Actual developments in normative regulations for Biological Resource Centers - the ISO initiatives on Biotechnology and Biorisk Management





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The ISO initiative

ISO/TC 276 Biotechnology

Standardisation World of ISO

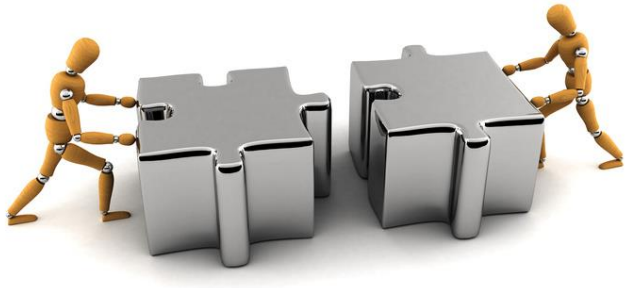
International Organization for Standardization

ISO Mission:

ISO develops **voluntary** International Standards which **facilitate** international exchange of goods and services, **support** sustainable and equitable economic growth, **promote** innovation and **protect** health, safety and the environment.

ISO in figures, means more:

- 160 members
- 100 000 experts
- 230 technical committees
- 1.800 projects
- 1.100 publications in 2013
- 19.500 standards in catalogue



http://www.iso.org/iso/home/about/iso-in-figures.htm

Standards are a Major Asset

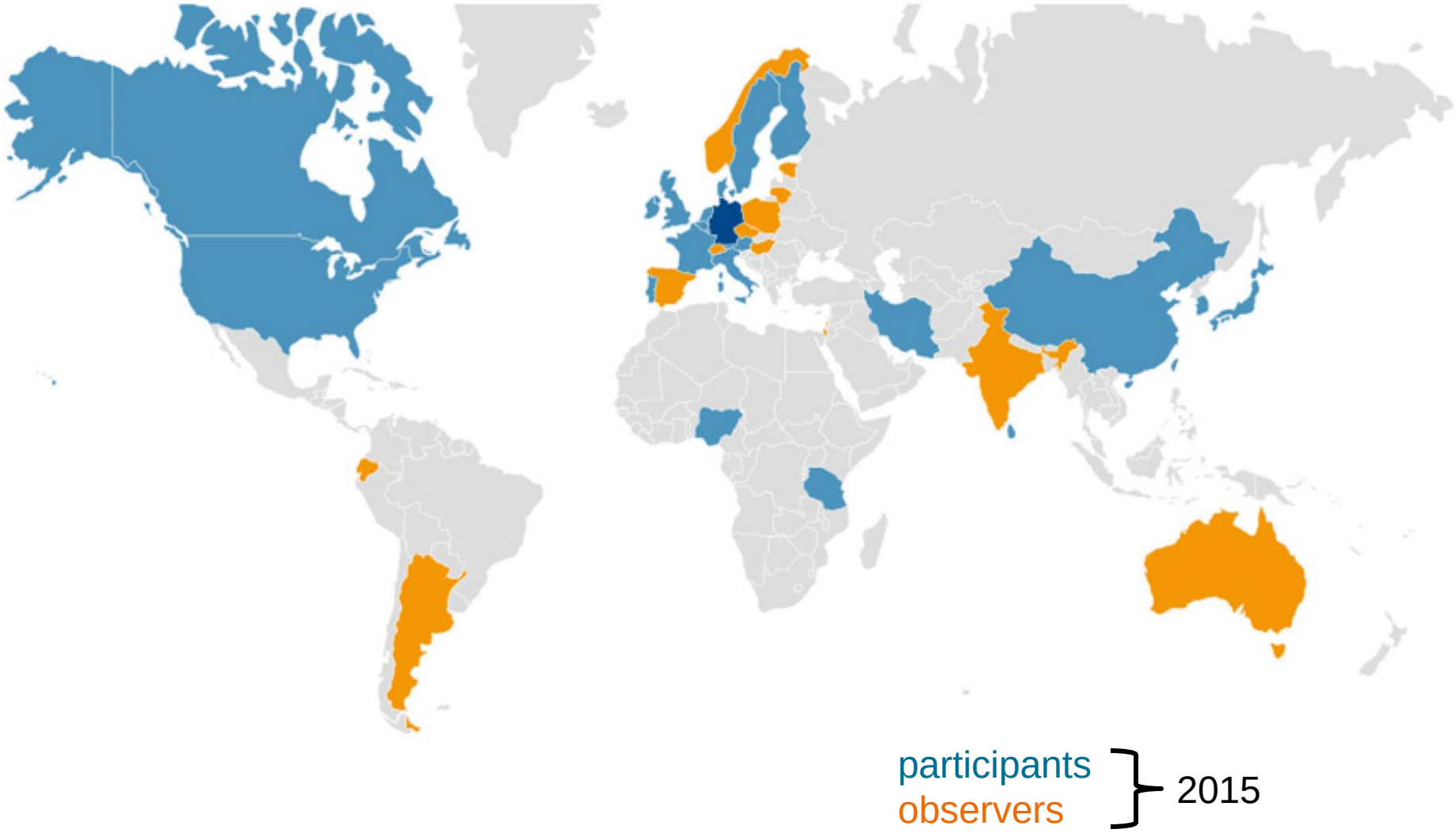
States and communities – Economic competitiveness and access to world markets, regulation, sustainable development, loyal competition, public purchase…

