

National and international Standardization

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German Institute for Standardization

AllBio Workshop on Standardization

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A brief history of standardization

For over 2000 years governments set standards (e.g. weights, the meter, electrical resistance Ω)

1887: German Imperial Inst. of Physics & Technology

1898: American Society for Testing and Materials (standards for the railroad industry)



1899: British National Physical Laboratory

1901: American National Bureau of Standards (weights, measures, ... to prevent waste in industry)



→ precision, mass-production, interchangeability

The need for standardization

Example: Great Baltimore fire of 1904



Individual fire hydrants depending on region
600 variations of couplings
→ Need for standards

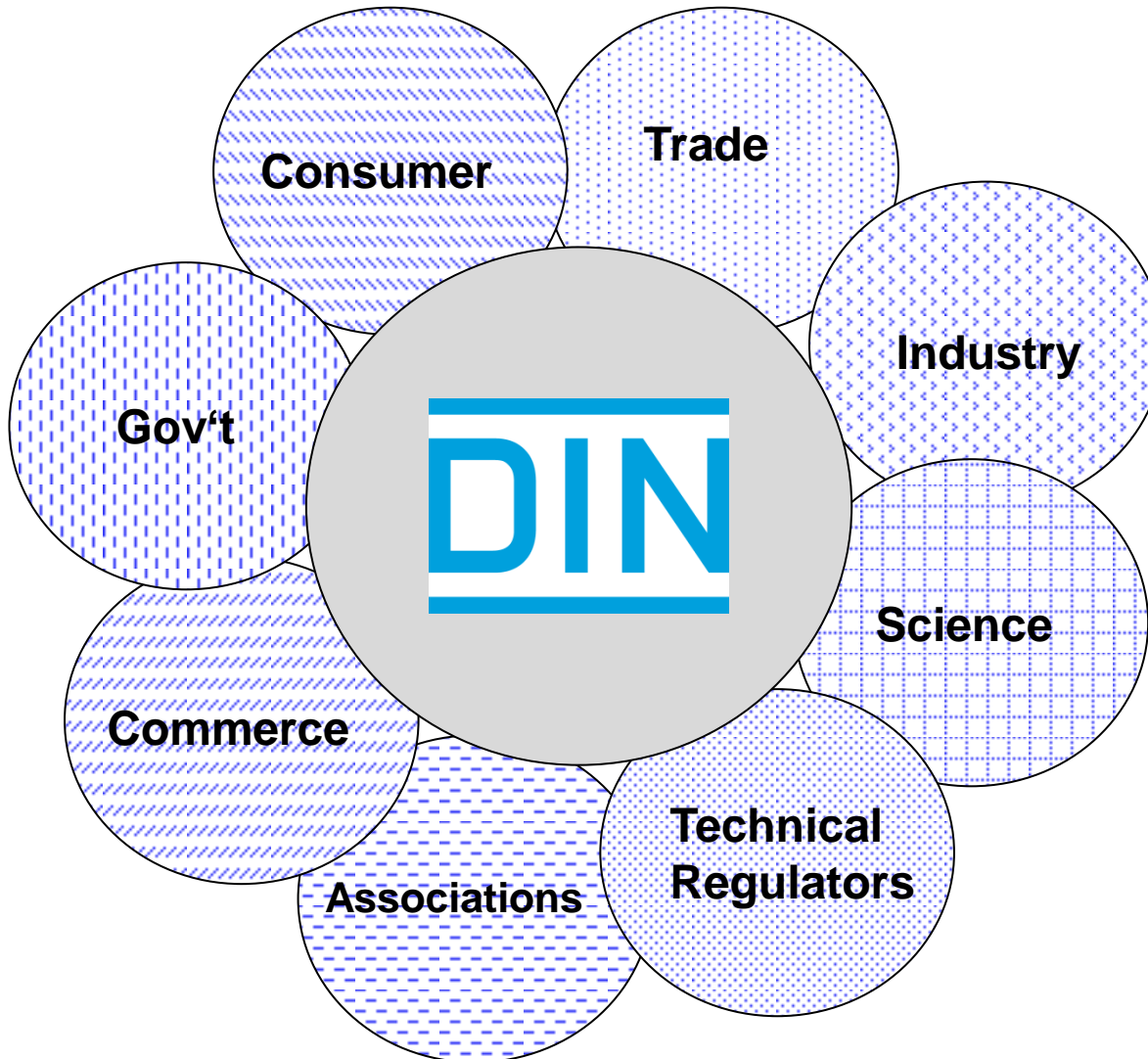


- Founded in 1917
- Non-profit
- For the industry,
with the industry

DIN employees	411
External experts	30.051
DIN Standards (total)	33.149
Standards committees	70

National Standardization Bodies (NSBs) provide a round table

DIN Deutsches Institut für Normung e. V.



