

The role of conformity assessment in the EU

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Conformity assessment – Principles

Conformity assessment:

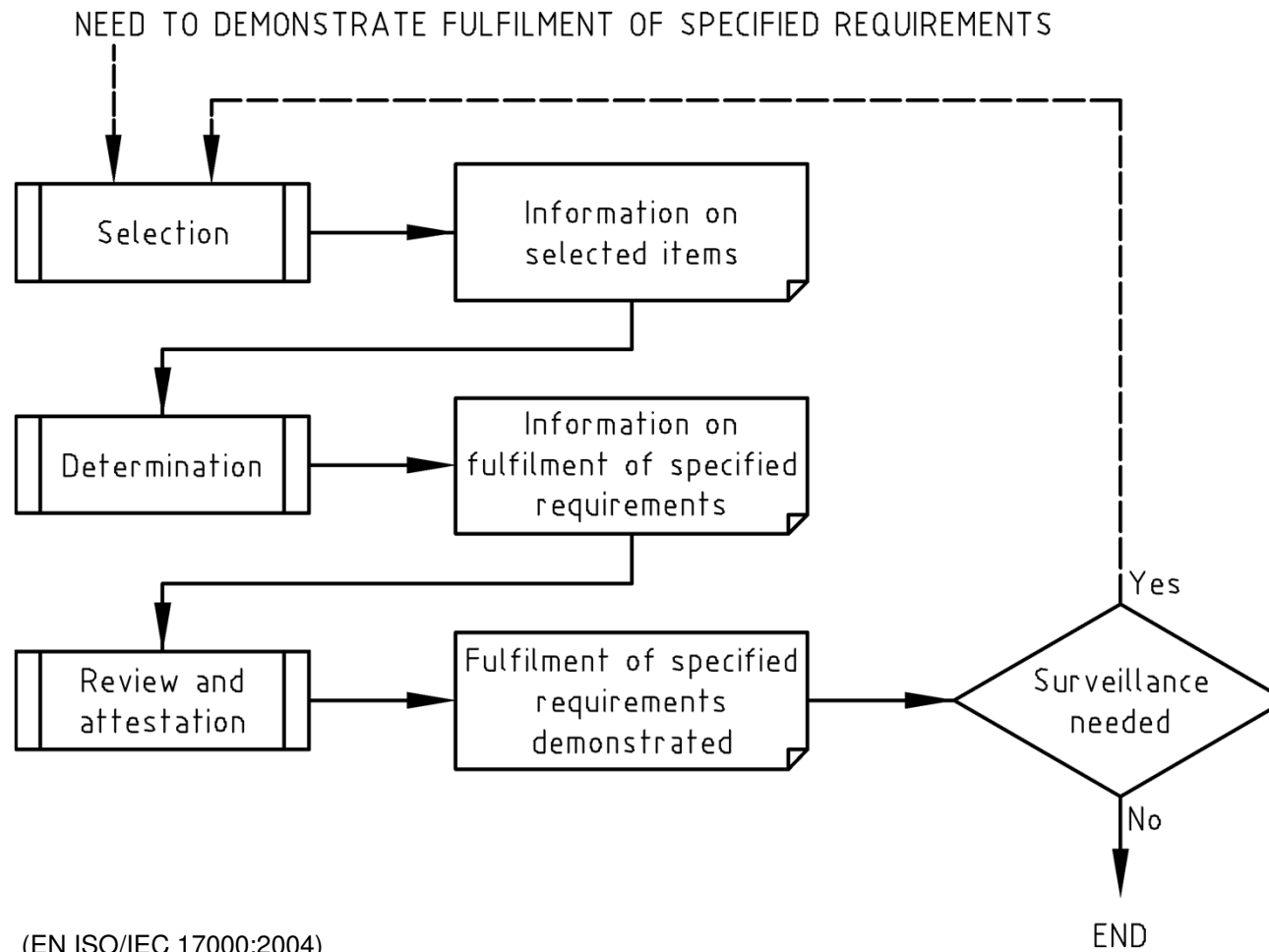
„**demonstration** that specified **requirements** relating to a product, process, system, person or body are **fulfilled**“

(EN ISO/IEC 17000:2004)

- Functions:
- selection
 - determination
 - review and attestation

 - surveillance (if applicable)

