

ABSA Laboratory Accreditation Task Force *2011 Activities*

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Christina Z. Thompson, MS, RBP, CBSP
Accreditation Task Force Leader



ABSA American Biological Safety Association

www.absa.org

Accreditation Task Force

- Started in response to concern about lack of oversight of BSL 3 labs that are not in the Select Agent program
- US regulators suggested that ABSA start a program before the US government developed regulations and inspected these labs



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



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
- Face-to-face meetings (July and December 2009; January 2010)
- Many phone conferences
- Web conferences to develop Standards and Checklists



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



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)
- Developed inspection/audit checklists



2011 Pilot Site Visits

- \$10,000 budget approved by Council
- 3 sites volunteered:
 - Veterans Administration research laboratory (Indianapolis)
 - University of Texas Southwestern Medical Center (Dallas)
 - Colorado State University (Ft. Collins)



Pilot Site Visits (cont)

Evaluated:

- Management of biosafety programs
- Facilities and equipment
- Work practices

CWA 15793, *Laboratory Biorisk Management Standard*

BMBL 5th edition;
NIH rDNA Guidelines



Pilot Site Visits (cont)

- Two task force members for each visit
- Consultative, friendly, cooperative
- Final report issued
 - Observations
 - Recommendations
 - Best practices
- Value to all parties

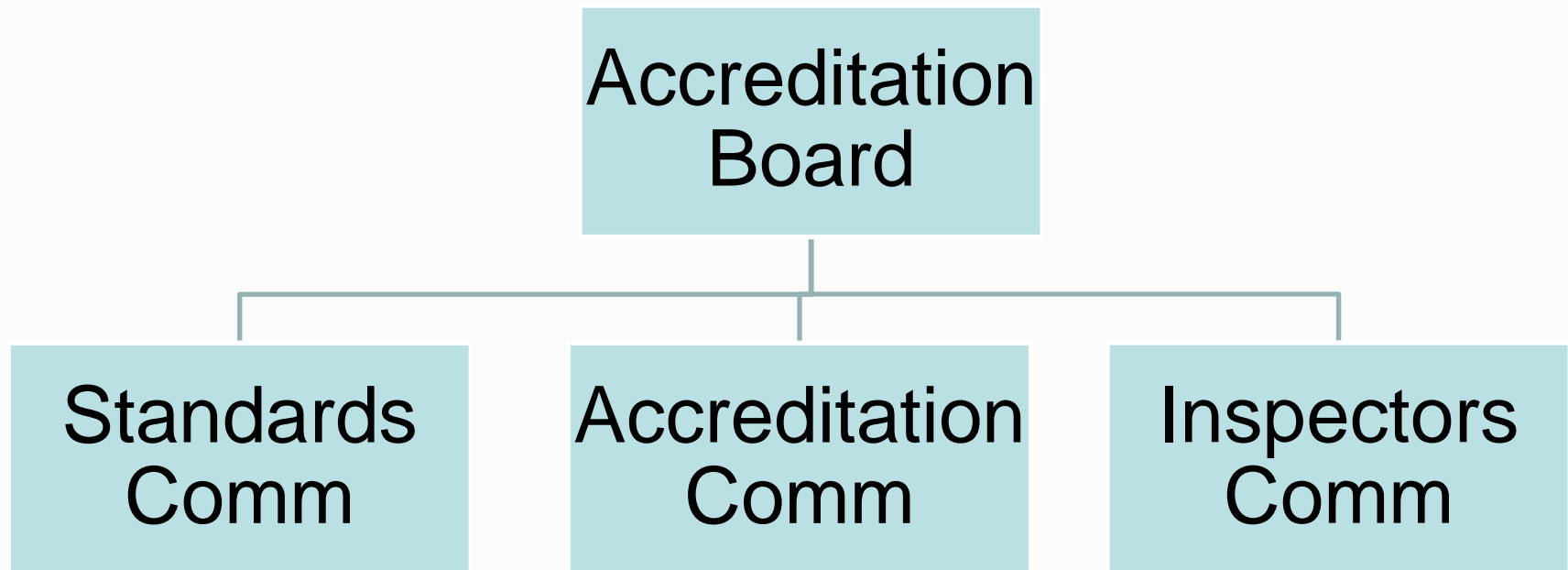


2011 Council Meeting

- Reported on site visits
- Council made decision to proceed (cautiously)
 - Conservative forecast
 - Reasonable cost to entities
 - Most likely graduated fees based on size (ala AAALAC)
- Plan to grow with demand



Accreditation Board Structure



Bylaws and Policies & Procedure

- Will work with attorney to establish bylaws and policy & procedure to protect from legal risks
- Will ensure objectivity and a fair process
- When to become its own entity?



Next Steps

- Develop specific startup plan
- Form Accreditation Board & Committees
- Develop guidance documents and training for inspectors
- Establish Bylaws and P&Ps
- Solicit advice from external stakeholders
- Engage partners?
- **Solicit entities interested in accreditation**

