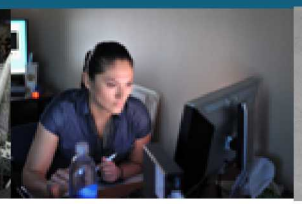
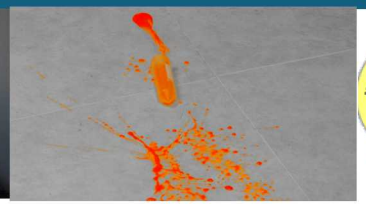
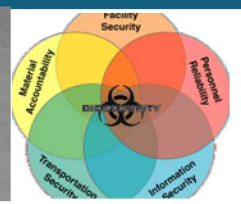
SAND2019-0513PE

ISO/DIS 35001 – Biorisk Management for Laboratories and Other Related Organizations



Roundtable on the Role of Standards for Strengthening the Security of Radioactive Sources Used in Medical Applications
Vienna, Austria; 22 January 2019

PRESENTED BY

Ben Brodsky, PhD

Global Chemical and Biological Security

Sandia National Laboratories

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Disclaimer

The views expressed herein are my own, and do not necessarily represent the views of the International Organization for Standardization (ISO), the American National Standards Institute (ANSI), Sandia National Laboratories, the U.S. Department of Energy, or the United States Government.

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Background

Thousands of organizations worldwide produce, handle, store, and transfer **biological hazards**

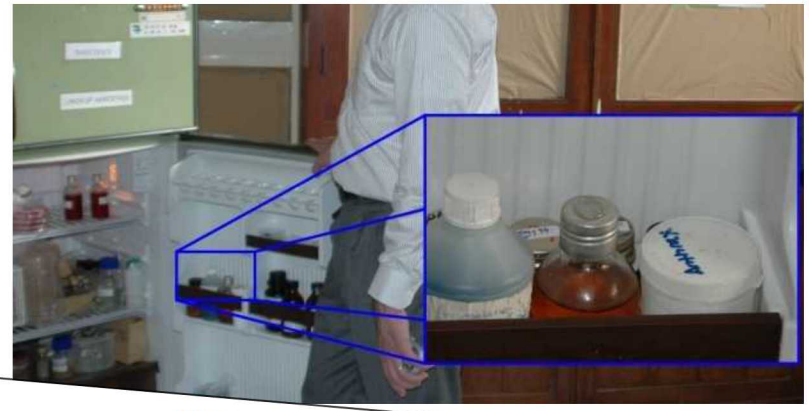
- Highly diverse community

Current absence of a global standard for the safe and secure **biorisk management** of these materials

Biorisk management enables effective assessment, control, and evaluation of **biosafety** and **biosecurity** risks

"Closest thing" in 2014: CEN Workshop Agreement 15793:2011 – *Laboratory Biorisk Management*

