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European Standards - The role of NSBs and CEN

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24th September 2012

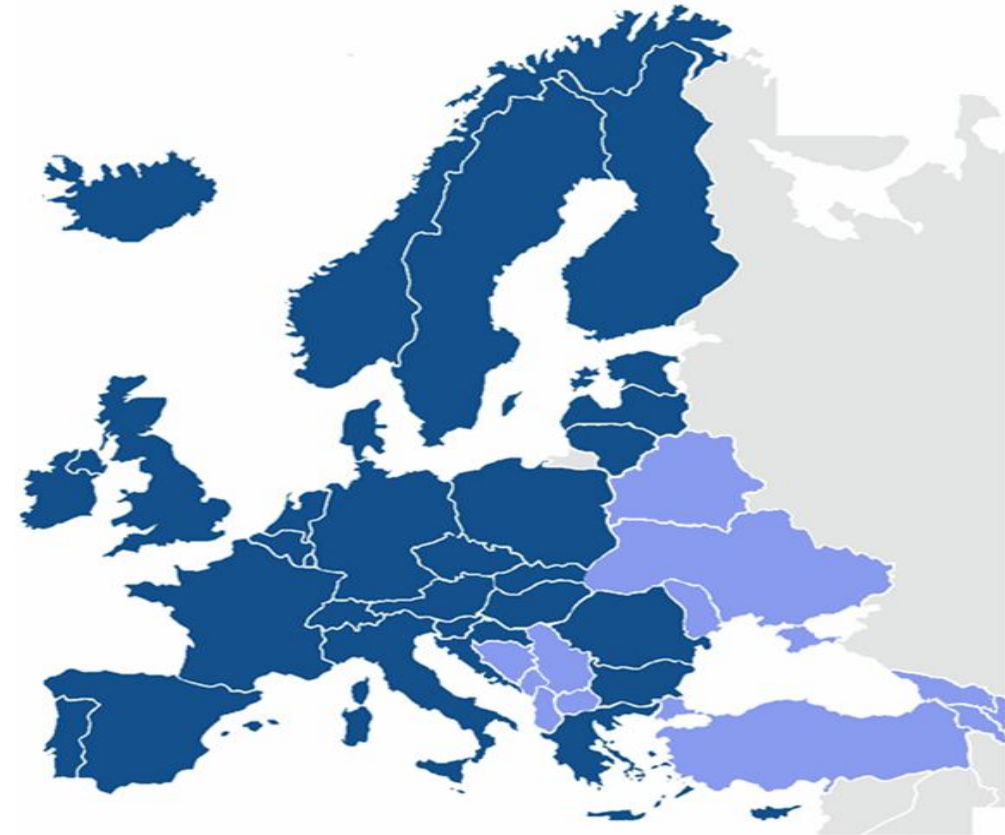


About CEN...



- Member
- Affiliate

30 Members of EU/EFTA
Croatia, FYROM, Turkey
17 Affiliates



Partnering with ISO



Main differences

- ISO standards take account of global interests;
- No automatic transposition of ISO standard at national level;
- ISO brand identity.

***Collaboration agreement between CEN and ISO
(Vienna Agreement) avoids duplication of work***

What is a European standard ?

- Characterized by public enquiry and national vote;
- Developed by consensus;
- Automatically transposed into national standards and conflicting standards are withdrawn;
- Can become a tool to underpin EU Directives.



European Standards are, from a legal point of view voluntary in use, but at the same time "unavoidable" in practice

Developing EN Standards

Timeframe: 36 Months

6 Months

Proposal

Drafting

**Public
Enquiry**

Approval

Publication

**Draft
Standard**

**European
Standard**

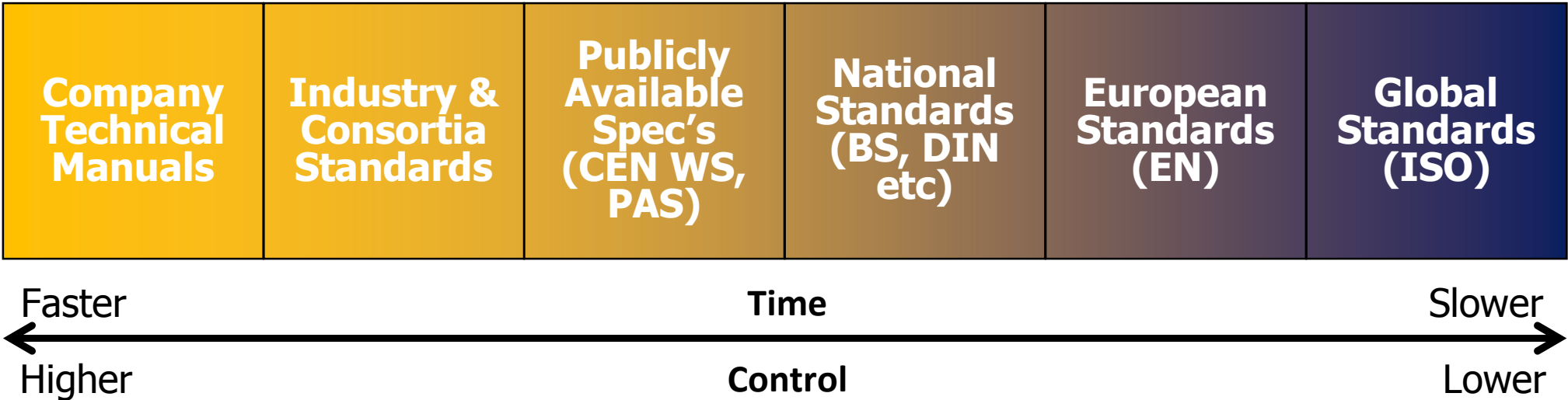
Consensus

ISO/IEC Guide 2:2004, definition 1.7

*“General agreement, characterized by the **absence of sustained opposition to substantial issues** by any important part of the concerned interests and by a process that involves seeking to **take into account the views of all parties concerned** and to reconcile any conflicting arguments*

NOTE Consensus need not imply unanimity.”