Companies – technology transfer, market knowledge, good management practices, quality recognition…

Consumers – products and services comparison, quality improvement, information on performance, security and impact on environment

Researchers – measurements, risk assessment, dissemination of innovation, not re-inventing the wheel

ISO/TC 276 Biotechnology as a Global Effort



ISO/TC 276 Biotechnology in Figures

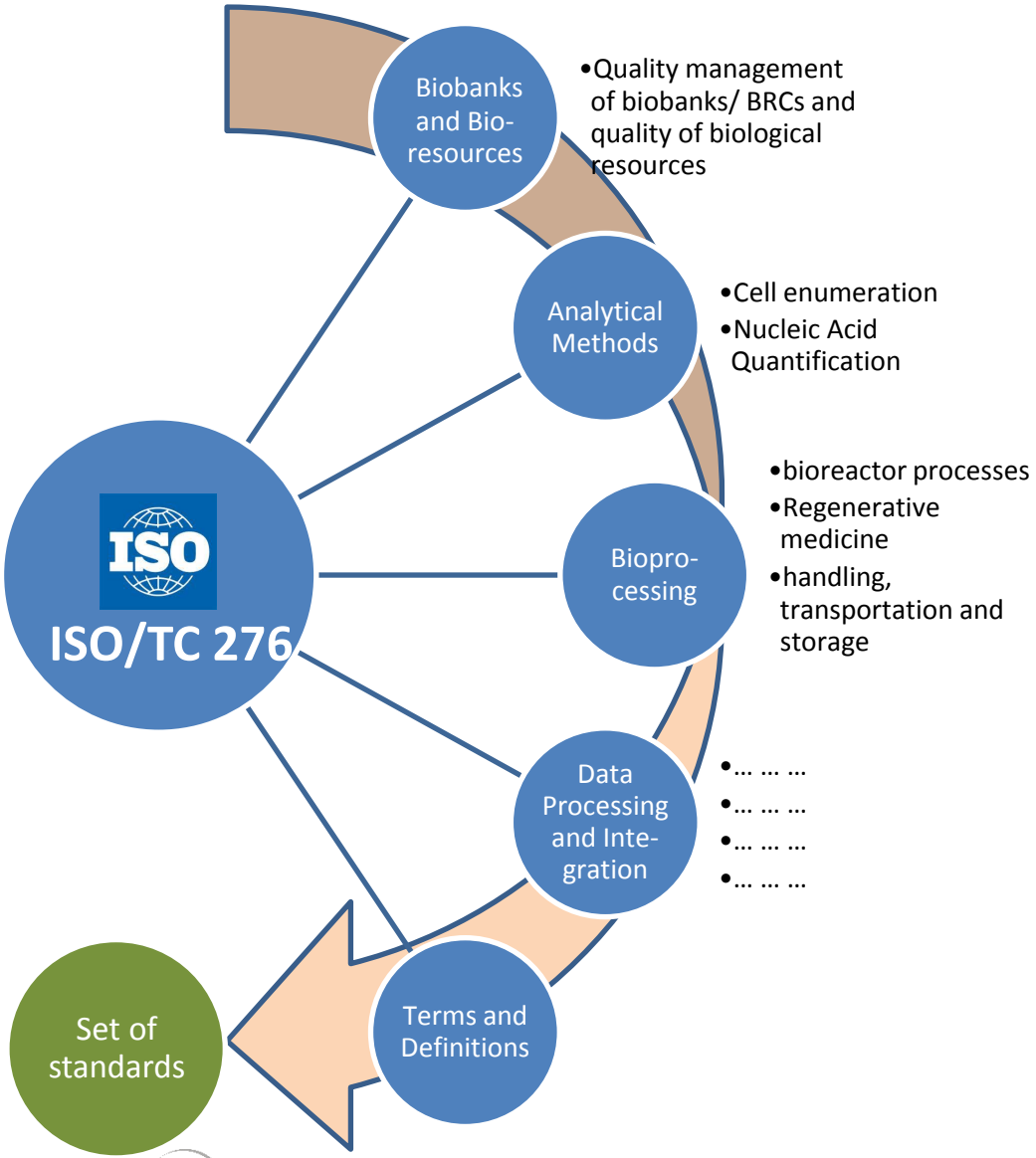
- Secretariat: Germany / DIN
- Chair: Dr. Ricardo Gent, DIB/VCI
- Members: 22 participating, 13 observing (as of March 2015)

  p: Austria, Belgium, Canada, China, Denmark, Finnland, France, Germany, Iran, Ireland, Italy, Japan, Korea, Luxembourg, Netherlands, Nigeria, Portugal, Sri Lanka, Sweden, Tanzania, UK, USA

  o: Argentina, Australia, Czech Republik, Ecuador, Estonia, Hungary, India, Israel, Lithuania, Norway, Poland, Spain, Switzerland