- **Expired officially in 2014**



CEN

WORKSHOP AGREEMENT

CWA 15793

September 2011

ICS 07.100.01

Supersedes CWA 15793:2008

English version

Laboratory biorisk management

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

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CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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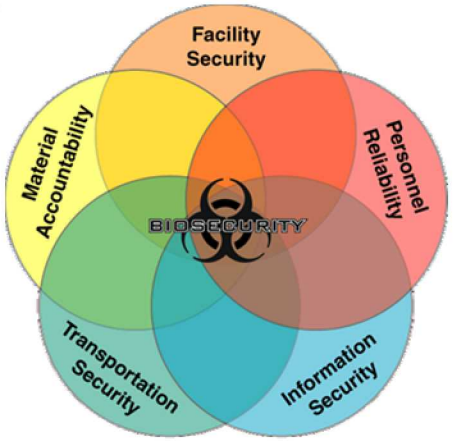
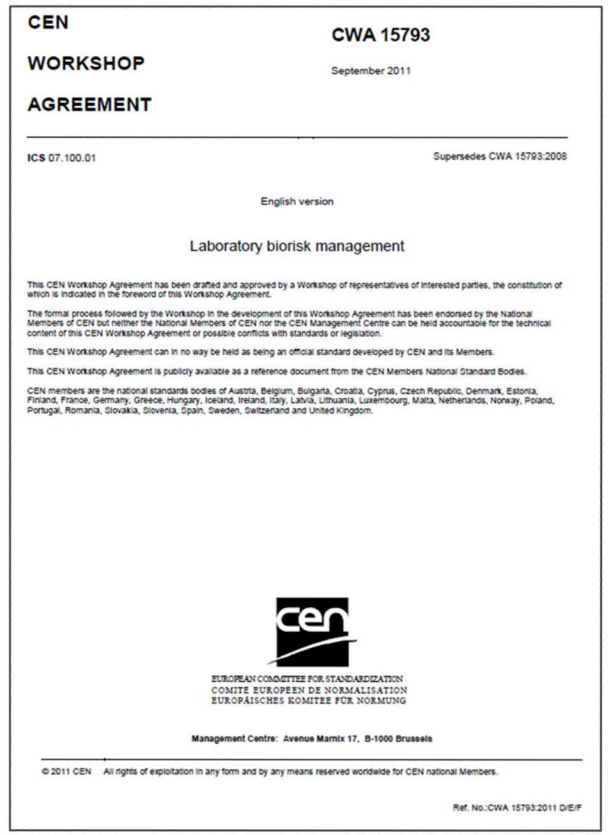


Objective: Conversion of CEN Workshop Agreement 15793:2011 to Provide a Global Performance Benchmark for Biorisk Management



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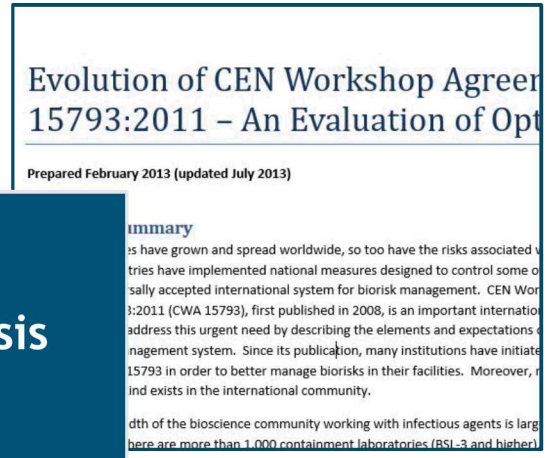
Considerations

Analysis


Evolution of CEN Workshop Agreer
15793:2011 – An Evaluation of Opt

Prepared February 2013 (updated July 2013)

ımmary

ɜs have grown and spread worldwide, so too have the risks associated v
tries have implemented national measures designed to control some o
sally accepted international system for biorisk management. CEN Wor
ɜ:2011 (CWA 15793), first published in 2008, is an important internatio
address this urgent need by describing the elements and expectations
nagement system. Since its publication, many institutions have initiate
15793 in order to better manage biorisks in their facilities. Moreover,
ind exists in the international community.

dth of the bioscience community working with infectious agents is larg
here are more than 1,000 containment laboratories (BSL-3 and higher)

Community Engagement

Preparing ISO/DIS 35001


ISO/DIS 35001
Biorisk management for

eral information

Under development

Analysis: What Are the Options?

Options Examined:

- International Organization for Standardization (ISO) deliverables
- Other national, regional or international standards development organization deliverable
- "Guidance" document under an international organization

Considerations:

- Initiation mechanism
- Level of international recognition
- Level of consensus required for approval
- Stakeholder involvement
- Development timeframe
- Document lifetime

Why an ISO Deliverable?

