

# ABSA Laboratory Accreditation *2013 Update*

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ABSA  
Kansas City, MO

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**ABSA** American Biological Safety Association

[www.absa.org](http://www.absa.org)

# Purpose of Accreditation

To provide entities recognition of excellence  
and compliance with high biosafety  
standards



# Benefits of Accreditation

- Verification that organizations are meeting industry standards
- Safety assurance for staff, researchers, and the public
- Assurance for stakeholders
- Sharing best practices in an evolving industry
- Guidance in proper management and conduct of research in high-containment laboratories



# 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

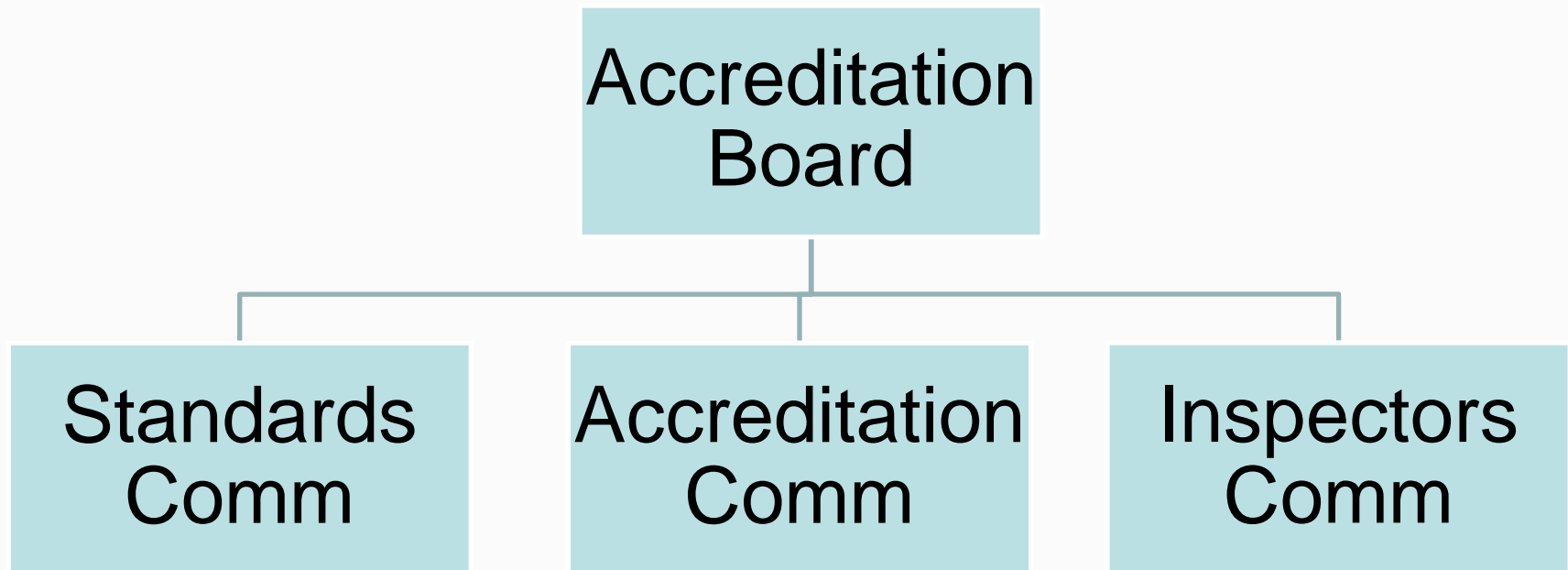


# Structure Development 2012-13

- Developed detailed start-up plan
- Formed Accreditation Board and Committees
- Populated with Task Force members plus credentialed ABSA members
- P&Ps developed for Board and Committees
- Supporting documents and Inspectors' Manual developed



# Accreditation Board Structure



All members sign Confidentiality Agreement & Conflict of Interest Disclosure



# Board & Committee Chairs

- ABSA Accreditation Board: Bob Hawley
- Standards Committee: Bill Homovec and Rob Heckert
- Accreditation Committee: Bob Ellis and Rebecca Caruso
- Inspectors Committee: Chris Thompson and Marian Downing





# To Seek Accreditation

- <http://www.absaaccreditation.org>
- Application:  
<http://www.absa.org/pdf/ABSAlabAccreditationInfo.pdf>
- 2 pages + 1 information page



# Fees\*

Number of Laboratories (approximate size range)	Application Fee	Annual Accreditation Fee
1-2 (<3000 ft <sup>2</sup> total)	\$ 250.00	\$ 2,000.00
3-5 (3000-7500 ft <sup>2</sup> )	\$ 250.00	\$ 5,000.00
6-10 (7500-15,000 ft <sup>2</sup> )	\$ 250.00	\$ 7,500.00
> 10 (>15,000 ft <sup>2</sup> )	\$ 250.00	1ft <sup>2</sup> x \$.50/ft <sup>2</sup>

\* Your category depends on complexity of laboratories



# Process Timeline

	<b>Time allotted (days)</b>	<b>Est. days after app receipt</b>
App received/assign inspectors	1-20	1-20
Document review & inspection	10-30	20-50
Assessment report submitted by inspectors	1-20	50-70
Assessment results processed	5-15	70-85
Decision by Accreditation Board	1-10	85-95
Entity Notification	1-5	95-100



# Site Visits

Will evaluate:

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

CWA 15793, *Laboratory Biorisk Management*

BMBL current edition;  
NIH rDNA Guidelines



# Site Visits (cont)

- Two inspectors for each visit
  - Site pays travel expenses (airfare + per diem)
- Consultative, friendly, cooperative
- Final report issued
  - Observations
  - Recommendations
  - Best practices



# Key Components Assessed

- Biosafety expertise and training of personnel managing and conducting the research
- Adequacy and function of the biosafety management structure supporting the research activities
- Adequacy and function of biocontainment measures: facilities, equipment, practices, and record-keeping systems



# Accreditation Decision

- Approval – effective for 3 years
  - Certificate issued to entity
- Provisional approval (based upon correction of minor issues determined by the Accreditation Committee)
  - Corrections for provisional approval will be verified by the Accreditation Committee
  - Issues resolved and documented in writing by the entity within 20 working days
  - Once deficiencies are corrected, full approval status will be granted
- Denial



# Site Duties in Off-Years

- Annual self inspection
- File short report
- Report any major changes
  - additional facilities
  - new processes; e.g., large scale, large animals





# For More Information

Contact the ABSA office:

**1-866-425-1385 or [info@absa.org](mailto:info@absa.org)**

## Questions??



**ABSAs** American Biological Safety Association

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