

Laboratory Biosecurity: Present status and future trends

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US Legislation



- **Possession and transfer are regulated**
 - **DHHS 42 CFR 73 (2003)**
 - **USDA 7 CFR 331 (2003)**
 - **USDA 9 CFR 121 (2003)**
 - **US Patriot Act of 2001**
 - **Public Law 107-188 (2002)**

Possession, Use, and Transfer of Select Agents and Toxins: 42 CFR Part 73



- *Identifies ‘select biological agents/toxins’ and ‘overlap agents’*
- *Safety/security/emergency response plans*
- *Laboratory registration and inspection*
- *Personnel restrictions/restricted access*
- *DOJ screening*
- *Exemptions: facilities, products, situational*
- *USDA x HHS program coordination*
- *Civil penalties*

Effective Dates

Date	Applicants Possessing Agents on or before 2/7/03	Applicants Not Possessing Agents on or before 2/7/03
Feb. 7, 2003	Safety; Emergency Response; Training; Records; Notification of Theft, Loss or Release	Safety; Emergency Response; Training; Records; Notification DOJ review for entity, RO, and individuals; Transfer Section Effective
Mar. 12, 2003	Applications for DOJ review for for entity and RO submitted; Transfer Section Effective	
Apr. 12, 2003	Application for DOJ review for Individuals submitted;	
Jun. 12, 2003	Development of Security Plan	Development of Security Plan
Sep. 12, 2003	Security Plan Implemented; Training (Security Provisions)	Security Plan Implemented; Training (Security Provisions)
Nov. 12, 2003	Registration Section Effective; Entity must be in full compliance with 42 CFR 73.0	Registration Section Effective; Entity must be in full compliance with 42 CFR 73.0

Challenges in Securing Biological Pathogens



- **Accounting for Material that Replicates**
- **Accounting for Material in Many Waste Streams**
- **Transient Worker Populations (animal handlers, visiting scientists, post-docs, maintenance workers, contractors, etc)**
- **Rapid Accountability Systems**
- **Theft Detection and “Tagging”- Not Applicable**
- **Change in Mind Set to Accept Personal Reliability**
- **Others...**

Sample Biosecurity Components



- *Personnel reliability/suitability*
- *Training and education of the workforce.*
- *Material accountability*
- *IT Security*

Sample Biosecurity Components (cont.)



- ***Biosecurity incident response plan***
 - emergency procedures
 - inventory violation
 - biocontainment security violations
 - incidents that could compromise biological materials

- ***Physical protection/technical solutions***

BTWC: Questions Under Consideration



- **Regarding proposed biosecurity rules:**
 - can they be reasonably implemented
 - do they actually enhance biosecurity
 - do they merely provide the ‘perception’ of biosecurity
 - do they deter legitimate research and legitimate public health initiatives
 - verification: who, how, when, metrics

Current and Future Challenges



- **Identifying hazards that need to be secured:**
 - **Australia list**
 - **CDC/USDA list**
 - **Country specific differences**
 - **What about agents that are not on 'the list', but are hazardous/newly emergent?**

Possible Paths Forward



- **States parties develop strategies that address their biosecurity needs, and can work at their institutes/countries**
- **Developing a unified global approach to biosecurity, if possible**
- **Inviting professional organizations to review and provide constructive comment on proposed biosecurity rules**

ANSI Potential Role

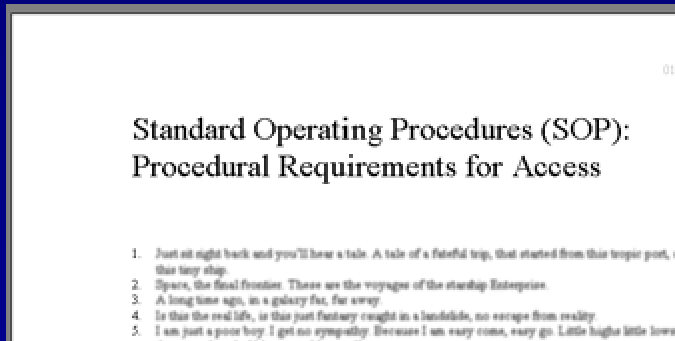


- **Provide consultation to USG**
 - review USG proposed guidelines
 - review and comment on future CFR
 - suggest metrics for success
 - develop listing of technical products (consumers guide approach)
- **You must**
 - understand the problem
 - understand bio
 - understand the ultimate customer base

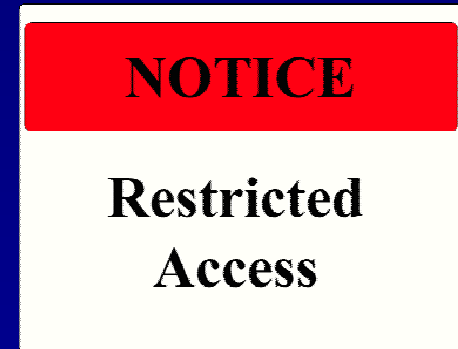
Control Access to Biological Research Area

Some Sample Solutions:

Administrative Practices



Sign on Door



Key Pad



Card Reader



Etc...

Monitor & Record Activities in Restricted Areas



Some Sample Solutions:

Logbook/no security

Security with entry logbook

CCTV Digital Recorder