➤ Conformity assessment – Principles



Conformity assessment – Techniques

Testing:

„**determination** of one or more characteristics of an object of conformity assessment, according to a **procedure**“

(EN ISO/IEC 17000:2004)

EN ISO/IEC 17025:2005

„General requirements for the competence of testing and calibration laboratories“

Conformity assessment – Techniques

Calibration:

„operation that, under specified conditions, in a first step, establishes a relation between the **quantity values** with **measurement uncertainties** provided by **measurement standards** and corresponding **indications** with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a **measurement result** from an indication“

(VIM – International vocabulary of metrology, 2012)

Conformity assessment – Techniques

Inspection:

„**examination** of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of **professional judgement**, with general requirements“

(EN ISO/IEC 17000:2004)

EN ISO/IEC 17020:2012

„Conformity assessment – Requirements for the operation of various types of bodies performing inspection“

Conformity assessment – Techniques

Certification:

„**third-party** attestation related to products, processes, systems or persons“

(EN ISO/IEC 17000:2004)

- selection, determination
- **review**: verification of the suitability, adequacy and effectiveness
- **attestation**: issue of a statement, based on a decision

Conformity assessment – Techniques

EN ISO/IEC 17021:2011

„Conformity assessment – Requirements for bodies providing audit and certification of **management systems**“

EN ISO/IEC 17065:2012

„Conformity assessment – Requirements for bodies certifying **products**, processes and services“

EN ISO/IEC 17024:2012

„Conformity assessment – General requirements for bodies operating certification of **persons**“

