Laboratory Biosecurity: Present status and future trends

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Possession and transfer are regulated

- USDA 7 CFR 331 (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
<table>
<thead>
<tr>
<th>Date</th>
<th>Applicants Possessing Agents on or before 2/7/03</th>
<th>Applicants Not Possessing Agents on or before 2/7/03</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb. 7, 2003</td>
<td>Safety; Emergency Response; Training; Records; Notification of Theft, Loss or Release</td>
<td>Safety; Emergency Response; Training; Records; Notification DOJ review for entity, RO, and individuals; Transfer Section Effective</td>
</tr>
<tr>
<td>Mar. 12, 2003</td>
<td>Applications for DOJ review for entity and RO submitted; Transfer Section Effective</td>
<td>Application for DOJ review for Individuals submitted;</td>
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<tr>
<td>Apr. 12, 2003</td>
<td>Application for DOJ review for Individuals submitted;</td>
<td></td>
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<tr>
<td>Nov. 12, 2003</td>
<td>Registration Section Effective; Entity must be in full compliance with 42 CFR 73.0</td>
<td>Registration Section Effective; Entity must be in full compliance with 42 CFR 73.0</td>
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</tbody>
</table>
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
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?
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

Standard Operating Procedures (SOP):
Procedural Requirements for Access

Sign on Door

NOTICE

Restricted Access

Key Pad

Card Reader

Etc…
Monitor & Record Activities in Restricted Areas

Some Sample Solutions:

- Security with entry logbook
- Logbook/no security
- CCTV Digital Recorder