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# **Medical Sector – Feedback on Biosurety and Sales of Equipment Developed for DoD to State and Local Governments**

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September 27, 2007**

# Biosurety Background

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**Biosurety** – “The Combination of security, biosafety, agent accountability, and personnel reliability needed to prevent unauthorized access to select agents of bioterrorism”\*

*\*Carr, K. et al, “Implementation of Biosurety Systems in a Department of Defense Medical Research Laboratory”*

- Initiated due to research in DoD labs with select agents and the threat of terrorist and criminal acts
- Regulations and guidelines with the objective to enhance physical security, monitoring, personnel reliability, and inventory registration and tracking
- Applies to military research laboratories and contractors that are supporting the development of biological defense programs

# Biosurety – Medical Sector Concerns

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- Costs associated with compliance
  - Enhancements or changes to facilities
  - Personnel testing requirements
  - Implementation of additional security requirements
  - Incorporation of new standards and procedures
- Affect on overseas laboratories and manufacturing facilities
- Affect on foreign born investigators
- Delays with the development of needed products
- Additional changes to the requirements and timing of implementation
- Biosurety requirements may discourage future partnerships between civilian contractors and the DoD

# Biosurety – Medical Sector Recommendations

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- Coordination with Industry on new regulations and requirements
- Clear direction on requirements provided to contractors
  - Make regulations readily available and discussions open to industry
- Proper lead time to incorporate new requirements
- Shared costs in incorporation of requirements
- Long term market assurance
- Coordination with HHS/FDA/USG requirements
  - Inspections, review cycles, vulnerability assessments, and security clearances
- Effort to communicate to industry and further development the partnership

# Sale of Equipment Developed for DoD – Medical Sector Concerns

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- Conditions of procured materials and equipment
  - Obsolete technologies
  - Expired lots of medicinal products
  - Potency, quality, and sterility issues
- Proper training on use
  - Special handling requirements
  - Proper use and storage
- Indemnification Issues
- Lack of Specificity on the types of technologies that will be procured by State and local governments

# Sale of Equipment Developed for DoD – Medical Sector Recommendations

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- Clarification on the types of technology and services that will be procured by State and local governments
  - Receive input from the Industry
- Ensure all procured materials are in proper working condition, safe, and ready for use
- Coordination with Industry on Public Law changes and implementation
- Clear direction on any new requirements
  - Shared costs in the incorporation of requirements
  - Make the requirements accessible
- Extend indemnification to State and local government use