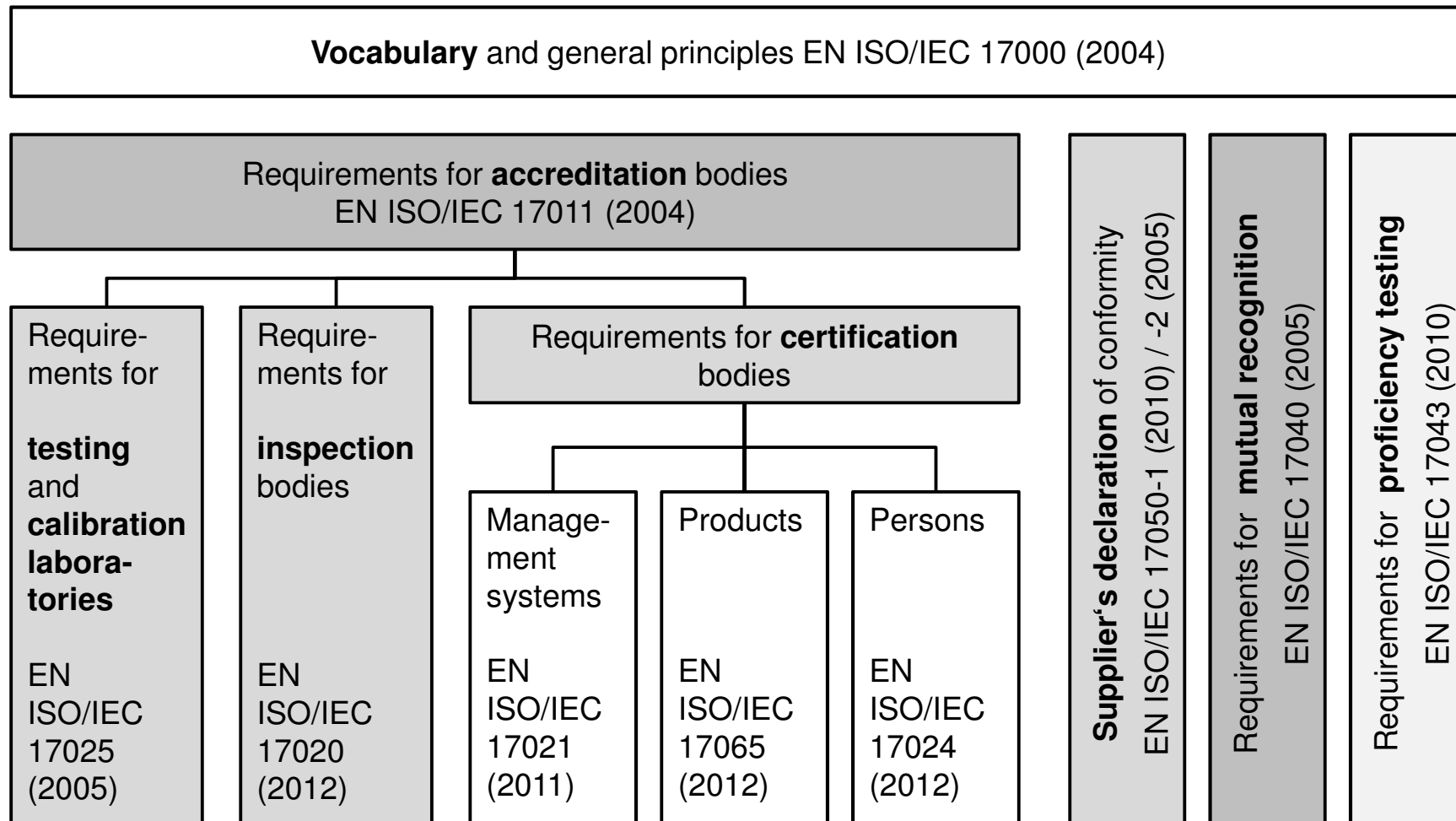
Conformity assessment – Activities

First-party conformity assessment activity is performed by the person or organization that **provides the object**.

Second-party conformity assessment activity is performed by a person or organization that has a **user interest** in the object.

Third-party conformity assessment activity is performed by a person or body that is **independent** of the person or organization that provides the object and of user interests in that object.

➤ Conformity assessment – Standards





Conformity assessment – Standards

25.5.2012

EN

Official Journal of the European Union

C 149/1

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND
AGENCIES

EUROPEAN COMMISSION

Commission communication in the framework of the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008, Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008, Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009

(Text with EEA relevance)

(Publication of titles and references of harmonised standards under the directive)

(2012/C 149/01)

Conformity assessment

Preconditions:

- specified **requirements** for objects
- determined **objects** of conformity assessment
- selected **type** of conformity assessment
- **responsibility** for the results of conformity assessment

Effectiveness:

- **confidence** in results of conformity assessment bodies
- reduction of technical barriers to trade
- level of protection of public interests

Conformity assessment – EU Legislation

L 218/30

EN

Official Journal of the European Union

13.8.2008

REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 July 2008

setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

- overall system to assess and ensure conformity with the applicable requirements
- CE marking



Conformity assessment – EU Legislation

L 218/30

EN

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REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

- **selection of conformity assessment bodies** can be provided for implementation of harmonisation legislation
- **accreditation** as preferred means of demonstrating the technical **competence** of conformity assessment bodies
- no distinction between the regulated or the non-regulated area by system of accreditation

Conformity assessment – EU Legislation

DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 July 2008

on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

- system of conformity assessment, approvals, mutual recognition, surveillance throughout the Community
- common principles to apply across sectoral legislation
- requirements for notification procedures

Conformity assessment – Standardisation



Vienna Agreement (1991, actual version 2001)

Agreement on Technical Co-operation between ISO and CEN



Dresden Agreement (1991, actual version 1996)

IEC – CENELEC Agreement on Common planning of new work and parallel voting

Conformity assessment – Standardisation

Co-operation between ISO/IEC and CEN/CENELEC:

- **primacy** of international standards
- **particular needs** e.g. of the Single European Market
- collaborative development of standards under **lead** by ISO/IEC or CEN/CENELEC
- **approval** of documents developed within one body simultaneously by the other

Conformity assessment – Standardisation

Co-operation between ISO/IEC and CEN/CENELEC:

- **coherence** of results
- avoidance of duplication of work, **synchronised** processes, simultaneous publication
- when expected results are not attained, the party which is not satisfied can decide to proceed separately
- ISO/IEC recognise that CEN/CENELEC operate within and must respect a **political environment**

Conformity assessment – Standardisation

CEN/CLC/TC 1 Criteria for conformity assessment bodies

- development of particular European Standards only if
 - no international need
 - International Standards **conflict** with EU requirements
- **participation** in ISO/CASCO work, decision on **endorsement** of International Standards
- **legal provision** set by European authorities respecting **technical requirements** of International Standards
- specific TC 1 Task Forces to **align** particular sets of rules