

PLENARY SESSION

Five step method - “risk” assessment

Gonçalo ASCENSÃO

Customer Service Specialists - Manufacturing

Decision CLC BT 155/003

Decision CEN BT 6/2017

Subject: CEN-CLC/BTWG 127-2 – Proposed Guide

BT

- having noted

- the development and finalization, by the CEN-CLC/BTWG 127-2 'Tasks and responsibilities of the New Approach Consultants', of a proposed CEN-CENELEC Guide on 'Harmonised standards – Methodology for self-assessment by technical bodies' that will support CEN and CENELEC in fulfilling 7.2, i. of Part I of the Vademecum on European standardisation;
- the comments received

- invited the CEN-CLC/BTWG 127-2 or its successor to assess the comments received and to update the proposed CEN-CENELEC Guide for subsequent approval by correspondence at BTs level.

- invited the CEN-CLC/BTWG 127-2 or its successor to launch a pilot phase for self-assessment of Harmonized Standards with a number of selected TCs as of March 2017.

The methodology for “risk”-assessment

Objective

Ensuring standard complies with:

- ▲ Standardization request
- ▲ New Approach (NLF) legislation

5-step approach

Primarily related to safety standards

1. Scope definition:
 - i. Limits of the product and characteristics to be covered*
 - ii. Identify in foreword changes in the scope*
 - iii. Check if the scope is narrowed (provide justification of what is intended for residual content)*
 - iv. Ensure changes are reflected in the WP of the Sreq*
2. Identify relevant hazards related to ER (possible limitations scope)
3. Specification of risk reduction measures for identified risks
4. Verification of risk reduction measures
5. Annex ZA/ZZ
 - i. Correct template*
 - ii. Correct legislation and Sreq*
 - iii. ER linked to the clauses*
 - iv. Identification of ER/safety objectives is clear and reflecting the scope*

5-step approach

Not primarily related to safety standards

1. Scope definition:
 - i. Limits of the product and service to be covered*
 - ii. Identify changes in the scope*
 - iii. Check if the scope is narrowed (provide justification of what is intended for residual content)*
 - iv. Ensure changes are reflected in the WP of the Sreq*
2. Identify relevant *ER were identified* (possible limitations scope)
3. Specification of **appropriate measures**
4. Verification of **the measures**
5. Annex ZA/ZZ
 - i. Correct template*
 - ii. Correct legislation and Sreq*
 - iii. ER linked to the clauses*
 - iv. Identification of ER/safety objectives is clear and reflecting the scope*

Standardization Requests can include specific requirements:

- ▲ Need to demonstrate how the work has been organized and managed;
- ▲ Requirements on stakeholder participation;
- ▲ Justifications on technical decisions (about risks not considered, etc)

Provisions in Sectoral guidance

How to report

- ▲ Establish checklists to report achievements of TC verifications;
- ▲ Handling of table of comments;
- ▲ Reports of WG meetings (highlighting harmonization elements);

Keep in mind

- ▲ Objective is to ensure the acceptance of the hENs;
- ▲ Keep track of the work done;
- ▲ Support any possible future queries;
- ▲ Help to structure the discussions on hENs



Thank You

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