What exactly is a *standard*?

Definition:

A document established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context

Source: ISO/IEC Guide 2

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Source: ISO/IEC Guide 2

Standardization Organizations (an excerpt)

DIN

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- Founded: 1975
- 33 Member countries
- 307 Technical Committees
- 1434 Working Groups
- 14.885 Standards

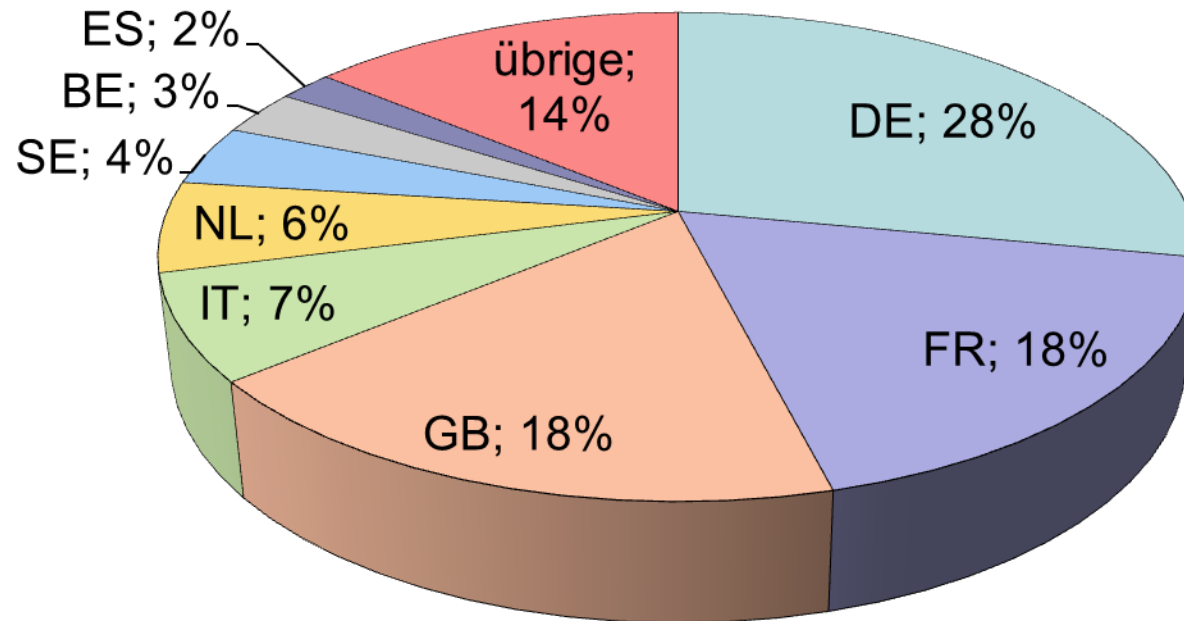


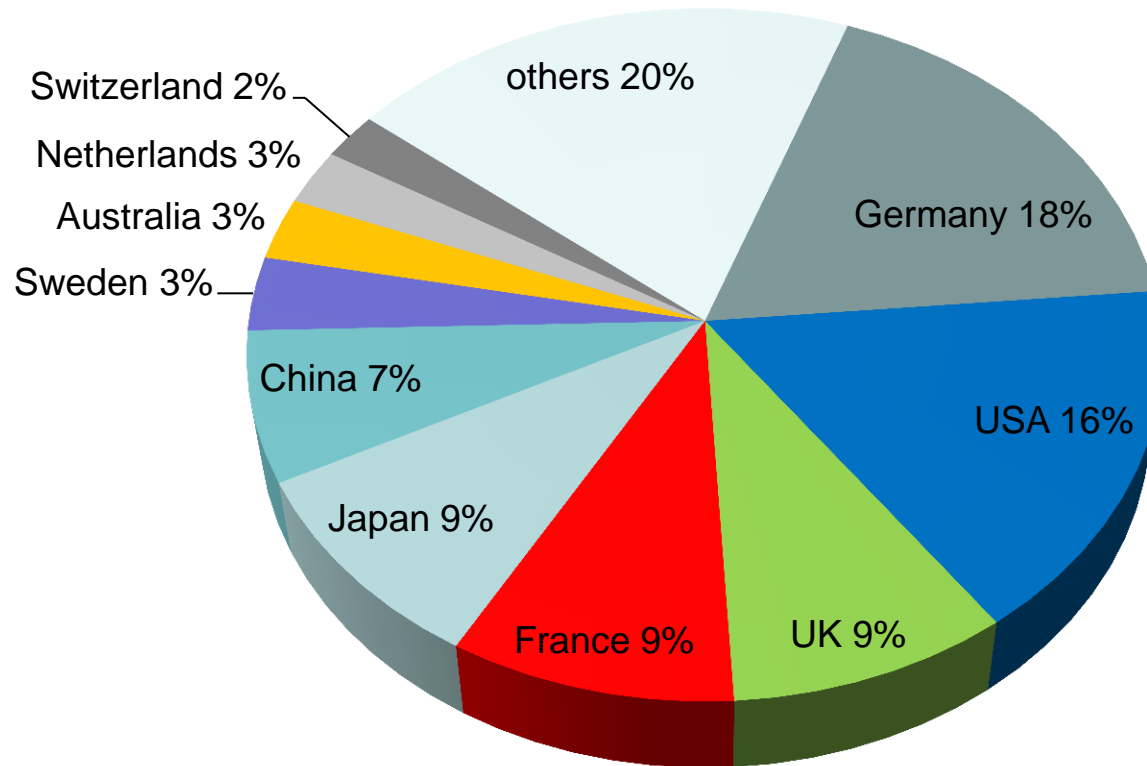
CEN standards: **14885**
+ x national standards
+ y ISO standards

DIN Standards (total) 33.149

- Founded: 1947
- 163 Member countries
- 224 Technical Committees
- 2516 Working Groups
- 19.500 Standards