- Liaisons: 16 ISO / CEN TCs, BBMRI-ERIC, EDQM, ESBB, ICH, ISBER

New Work Item Proposals within ISO/TC 276

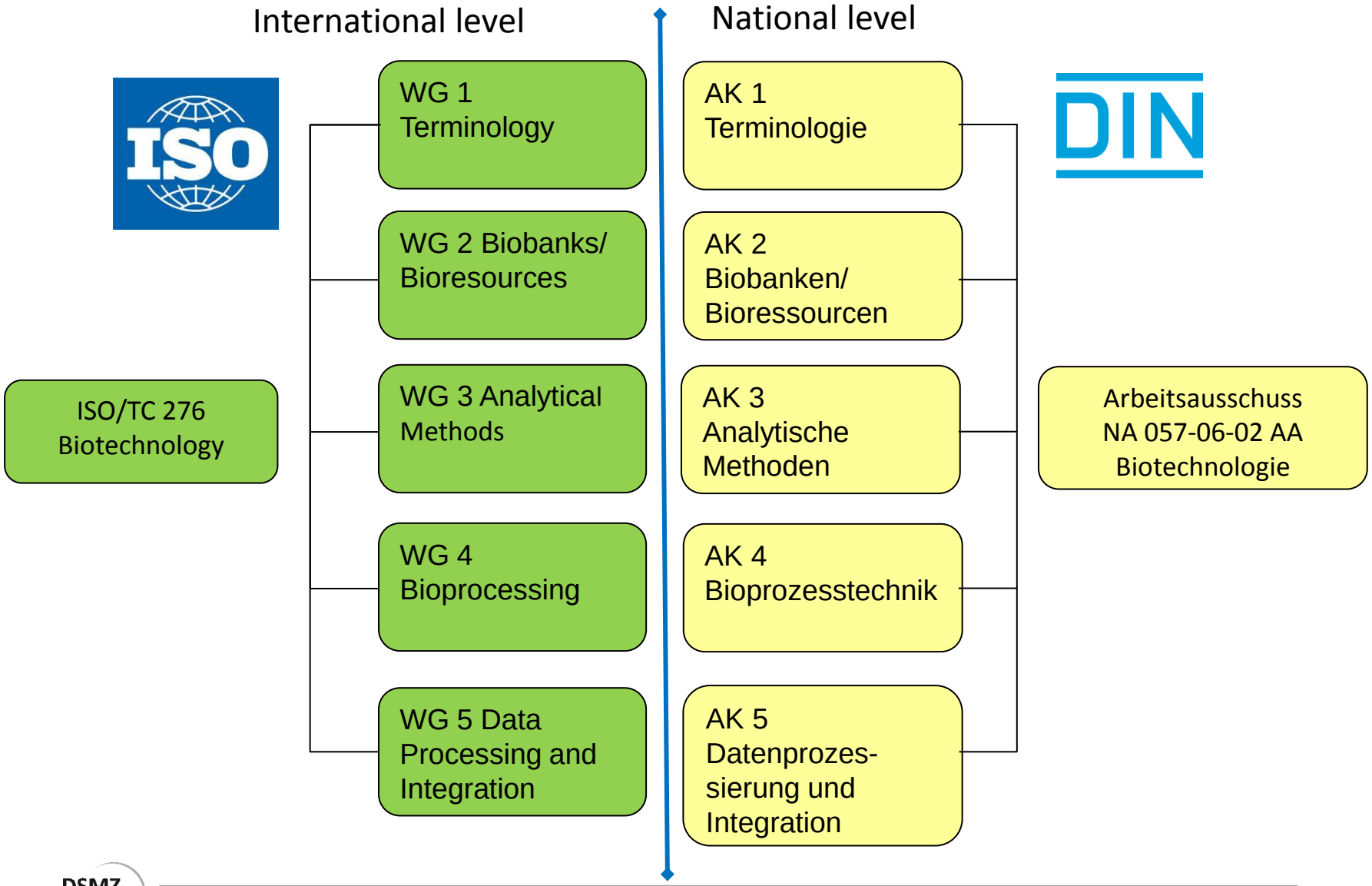


Scope:

Standardization in the field of biotechnology processes that includes the following topics: terms and definitions; biobanks and bioresources; analytical methods; bioprocessing; data