

An Analysis of Options for the Future Evolution of International Laboratory Biorisk Management Standards

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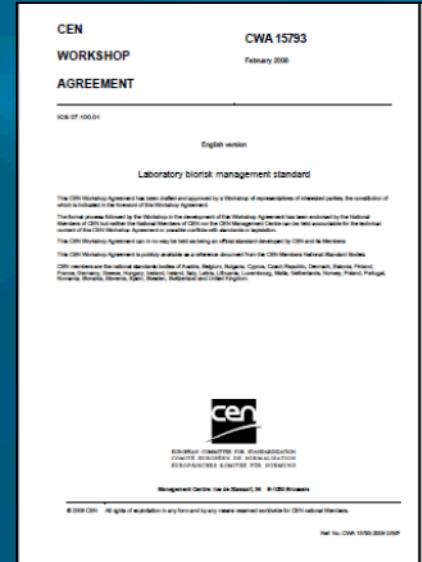
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Ben Brodsky
International Biological Threat Reduction
Sandia National Laboratories
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CWA 15793:2011

- CEN Workshop Agreement 15793:2011
Laboratory Biorisk Management
 - Adopted in 2008; Renewed in 2011
 - Describes a biorisk management system consistent with other standards
 - Key Issue: **Expiration in September 2014**



Available from :

ftp://ftp.cenorm.be/CEN/Sectors/TCandWorkshops/Workshops/CWA15793_September2011.pdf

How Do We Utilize CWA 15793:2011?



A framework for biorisk management systems



A bridge for communication



A foundation for learning

Is CWA 15793:2011 Worth Saving?

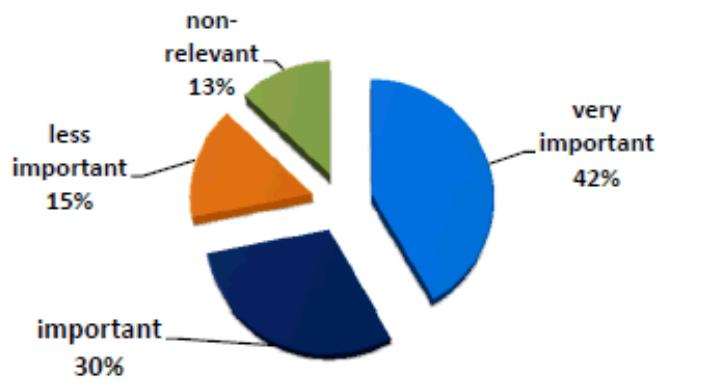
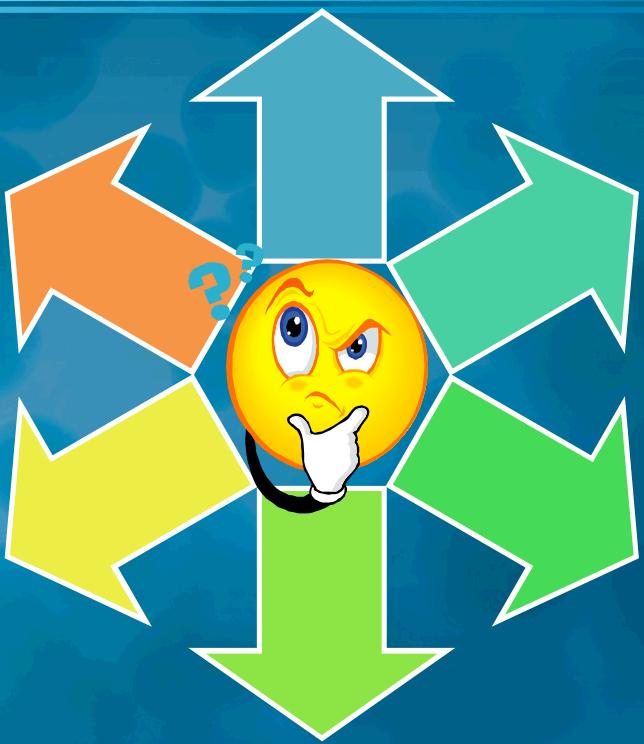


Fig 2. Survey Q7: The CWA 15793 will expire in September 2014 with a possible (final) extension until 2018. How important is it to you that the Laboratory biorisk management has a lifespan after 2014/18

- Existing data suggests support within biorisk management community
- Increasingly utilized as key reference in international guidance documents