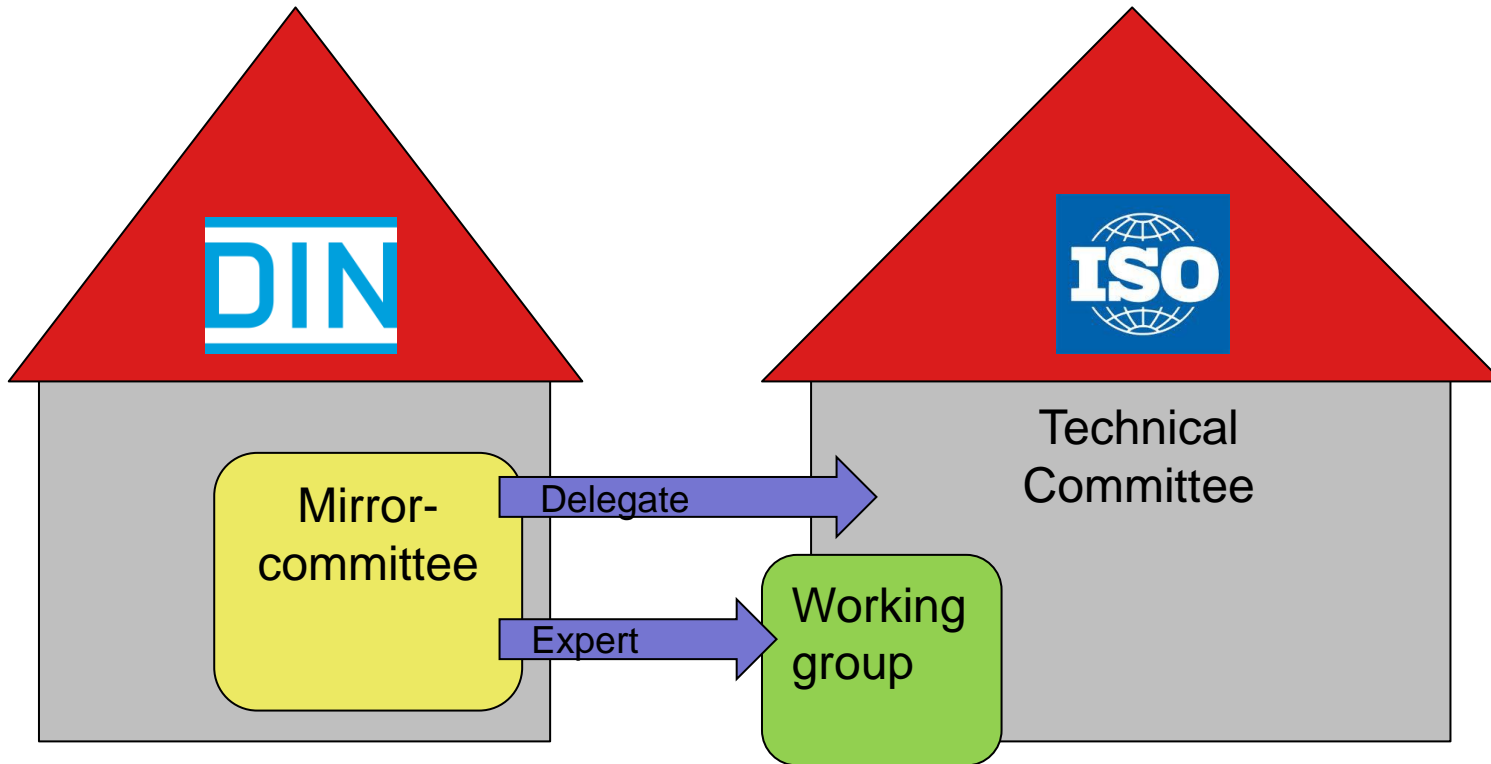
Distribution of CEN/TC Secretariats





Source: ISO Annual Report 2012

National input in int'l Standardization projects



Development of an international standard

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→ Development time: up to **3 years**

Traditional Role of Standards



- Source of technical know-how
- Trade facilitation and technology transfer
- Complementing legislation in the health, safety and environmental sectors

Valued-added role for research and innovation



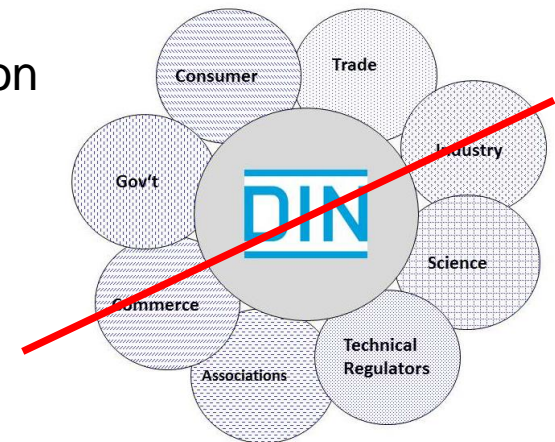
- Standards as the starting point for innovation
 - Speeding up innovation by providing the required knowledge base
- Develop specifications as a precursor for international (ISO) standards

➤ Norm (Standard)

- ✓ High level of acceptance
- ✓ Great economic benefits
- ✓ Reflects current state of technology

➤ Specification (Standard)

- ✓ Quickly available because full consensus is not required
- ✓ Effective diffusion of innovations
- ✓ A first step towards international (ISO) standardization