processing including annotation, analysis, validation, comparability and integration; metrology.

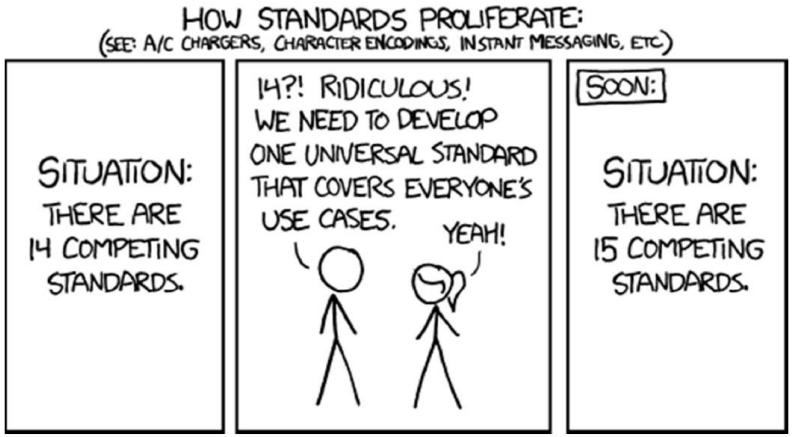
Excluded from the scope: highly regulated markets, esp. "Clinical Laboratory testing and in vitro Diagnostic Test Systems", "Food Products" and "Horizontal Methods for Molecular Biomarker Analysis"

