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Webinar for standard drafters: Conformity Assessment



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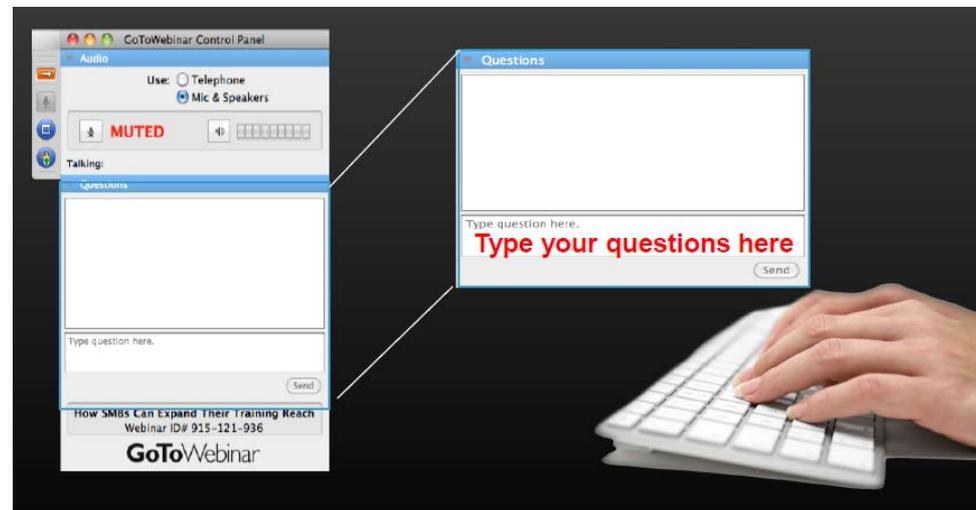


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Project Manager
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Your speakers today



Stefanie Vehring
Accreditation and Standardization
VdTÜV (Association of Technical
Inspection Agencies)



Frédéric DUFOUR
Project Manager – Mobility
Standardization & Digital Solutions

Conformity assessment as a concept



Conformity is understood as fulfilment of specified requirements.

These requirements can be **general** (e.g. “shall be safe to use”) as well as **detailed** (e.g. exact dimensions) and can be specified by a variety of sources, such as legal provisions, standards, regional arrangements, contractual agreements etc.

See [EN ISO/IEC 17000](#)

Conformity assessment as a concept



Conformity assessment is the demonstration that specified requirements relating to a particular object are fulfilled.

This assessment is conducted as a sequence of defined functions (functional approach):

1. **selection** of the representative samples of the object under assessment;
2. **determination** of evidence for fulfilment of the specified requirements;
3. **review** of the determined evidence with regards to the conformity with specified requirements;
4. **decision** whether or not the object conforms;
5. **attestation** of the conformity statement,
6. if applicable, **surveillance** by repeating the functions above

Object of conformity assessment



- 1. Product**
- 2. Service**
- 3. Process**
- 4. System**
- 5. Management system**
- 6. Person**
- 7. Body**
- 8. Claim**

Conformity assessment activities



Can be conducted by:

1. **first-party**, i.e. the person or organization that provides the object;
2. **second-party**, i.e. a person or organization that has a user interest in the object;
3. **third-party**, i.e. 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 tools



The following are conformity assessment tools:

1. **Testing**
2. **Inspection**
3. **Certification**
4. **Validation**
5. **Verification**



Conformity assessment tools



Requirements for competence, consistent operation and impartiality of **conformity assessment bodies** are specified by EN ISO/IEC 17000 series:

- [EN ISO/IEC 17025](#) Testing and calibration laboratories (1st, 2nd, 3rd party)
- [EN ISO/IEC 17020](#) Inspection bodies (1st, 2nd, 3rd party)
- [EN ISO/IEC 17029](#) (under development) Validation/verification bodies (1st, 2nd, 3rd party)
- [EN ISO/IEC 17024](#) Certification bodies for persons (3rd party)
- [EN ISO/IEC 17021-1](#) Certification bodies for management systems (3rd party)
- [EN ISO/IEC 17065](#) Certification bodies for products, services, processes (3rd party)
- [EN ISO/IEC 17050](#) Supplier's declaration of conformity (1st party)

Accreditation and Notification



Means of **recognition of conformity assessment** bodies are e.g. peer assessment ([EN ISO/IEC 17040](#)) or accreditation by independent accreditation bodies ([EN ISO/IEC 17011](#)).

Agreements among accreditation bodies, based on evaluation of their operations, can ensure **mutual recognition** of the accredited conformity assessment bodies and their results, e.g. certificates, within a particular scope

Accreditation and Notification



Accreditation can serve as a basis for **notification** by an EU Member State that a body has been designated to carry out **conformity assessment according to a directive**. Lists of designated notified bodies, established per directive, are published by the European Commission.

Where Community harmonisation legislation provides for the selection of conformity assessment bodies for its implementation, transparent accreditation is the preferred means of demonstrating the technical competence of those bodies (see Regulation (EC) No [765/2008](#)).

Principles for standards drafting



Principles for standards drafting (see [CEN/CENELEC Internal Regulations Part 3:2017](#))

- 33. Aspects of conformity assessment
 - 33.1. Documents containing requirements for products, processes, services, persons, systems and bodies
 - 33.2. Conformity assessment schemes and systems
 - 33.3. References to ISO/IEC conformity assessment documents
 - 33.4. For CEN purposes



Internal Regulations Part 3

Principles and rules for the structure and drafting of CEN and CENELEC documents
(ISO/IEC Directives — Part 2:2016, modified)
February 2017



Principles for standards drafting



Separation of requirements for the object from those for the conformity assessment:

Documents containing requirements for products, processes, services, persons, systems and bodies shall not include requirements related to conformity assessment.