Analysis: ISO Deliverables

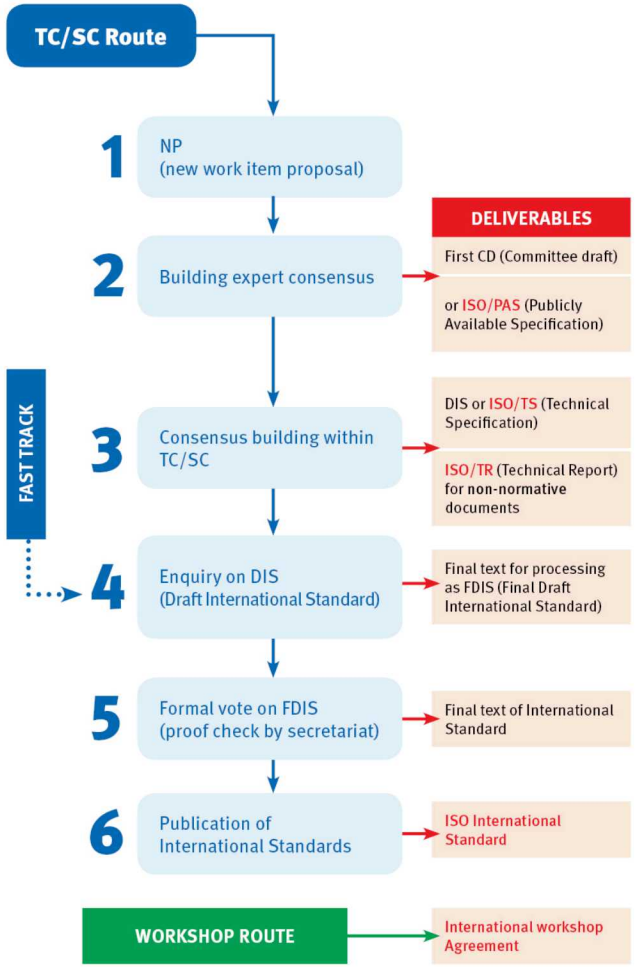
International Standard

Technical Specification

*Technical Report**

Publicly Available Specification

ISO Workshop Agreement



https://www.iso.org/deliverables-all.html

References:

http://www.iso.org

ISO/IEC Directives, Part 1, ISO/IEC Directives, Part 1 - Procedures for the technical work, 14th Edition, 2018

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

ISO Development Pathways

Initiation (Proposal Stage):

- Preliminary Work Item (PWI) or
- **New Work Item Proposal (NWIP) – Form 4 (ISO)**
- NWIP Information includes (not limited to):
  - **Title**
  - **Scope**
  - **Proposer**
  - **Proposed Project Leader**
  - **Management System Standard (ISO) (Y/N)?**
  - **Type of Deliverable**
  - **Stakeholder benefits/impacts**

Preparation of Draft (Preparatory Stage)

- Working Group
  - Convener

F.1 Simplified diagram of options

Project stage	Normal procedure	Draft submitted with proposal	"Fast-track procedure" [a]	Technical Specification [b]	Technical Report [c]	Publicly Available Specification [d]
Proposal stage (see 2.3)	Acceptance of proposal	Acceptance of proposal	Acceptance of proposal [a]	Acceptance of proposal		Acceptance of proposal [g]
Preparatory stage (see 2.4)	Preparation of working draft	*Study by working group* [e]		Preparation of draft		Approval of draft PAS
Committee stage (see 2.5)	Development and acceptance of committee draft	*Development and acceptance of committee draft* [e]		Acceptance of draft	Acceptance of draft	
Enquiry stage (see 2.6)	Development and acceptance of enquiry draft	Development and acceptance of enquiry draft	Acceptance of enquiry draft			
Approval stage (see 2.7)	*Approval of FDIS* [f]	*Approval of FDIS* [f]	*Approval of FDIS* [f]			
Publication stage (see 2.8)	Publication of International Standard	Publication of International Standard	Publication of International Standard	Publication of Technical Specification	Publication of Technical Report	Publication of PAS

ISO/IEC Directives, Part 1 - Procedures for the technical work, 14th Edition, 2018

Community Engagement – Critical!

