Session: Implications and Interactions with Government, Scientific, and Academic Community

Impact of the Select Agent Rule on Veterinary Laboratories

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Impact of the Select Agent Rule on Veterinary Laboratories

- New SA Rule added agencies, labs, agents, activities
  - Coordination required
  - Phases useful but deadlines difficult to meet

- The rule is expensive to implement
  - Zoning in University settings
  - Retrofitting older facilities
  - BSL-3 space for storage and use is limited
  - Security equipment, personnel, recordkeeping

- 7-Day provision impairs function
  - Restricts full work-ups, characterization
  - More definition on “threshold of identification” needed
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- Exclusions and exemptions are helpful
  - Exclusions for fixed tissue and genetic elements
  - Exemptions for vaccine/QC control strains and diagnostic specimens
  - More 'advertisement' of exemptions needed

- Rule helps increase attention on the biosafety and biosecurity of the agents
  - Specialists hired or focused
  - Chain of custody, shipping addressed concurrently
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- **Inspections**
  - Have gone well for the most part
  - More training of inspectors needed
  - Checklist needs refinement
  - Double-inspection is a concern

- **Personnel**
  - Clearance procedures are slow
  - Accompaniment is difficult (esp. in biocontainment)

- **Associated activities**
  - Permits for movement need streamlining