Mirror-Principle of ISO/TC 275 Biotechnology



Availabe Standards for BRCs / Biobanks

- Thousands of SOPs
- > 50 *Guidelines* and *Best Pratices*: (http://www.p3gobservatory.org/repository/guidelines.htm)
- GCP, GLP, ...
- ISO 9001 certification (approx. 30 Biobanks certified in Europe)
- ISO 17020 and 17025 accreditation
- ISO Guide 34 for Reference Material producers
- OECD Best Practice Guidelines for BRCs since 2006
- French Standard NF S96-900: > 70 Biobanks in France certified (human derived material, samples, microorganisms, plants)
- UK Biobank Quality Standard since March 2014
- ...



Working Group 2: Bioressource - Is there a Need for a Standard?

Needs for a standard

- Encourage the adoption of a set of guiding principles and operating procedures
- Improve the access to biological resources of appropriate quality (fit for purpose)

Expected Impacts

- Reinforce collaborations
  - Improve trust between partners (public and private fields)
  - Optimise the efficiency of research projects
  - Create sustainable relationship
- Enhance transnational research
- Improve the competiveness of research
- Foster innovation

Value to society

- Better understanding of diseases, epidemics
- Development of appropriate treatments
- Better healthcare

Source: Dr. Georges Dagher (INSERM US 13) for ISO/TC 276

Working Group 2 – Bioresources

Gap/Consensus analysis of common standards & guidelines

Guidelines

- OECD
- ISBER
- NCI
- Biobank Quality Standard (UK)
- NF S96-900
- MMI (Ireland)
- Brazilian Standard
- Tissue/cells regulation

Standards

- ISO 15189
- ISO 17025
- ISO Guide 34
- ISO 17020
- ISO 27799
- ISO 13485

Gap/Consensus analysis of relevant processes in a BRC

- Access procedure to samples and data :Emma Snapes (IR) and Anne Carter (UK), Koh Furuta(JP)
- IT (clinical and sample data management, interoperability, authenticity of data…) : Diarmuid Calahane (IR)
- Financial Sustainability : Kyungsook Ahn (KR)
- Perenity of collection : Nilsa Ramirez (US)

Working Group 2 – Bioresources

Gap/Consensus analysis of relevant processes in a BRC

- Premises/equipment : Marine Thiebaud (FR)
- Staff competence and training : Georges Dagher (FR)
- Validation of methods : Peadar Mac Gabhann (Ire)
- Quality control of biological resources : Sabine Lehmann (Lux)
- Non-conforming products : « ISO Standard subgroup »
- Compliance with regulations, including confidentiality issues : Georges Dagher, Marine Thiebaud (FR)
- Ethical issues: Tohru Masui (JP)
- Sample traceability/labeling: Nilsa Ramirez (US)
- Sample reception: Nilsa Ramirez (US)
- Sample collection and processing : Yong Zhang (CN)
- Sample preservation and storage : Peadar Mac Gabhann (IR), Koh Furuta(JP)
- Sample transport/shipping : Yong Zhang (CN)
- Biological risk management: Dunja Martin (DE)

Working Group 2 – Bioresources
Purpose of the new Standard

- Harmonise procedures for biobanks, Biological Resources Centres and specimen repositories
- Ensure samples of known quality
- Improve access to samples and related data
- Stimulate access of partners from the public and private sector
- Improve trust between stakeholders ultimately optimising the outcome of collaboration
- Foster research & innovation

Scope
The ISO/TC 276/WG2 will elaborate a package of International Standards in the Biobanking field including human, animal, plant and microorganism resources for Research & Development, but excluding therapeutic products.