Principles for standards drafting



Neutrality principle with regards to the assessing party:

All documents containing requirements for products, processes, services, persons, systems and bodies shall be written in such way, that conformity can be assessed by a first party, a second party, or a third party.

Do's and Don'ts



Standards for conformity systems or schemes shall not contain requirements for:

- Products;
- Processes;
- Persons;
- Products;
- Systems;
- Bodies;



However, items can be included in notes, informative annexes or introduction.



Do's and Don'ts



Test methods shall simply outline the process and thresholds of testing and not include provisions on:

- Who should undertake the test;
- Establish conformity assessment structure within the testing



Clear distinction between standards containing **specifications for a product, management system, personnel, etc.**, and documents setting down the operating procedures for a sector **specific conformity assessment scheme.**



Role of CEN/CLC TC 1



- Conformity assessment at international level - TC/SC must consult with ISO/CASCO;
- CEN/CENELEC Internal Regulations (Part 3) translates this requirement to a consultation of CEN/CENELEC/TC 1 instead.
- Derogation on CEN policy for the inclusion of conformity aspects (related to standardization request);
- Guidance to CEN-CLC TCs;
- Additional information on the BOSS website:

<https://boss.cen.eu/reference%20material/guidancedoc/pages/confassess.aspx>

Examples for Do's and Don'ts in ENs



Don'ts

21 Third party inspection

*The sprinkler system **shall** be periodically inspected at least once a year **by a third party**. The inspection report shall assess whether the system is in accordance with this standard, with regard to maintenance, operation and adequacy for the risk involved. A list of deviations shall be issued for action.*

Examples for Do's and Don'ts in ENs



Don'ts

Annex H (normative)

Determination of the ΦM values of the master radiators primary set

This annex contains the ΦM reference values of a primary set of master radiators complying with this European Standard as indicated in Table H.1. These ΦM values have been determined by a circuit of test installations as specified in 5.2.4.1.

*The **test installations** forming the circuit **comply** with EN ISO/IEC 17025, **accredited** by a **National Standards Body**.*

The ΦM reference values contained in the following

Examples for Do's and Don'ts in ENs



Don'ts

5.4 Guidance on the use of historical test data

When undertaking extended application (EXAP) a good understanding of the product performance in fire is required. Some of this information will be known from the EN tests according to CEN/TS 1187, however for some products there shall exist a record of test results against previous standards.

NOTE Under certain circumstances this information can be used as part of the EXAP procedure. This will help to reduce the number of new tests which are required.

In applying these principles, the **following conditions shall be met:**

- **EXAP is only undertaken by a Notified Body;**
- Primary data shall be obtained from the relevant CEN/TS 1187 Test 1 to 4.

Examples for Do's and Don'ts in ENs



Don'ts

Annex C (informative) – Provisions for voluntary involvement of third party(ies)

C.1 General

A manufacturer **may employ third party(ies) for conformity assessment**, which may involve a combination of type testing, inspection of factory production control, continuous surveillance and auditing of the product. The results of the conformity assessment by the bodies acting for regulators may be used by the third party(ies) in carrying out their assigned tasks.

Examples for Do's and Don'ts in ENs



Don'ts

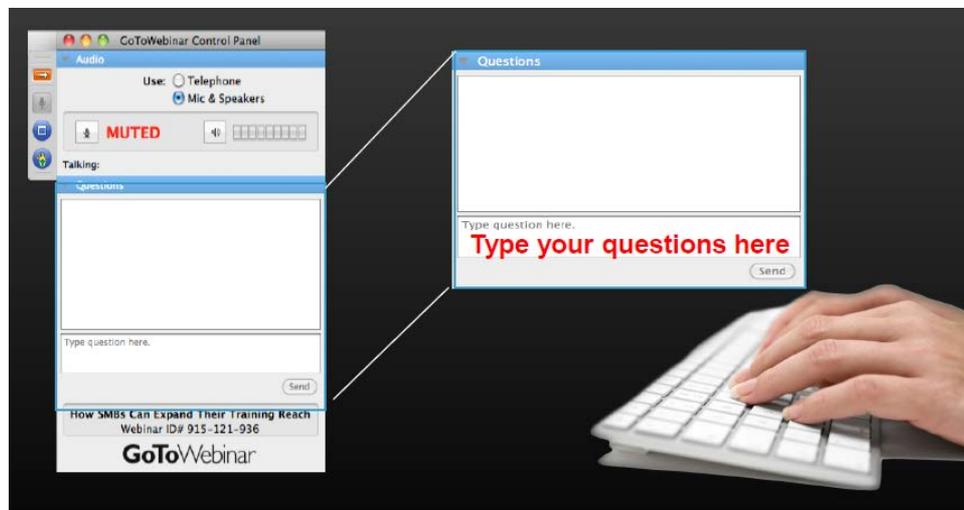
10.2 Assessment, surveillance and certification of production control

*Where it is required either in a contract or by provisions valid in the place of use of the concrete, that the producer's **production control shall be assessed and surveyed by an accredited inspection body and then certified by an accredited certification body**, the provisions for assessment, surveillance and certification given in **Annex C apply**.*

Question time



Use the Q&A panel to submit your questions



THANK YOU
FOR YOUR PARTICIPATION



Webinar for standard drafters: Conformity Assessment

Upcoming 10-10 webinar on 9 November at 10:00 AM CET
Register here: ["The Joint Initiative on Standardization two years later: Achievements and current discussions"](#)

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