Source: Toon de Kesel and Ingegerd Kallings, European Biosafety Association, *Report from the EBSA Survey on the awareness and usage of Laboratory biorisk management CWA 15793:2011 and its guidance document CWA 16393:2012*



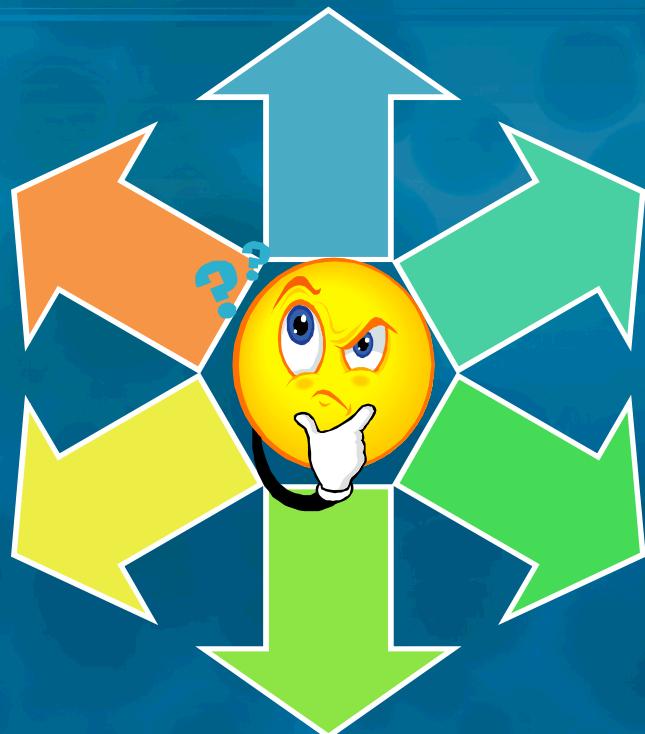
Factors Considered

- Initiation mechanism
- Level of international recognition/breadth of use
- Level of consensus required for approval
- Stakeholder involvement
- Development timeframe
- Document duration



What Are the Options?

- International Organization for Standardization (ISO) deliverable
- ASTM International Standard
- European Standard (CEN)
- NSF International (example of American National Standard)
- Further extension of CWA 15793:2011
- “Guidance” document under an international organization



Example: ISO Deliverables

International Standard

Technical Specification

*Technical Report**

Publicly Available Specification

ISO Workshop Agreement



**Closely related
development
processes**

References:

ISO (<http://www.iso.org>)

*ISO/IEC Directives, Part 1, Consolidated ISO Supplement –
Procedures specific to ISO, 4th Edition, 2013*

Stefan Marinkovic, "ISO Deliverables," Presentation Made at
Special Session on the Future of CWA 15793:2011, June 2013

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Summary and Conclusion

- Available data suggest robust international support for biorisk management system document
- Several potential management system standard-type deliverables were analyzed
- Additional international standardization activity using CWA 15793:2011 as basis is warranted

Key Resources Consulted

- CWA 15793:2011 – Laboratory Biorisk Management
- CWA 16393:2012 – Laboratory biorisk management – Guidelines for the implementation of CWA 15793:2008
- European Biosafety Association (<http://www.ebsaweb.eu/>)
 - *Report from the EBSA Survey on the awareness and usage of Laboratory biorisk management CWA 15793:2011 and its guidance document CWA 16393:2012*, July 2013
 - *Meeting Report: Special Session on the Future of CWA 15793:2011*, August 2013
- International Federation of Biosafety Associations (<http://internationalbiosafety.org/>)
 - *Position Statement: CEN Workshop Agreement “Laboratory Biorisk Management” CWA 15793: 2011*, April 2013
- CEN (<http://www.cen.eu/>)
 - *CEN/CENELEC Internal Regulations Part 2: Common Rules for Standardization Work*, 2013
 - Alina Aitan, “CEN-CENELEC Workshop Process,” Presentation Made at Special Session on the Future of CWA 15793:2011, June 2013
- ISO (<http://www.iso.org>)
 - *ISO/IEC Directives, Part 1, Consolidated ISO Supplement — Procedures specific to ISO, 4th Edition*, 2013
 - Stefan Marinkovic, “ISO Deliverables,” Presentation Made at Special Session on the Future of CWA 15793:2011, June 2013
- ASTM International (<http://www.astm.org/>)
 - *Regulations Governing Technical Committees*, April 2012
- NSF International (<http://nsf.org/>)
 - *Standards Development Handbook*, September 2011

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Thank you for your attention!

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