DIN SPEC 91335

Basic requirements for plasma sources in medicine

DIN SPEC 91287

Data interchange between information systems in civil hazard prevention

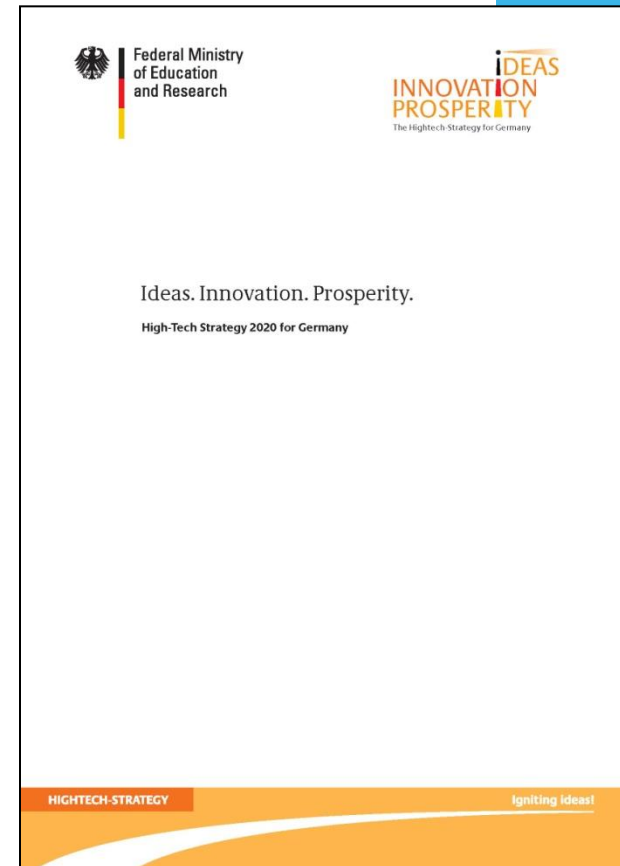
DIN SPEC 91280

Ambient Assisted Living (AAL) - Classification of Ambient Assistant Living services in the home environment and immediate vicinity of the home

→ **Development time: as short as 3 months**

High-Tech Strategy 2020 for Germany

- “Standardization is increasingly becoming an integral component of the research and innovation process in Germany, as precociously initialized it supports the transfer of research results into marketable products and services, as well as a fast access to the market for innovations.”
- “An active participation in standardization activities grants global competitive advantages for the German economy.”



Source: High-Tech-Strategy 2020,
BMBF 2010 (ed.), p. 10

European initiatives

to bring Standards and Innovations together

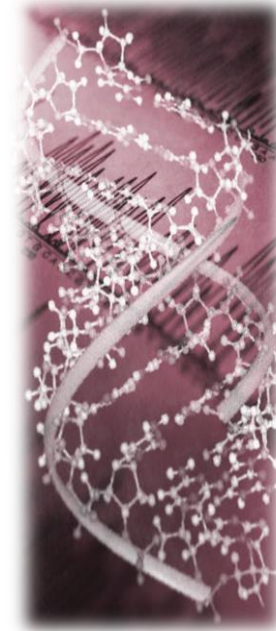


- **2014 to 2020** with an estimated budget of € 80 billion
- will combine all **research and innovation funding** currently provided through several individual framework programs
- **Bridge the gap between research and market**



- **September 2009:**
ISO Task Force Biotechnology
- **June & July 2011:**
ISO Webinars on Biotechnology Terminology
- **October 2011:**
ISO Workshop „International Standards for Biotechnology“
- **May-July 2012:**
Germany started national inquiries on interest and participation in a potential ISO/TC Biotechnology

- **July 2012:**
DIN submitted proposal for ISO/TC Biotechnology
- **November 2012:**
Proposal accepted, 11 P-Members, 13 O-Members
- **February 2013:**
ISO TMB Meeting in Sydney
Final decision on ISO/TC Biotechnology
- **Fall of 2013:**
Inaugural meeting of
ISO/TC Biotechnology in Berlin



Voting on TS/P 231 *Biotechnology*

23 approvals

Argentina, Australia, Austria, Belgium, Brazil, Canada, Ecuador, Finland, France, Germany, Iran, Japan, Korea, Lithuania, Malaysia, The Netherlands, Norway, Spain, Sweden, Tanzania, UK.

2 disapprovals: United States, Mexico.

4 abstentions: Czech Republic, Denmark, Italy, New Zealand

11 P-members

Belgium, Canada, Germany, Iran, Japan, Korea, The Netherlands, Spain, Sweden, Tanzania, UK.

13 O-members

Argentina, Australia, Austria, Czech Republic, Ecuador, Finland, France, Israel, Italy, Lithuania, Norway, Switzerland, USA.



ISO/TC Biotechnology is committed to working with all technical committees that overlap with its scope.

An excerpt:

ISO/TC 34/SC 16 "Methods for Molecular Biomarker Analysis"

ISO/TC 194 "Biological Evaluation of Medical Devices"

ISO/TC 272 "Forensic Sciences"



CEN/TC 275/WG 11 "Genetically Modified Foodstuffs"

CEN/TC 316 "Medical Products Utilizing Cells, Tissues, and Derivatives"

CEN/TC 411 "Bio-Based Products"



ASTM E 48 "Biotechnology"

ASTM E 55.04 "General Biopharmaceutical Standards"

ASTM E 55.90 "Manufacture of Pharmaceutical Products"



1. Terms and definitions
2. Analytical methods
in the realm of "-omics" technologies
3. Computing tools / bioinformatics
for int'l comparability and integrability of data
4. Biobanking
5. Bioreactors (particularly single-use items)

Questions?



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