Gauge needs and concerns of the community

Identification of key stakeholders

Establishment of steering group

Recruitment of technical experts

Ongoing outreach, communications and updates

Leveraging major meetings

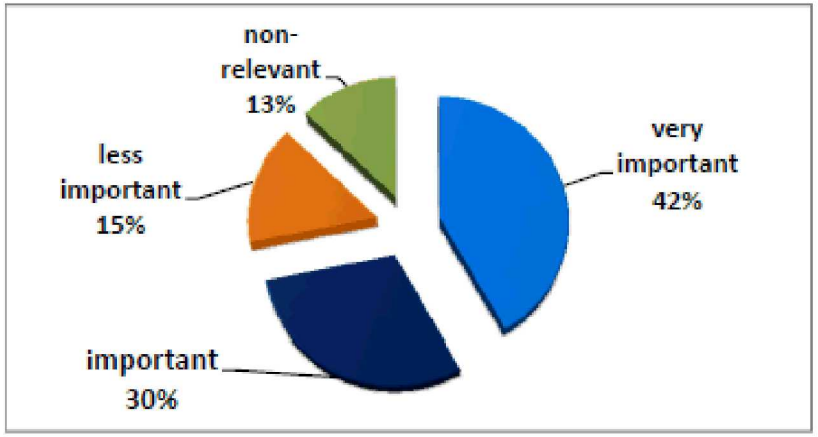


Fig 2. Survey Q7: The CWA 15793 will expire in September 2014 with a possible (final) extension until 2018. How important is it to you that the Laboratory biorisk management has a lifespan after 2014/18

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*

Special Session on the Future of CWA 15793:2011

June 20, 2013, 16:00 – 18:00
Basel Congress Center, Basel, Switzerland

Preparing ISO/DIS 35001

Navigating the process
- Role of Technical Committee Secretariat

Working Groups and Drafting Teams – Roles and Responsibilities
- Who's in charge?
- Who actually writes?

Importance of Scope Statement

Organizing Meetings
- In-Person
- Remote

Document Control and Sharing

Comment Tracking and Resolution

Confronting Reality: Timelines and Deadlines

Thank you!

Backup Slides

Comparison – ISO Options

Factor	International Standard (IS)	Technical Specification (TS)	Publicly Available Specification (PAS)	ISO Workshop Agreement (IWA)
Initiation Mechanism	National body, ISO technical committee, liaison organizations	National body, ISO technical committee, liaison organizations	National body, ISO technical committee, liaison organizations	Any source
Level of International Recognition	Highest degree of recognition	Lower than IS	Lower than IS and TS	Lower than IS, TS, and PAS
Level of Required Consensus	2/3 of P-members of ISO Membership; < ¼ negative votes	2/3 of P-Members of Technical Committee	>½ of P-Members of Technical Committee	Best possible consensus
Stakeholder Involvement	Through Technical or Project Committee	Through Technical or Project Committee	Through Technical or Project Committee	Direct participation in workshop
Development Timeframe	2 – 4 years	~18 months	~12 months	12 months or less
Document Lifetime	Indefinite	Six years	Six years	Six years