Standards Spectrum



Why European Standards ?

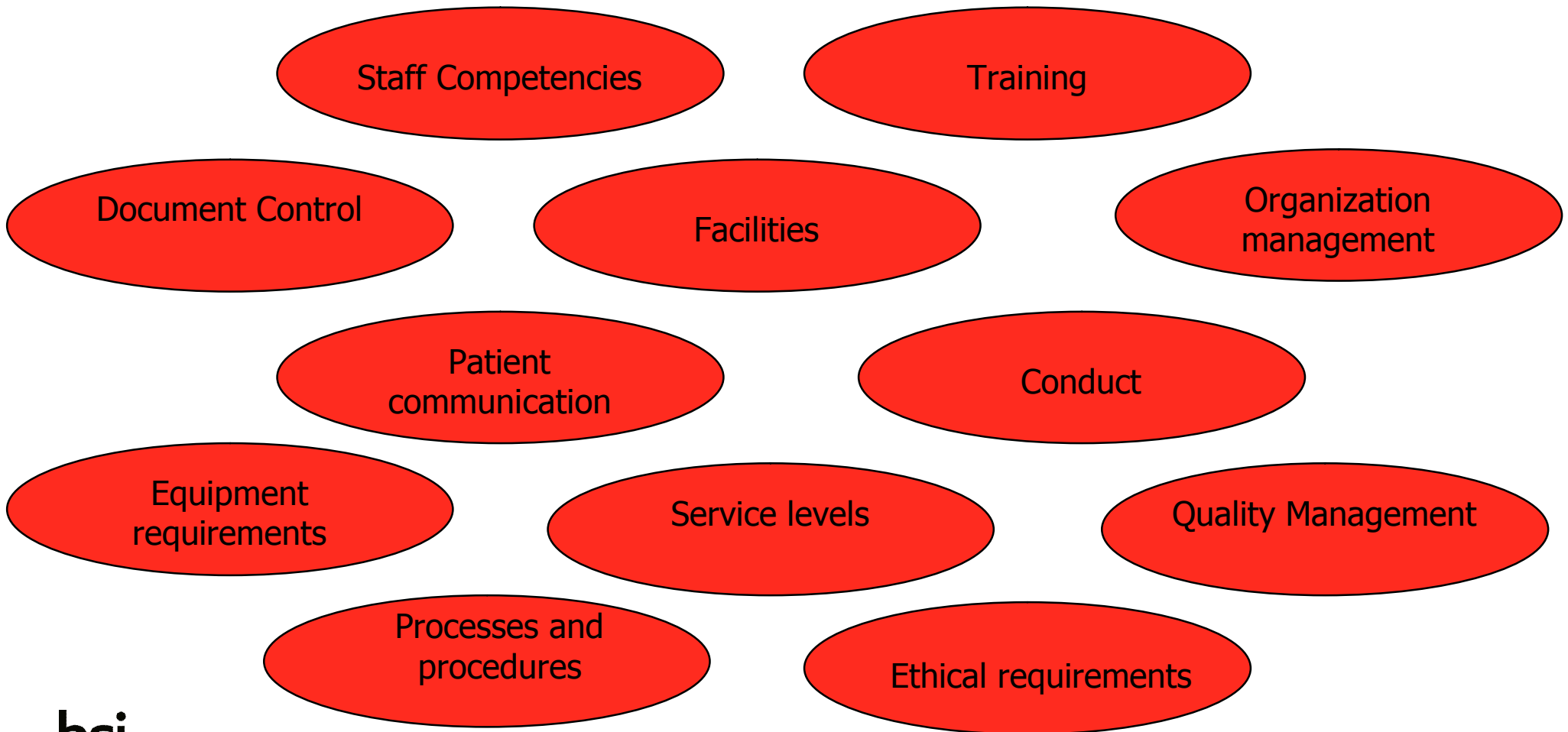
- Provide patient confidence and protection;
- Ensure safe provision of health services;
- Set requirements for patient service levels;
- Measure staff competence and quality of services / facilities;
- Provide a certification framework to distinguish service providers;
- Set an equal level playing field across Europe;
- Support legislation.

Current & developing CEN standards

- EN ISO 15189:2007 – *Medical laboratories quality and competence*
- EN ISO 22870:2006 – *POCT quality and competence*
- EN 15927:2010 – *Services offered by hearing aid professionals*
- CEN/TS 16118:2012 – *Services for sheltered housing*
- EN 16224:2012 – *Healthcare provision by chiropractors*

- prEN 15224 – *Healthcare services QMS (2012)*
- prEN 16372 – *Aesthetic surgery services (2014)*
- *Osteopathic healthcare provision (2015)*

What can CEN standards specify?



Healthcare and a changing Europe

- Increased competition between health service providers;
- Medical tourism in Europe is on the rise;
- Increasing age of population;
- Negative publicity e.g. aesthetic surgery;
- Some countries have little legislation on health care service levels.

Conclusions

- Use existing specifications or guidelines as base documents for CEN standards;
- For new standards ideas, CEN should use professional networks and NSBs to create a better common understanding from the outset;
- CEN should work closely with European organisations to establish their strategy for health service standards.

bsi.