The ISO initiative

ISO/TC 212 JWG 5 Laboratory Biorisk Management

Project Description

The purpose of this project is to **convert CEN Workshop Agreement 15793 - Laboratory Biorisk Management to an International Management System Standard** (MSS). CEN Workshop Agreement 16393 - Guidelines for the implementation of CWA 15793 may be incorporated into the MSS or developed as a separate guidance document.

CWA 15793:2008 was developed as an international effort to help laboratories manage biorisks associated with hazardous biological agents and toxins. **CWA 15793** was renewed in 2011 with no technical changes, but **is scheduled to expire in 2014**. The CEN Board has encouraged its conversion to a permanent standard because there are significant interest from countries outside the area with which CEN is concerned, an ISO MSS is the preferred option. CWA 16393 was developed in 2012 to provide implementation guidance to organizations for establishing a biorisk management system.

Open questions:

- Can an ISO standard serve as a robust international system for biorisk management?
- Why can't the existing relevant standards cover this concern?

ISO/TC 212 JWG 5 - Scope

This International Standard will establish **requirements and guidance for a biorisk management system for laboratories** and other organizations that handle, store, dispose or transport biological agents and/or toxins to identify, assess and control the risks to health, agriculture and the environment.

Excluded will be:

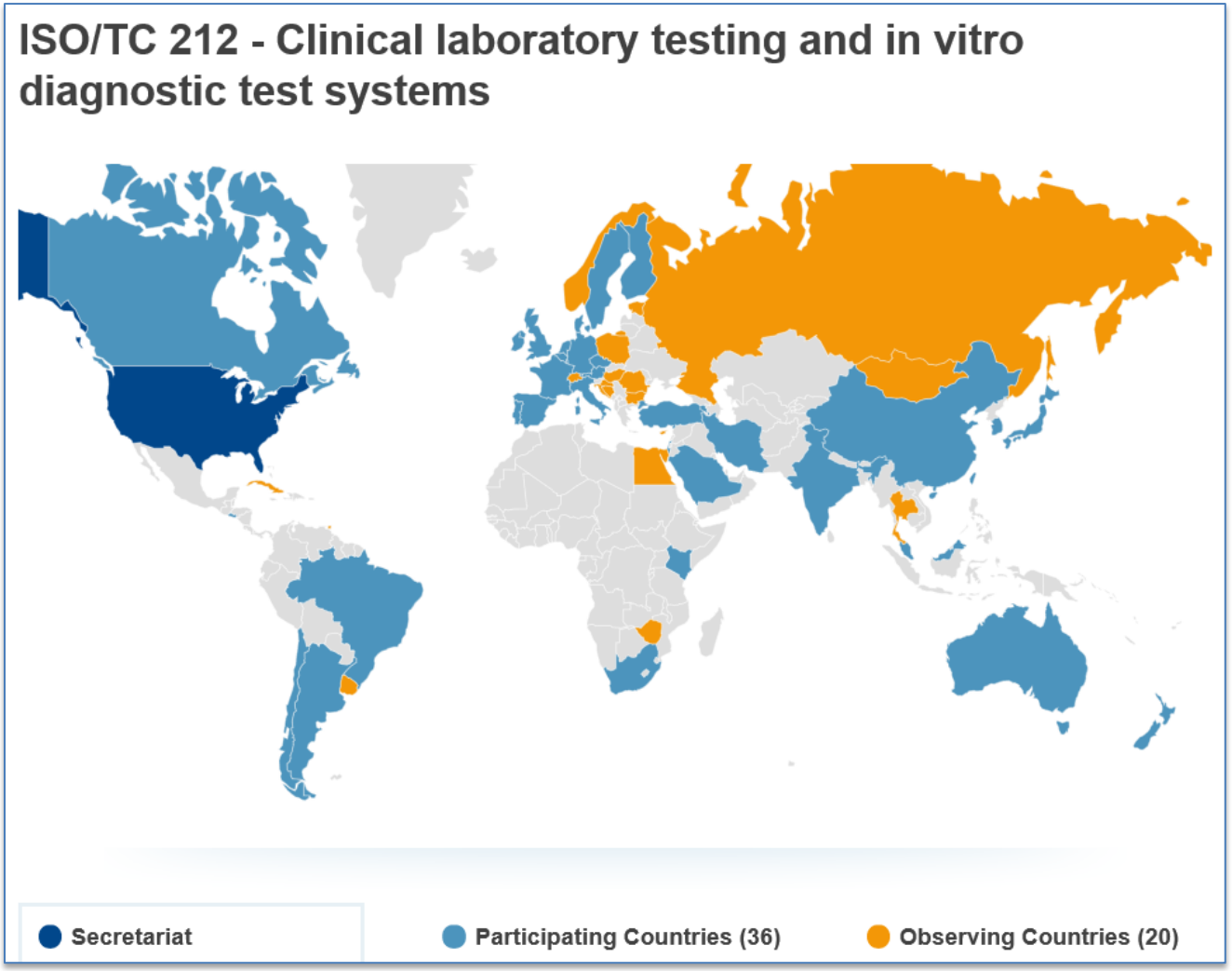
- Laboratories and other facilities performing only routine testing of specimens for diagnostic purposes, where other relevant standards apply (e.g. ISO 15189 and ISO 15190).
- Management of risks from the use of genetically-modified crops in agriculture or food safety.

