



Update on the ANSI BSL-3 Standard

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ABSA

American Biological Safety Association

www.absa.org

ANSI Z9.14 “Testing and Performance Verification Methodologies for Biosafety Level 3 Laboratories”

- ANSI Z9 Health and Safety Standards for Ventilation Systems
- Sponsors: ANSI and AIHA

ABSA Members on the Committee

- Jason Cohen
- Felix Gmuender
- Miguel Grimaldo
- Barbara Johnson
- Paul Jennette
- Joe Kozlovac
- Paul Langevin
- Paul Meechan
- Claudia Mickelson
- Barbara Fox Nellis
- Jonathan Richmond
- Ted Traum
- Stefan Wagener
- Susan Weekly
- Bruce Whitney
- Deborah Wilson

Other ABSA Members Involved

ABSA Task Team

- Allan Bennett
- Dan Frasier
- Craig Free
- Rob Heckert
- Jeff Owens
- Dee Zimmerman

ABSA Council

- Ben, Karen, LouAnn, Barb

ANSI Committee Organization

- Chair: Farhad Marmazadeh (NIH)
- Vice Chair: Lou DiBeradinis (MIT)
- Subcommittee Chairs:
 - Testing : Paul Langevin
 - Vis. Inspection: Krishnan Ramesh
 - Admin. Controls: Stephan Wagener
 - SOP & Doc'n: Bruce Whitney

Scope

- Initial Discussions Very Broad
- New Focus - Ventilation Issues (DRAFT):
 1. Directional Airflow
 2. Airlocks & anterooms
 3. Primary containment
 4. Ventilation systems
 5. HVAC testing
 6. Filtration
 7. ABSL-3 caging
 8. Document validation
 9. Pressure reversal
 10. Failure testing
 11. Leakage issues
 12. Tester qualifications
- BSL-3 and ABSL-3, Not BSL-3AG

Status

- Draft Standard under development
- Each subcommittee had started drafts
- February 2011 meeting – consensus on scope
- Testing and Vis. Inspection combined section draft, April 2011
- Concerns expressed May 2011
- Re-drafts underway by Subcommittee Chairs
- Formal communication on schedule pending

Formal Comments by ABSA

- January 2011:
 - **Scope** (verification of engineering controls)
 - **Performance-based versus prescriptive approach** (risk-based, appropriate to existing facilities versus new, high-tech, facilities)
 - **Schedule** (impact on quality)
 - **ABSA Accreditation Process** (scope)
- May 2011:
 - Concerns about implementation of changes agreed to at February Committee Meeting

Stay Tuned...