Other Standards Deliverables Options

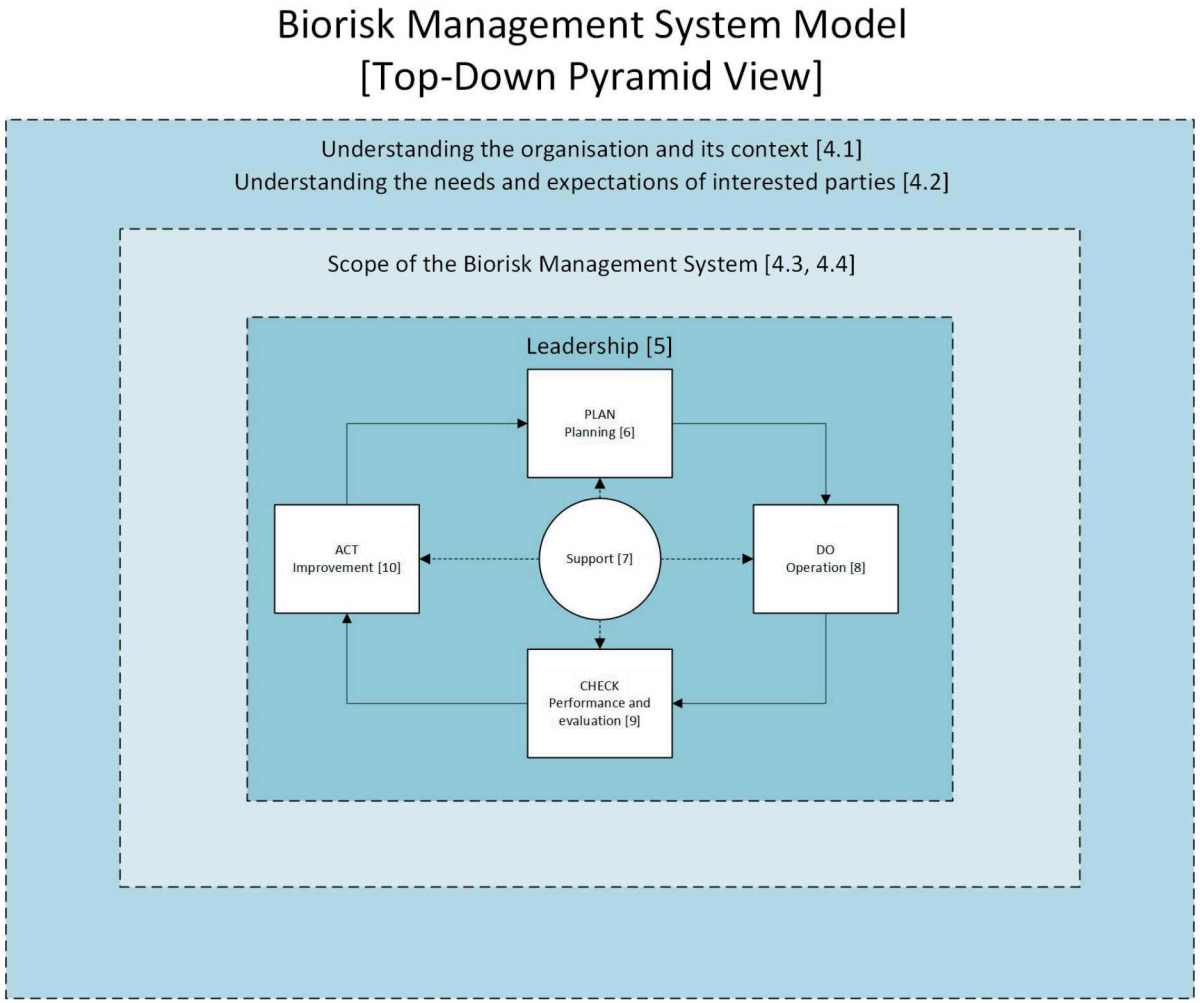
We considered a selection:

- European Standard (CEN)
- ASTM International Standard
- NSF International (American National Standard)
- Further extension of CWA 15793:2011

Comparison - Other Standards Options

Factor	European Standard	ASTM International Standard	NSF International (example of ANS)	Extension of CWA 15793:2011
Initiation Mechanism	CEN member body	Any source	Any source	CEN 31 Workshop
Level of International Recognition	High within Europe; lower elsewhere	Broad international; lower than ISO IS	High within US; lower elsewhere	Similar to existing CWA 15793:2011
Level of Required Consensus	Weighted vote of CEN member bodies	ASTM Sub-committee and Committee ballot approval; Review	Tiers of internal balloting; public review and comment	Requires CEN/BT approval of derogation
Stakeholder Involvement	Through CEN technical committee	ASTM members; others through task groups	Direct participation; public comment period	Direct participation through workshop
Development Timeframe	3 years of less			Immediate
Document Lifetime	Indefinite	Indefinite	Indefinite	3 years

General Organization of ISO/DIS 35001



https://www.iso.org/obp/ui/#iso:std:iso:35001:dis:ed-1:v1:en