The new standard ISO 35001 **shall be consistent and compatible with related standards**. Requirements that conflict with other ISO or IEC standards are not allowed.

Existing related standards:

Management system standards | Laboratory standards | Risk management standards | Safety standards | Biosafety and biosecurity guidelines

Coverage of ISO/TC 212



ISO/TC 212 JWG5 – Alignment with other Standards

Management System Standards

- ISO 13485:2003, Medical devices -- Quality management systems -- Requirements for regulatory purposes
- ISO 45001:201X, Occupational health and safety management systems – Requirements
- ISO 9001:2008, Quality management systems – Requirements
- ISO 14001:2004, Environmental management systems -- Requirements with guidance for use

Laboratory Standards

- **ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories***
- **ISO 15189:2012, *Medical laboratories — Requirements for quality and competence***
- **ISO 15190:2003, *Medical laboratories — Requirements for Safety***
- **ISO 7218:2007, *Microbiology of food and animal feeding stuffs — General requirements and guidance for microbiological examinations***

Risk Management Standards

- **ISO Guide 73:2009, *Risk management – Vocabulary***
- **ISO 31000:2009, *Risk management — Principles and guidelines***
- **ISO 14971:2007, *Medical devices - Application of risk management to medical devices***
- **ISO/TR 24971:2013, *Medical devices -- Guidance on the application of ISO 14971***
- **IEC 31010:2009, *Risk management – Risk assessment techniques***
- **ISO/TS 22367:2008, *Medical laboratories -- Reduction of error through risk management and continual improvement***

Biosafety/Biosecurity Guidelines

- WHO, Laboratory biosafety manual, 3rd ed.
- WHO, Biorisk Management – Laboratory biosecurity guidance
- OIE, Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
- OECD Best Practice Guidelines on Biosecurity

Need of Laboratories

Laboratories that handle, store, transport, and/or dispose of biological agents or toxins specifically need the following:

a. international consensus among scientific, medical, biosafety and biosecurity experts on a biorisk management system designed to **reduce the likelihood and consequences of accidents and incidents to acceptable levels**.
b. standardized biorisk concepts and terminology to facilitate communication between laboratories, customers and regulatory authorities in different countries.
c. a comprehensive framework for the management of biological risks and improvement of laboratory biosafety and biosecurity.
d. biorisk management system requirements that **represent good science and medical practice and are harmonized** with existing biosafety and biosecurity regulations and legislation
e. processes to **identify biohazards and biohazardous situations**, estimate the biorisks, and evaluate the biorisk acceptability
f. a process to **identify, validate and implement biorisk control measures** to prevent accidental laboratory-acquired infections, inadvertent releases of biological agents and toxins into surrounding communities or the environment, and deliberate misuse of biological agents and toxins acquired from laboratories and related facilities.

