

ABSA Laboratory Accreditation Task Force

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ABSA American Biological Safety Association

www.absa.org

Current Oversight in U.S.: Regulations and Guidelines

- Regulations are few
 - Select Agent Rule
 - BBP standard
 - Transportation regulations (DOT, ICAO, IATA)
 - Infectious waste regulations (by state)
- Guidelines set best practices for biosafety
 - BMBL
 - NIH Recombinant DNA Guidelines



Concerns of Congress (Their Perceptions)

- No oversight of high containment labs
- Isolated incidents are “the rule”
- Confusion between bioterrorism and legitimate research on RG3 and 4 agents
- Ignorance of microbiology
 - Organisms ubiquitous in nature
 - Ability to reproduce



Uniform Application of Standards

- Important to implement uniformity
- Must be flexible
 - Facility, institutional, research differences
 - One size does not fit all



Accreditation vs. Certification

- Different definition in US vs. International community
- National Institute for Standards and Technology (NIST) definitions differ from ISO



Certification

NIST SP 260-100

- Documented testing to a standard issued by a certifying body, national or int'l standards org.
- Performed by third party w/ authority to certify. Authority given by certifying body.
- Personnel qualified by reference organization.

ISO 17000

“Third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks”



Accreditation

NIST SP 260-100

- Certification plus proficiency testing and demonstration of an acceptable level of performance to a standard
- Observed and documented by a third party
- Documents adherence to a standard, competency, proficiency, and performance

ISO 17000

“Third-party attestation related to products, processes, systems or persons assessment [*sic*] except for conformity assessment bodies themselves, to which accreditation is applicable”



Laboratory Accreditation

In the U.S.:

- ABSA uniquely positioned to lead process
- Will assure workers and community of competence
- More effective and less costly than state and federal government regulation
- Will assess quality management and technical competence
- Will use relevant national and international guidelines



Key Components of Proposed Accreditation Program

- Evaluate biosafety expertise of personnel
- Evaluate biosafety management structure supporting research
- Adequacy of biocontainment measures
 - Facilities
 - Equipment
 - Methodologies
 - Record-keeping
- Voluntary
- Applies only to high containment labs (BSL-3)



Challenges of Laboratory Accreditation

- Must unify laboratory inspection programs
- Must not impede research
- Must not overburden institutions already subject to numerous inspections
- Must be performance-based and not force institutions to develop additional paperwork



ABSA Standards

- Base accreditation on CEN Workshop Agreement (management system)
- BMBL and NIH Recombinant DNA Guidelines (technical foundation)
- Partner with currently-involved agencies (CDC, USDA, NIH) and organizations (ASM, AALAS, AAVLD, APHL)



Trans-Federal Task Force

- Report published July 2009
- “OBJECTIVE 2: Encourage a robust culture of accountability characterized by individual and institutional compliance with biosafety and biocontainment regulations, guidelines, standards, and policies.”



Trans-Federal Task Force (cont.)

“Recommendations:

- 2.1: Mandate compliance with Federal biosafety and biocontainment guidelines, including the *BMBL* and the *NIH Guidelines*, for all high and maximum containment research institutions in all sectors.
- 2.2: Support the development of an accreditation system for biosafety/biocontainment management programs at high and maximum containment research institutions.”



Accreditation Task Force

- Initial meeting after Reno conference
- Many phone conferences
- Two face-to-face meetings (July and December 2009)
- Web conferences to develop and edit documents



Accreditation Task Force

- Studied feasibility (initial charge from Council)
- Engaged outside stakeholders
 - ASM
 - AAALAC
 - AALAS
 - USDA
 - CDC
- Studied models from other organizations
 - CAP
 - AAALAC
 - AAVLD
- Council approval to proceed



Accreditation Task Force (cont.)

- Developed Draft standards document
 - Management of biosafety (CWA 15793)
 - Operations, facilities, equipment, recordkeeping (BMBL, SA and NIH rDNA Guidelines)
 - Personnel – education and training
- Addressed comments from members (rev 17 on ABSA website)
- Developing inspection/audit checklists



Next Steps for TF

- Solicit comments from external stakeholders
- Develop guidance documents and training for inspectors
- Form accreditation commission & committees
- Do pilot inspections with instructors committee, use lessons learned in inspector and lab training
- Solicit/select and train inspectors
- Make standards & checklists available for interested parties
- Solicit volunteers for pilot accreditation program



Summary

ABSA Laboratory Accreditation Program

- Will be voluntary
- Will be in U.S. only
- Will be modeled after similar US-based accreditation programs
- Will proceed via pilot program
- Will evolve with feedback and self-assessment

