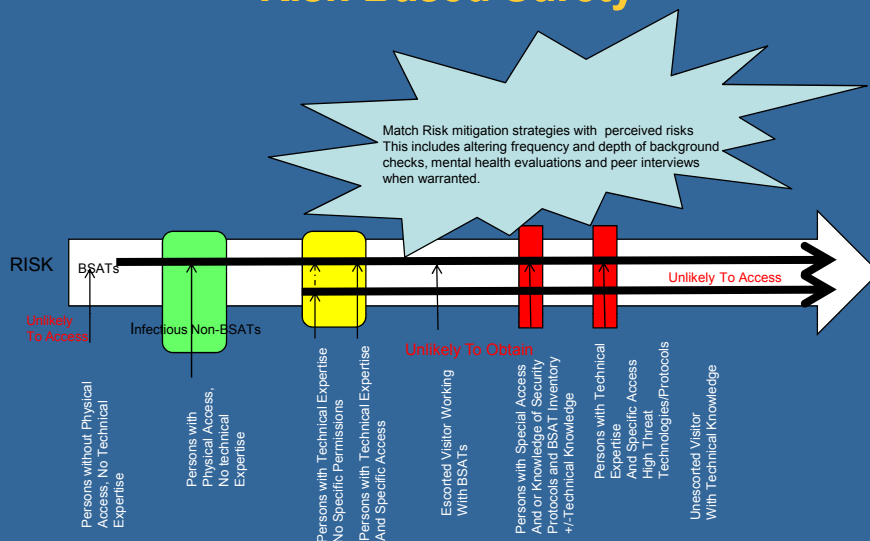


## Recent Biosurety Recommendations

- National Science Advisory Board for Biosecurity (NSABB): Enhancing Personnel Reliability among Individuals with Access to Select Agents.
  - No national Personnel Reliability Program recommended
  - Current SRA process should be strengthened.
  - Culture of responsibility and accountability should be enhanced.
  - Professional societies should encourage on ongoing dialog about PRP!!!!
  - List of select agents and toxins should be reduced or stratified.



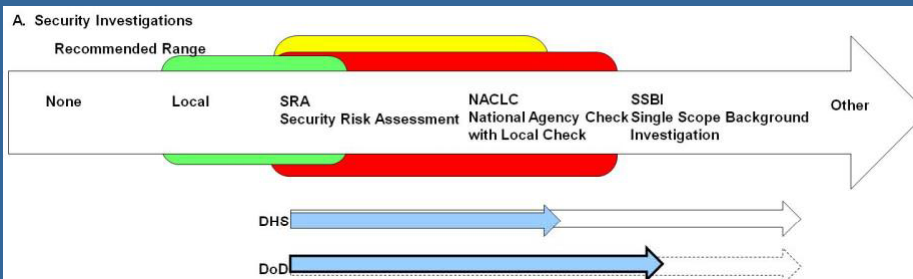
## Risk-Based Surety





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## Tools for Background Checks



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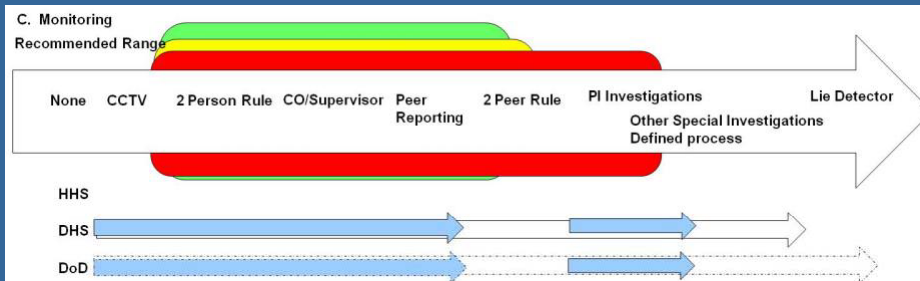
## Tools for Assessing Reliability





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## Tools for Monitoring Surety Enrollees



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## Recommendations

1. Adopt a risk-based methodology to guide background checks assessment and monitoring. Allow agencies to select from a suite of possible products to match response to risk.
2. Develop a unified approach to personnel reliability to mitigate “holes” in other government programs and to minimize the effect on the scientific enterprise.
3. Incorporate a standard form of mental health screening in reliability programs as a risk-mitigation option.
4. Downplay reliance on self-reporting as the primary source of PDI. When warranted by risk increase the frequency of background checks including peer interviews.
5. Include specific reviews and regulatory provisions in AR 50-1 and other national regulations to minimize the impact on the scientific enterprise.
6. Include specific provisions to accommodate DoD funded research in overseas locations and to cover sponsored research by foreign nationals from/in friendly countries.<sup>14</sup>
7. Develop and follow an effective 2-Peer rule vs. 2 Person rule. Rely less on CCTV as a surety measure.
8. Define and implement standardized risk-based training for all CO and CMA personnel.



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## **What Are Your Thoughts?**



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## **Backup Slides**



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## Other General Considerations

- Accreditation
- Licensure
- Alternative HR policies



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## Completed Studies

- Congressional Research Report March 5, 2009, Oversight of High-containment Biological Laboratories.
- Trans-federal Task Force on Optimizing Biosafety and Biocontainment
- American Association for the Advancement of Science Report: Biological Safety Training Programs as a Component of Personnel Reliability





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## **Pending Legislation and Studies Involving Personnel Reliability**

- HR 1225/S485 Select Agent Program
- National Academy of Sciences Report on (Personnel Reliability Sept 09)