Need of Laboratories and Intended Users

g. a process to **monitor the biorisk control measures**, continually evaluate their effectiveness, and improve biorisk management system performance through corrective and preventive actions.
h. compatibility with other standards that the laboratory or its parent organization has implemented or may implement in the future (i.e., no conflicts), so that ISO 35001 can be integrated into the laboratory's overall management system and assist biorisk management decision-making
i. a **voluntary standard** suitable for 1st, 2nd and 3rd party certification according to the ISO neutrality principle

Human healthcare

- Centers for disease control and prevention
- Clinical diagnostic laboratory enterprises
- Human specimen repositories ("biobanks")
- In vitro diagnostic medical device companies
- Medical centers and research institutes
- Pharmaceutical companies
- Public health agencies

Intended Users

Food, aquaculture and agriculture

- Agricultural biotechnology companies
- Agriculture and aquaculture research institutes
- Commercial fisheries
- Food safety institutes
- Plant pathology research institutes
- Plant specimen repositories (“biobanks”)

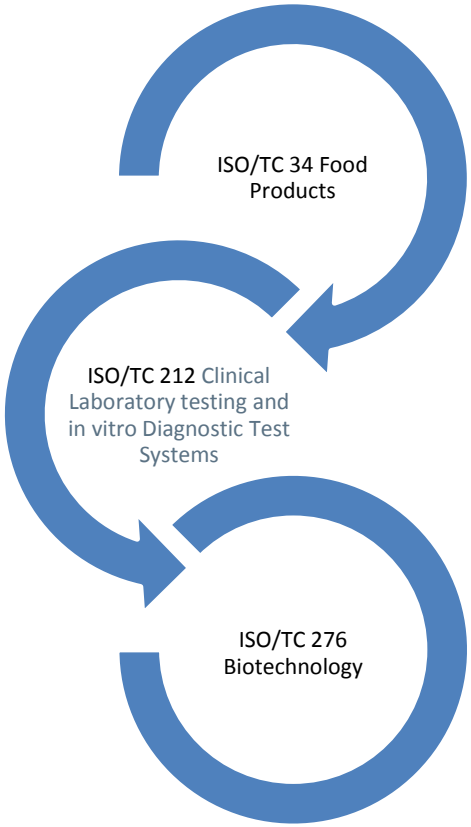
Veterinary medicine

- Animal research institutes
- Animal specimen repositories (“biobanks”)
- Veterinary care facilities
- Veterinary pathology laboratories

Stage	Target
AWI 35001	October 2014
DS 35001	February 2015
WD 35001	June 2015
CD 35001	December 2015
DIS 35001	October 2016
FDIS 35001	April 2017
ISO 35001	October 2017

ISO/TC 212 JWG 5 – Compatibility through Collaboration

To ensure the utmost **compatibility** to all other relevant standards and to meet all **stakeholder needs and concerns**, the project is a collaborative work between three ISO/TCs.



But: The CEN workshop agreement 15793 represents a lower level of consensus and transparency than that represented by the European Standard (EN) and is **not designed to support legislative requirements** or to meet market needs where significant health and safety issues are to be addressed.

Aspects to consider: Will the new standard make a clear distinction between **standardization and legislation**?

Will an external certification increase administrative burden and costs without no recognizable **added value for safety**?

Fragen & Hinweise

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Compliance Management

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