Preparation of harmonised standards under the Vienna and Frankfurt Agreements (including the addressing of negative assessments)

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  Manufacturing
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Structure

1. Coordination with ISO and IEC
2. Role of CEN and CENELEC TCs
3. How to handle ‘Lack of compliance’ assessments
4. Final remarks
1. Coordination with ISO and IEC

2. Role of CEN and CENELEC TCs

3. How to handle ‘Lack of compliance’ assessments

4. Final remarks
Vienna and Frankfurt Agreements

Principles:

- Avoid duplication of work on standards at global and European level;
- Aim at identical worldwide and European standards
- Establish agreement on repartition of work;
- Apply simultaneous commenting and acceptance procedures on single drafts.

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#MachineryDirective
Agreement on Work Programme

- Defining objectives of parallel work;
- Agreement on the scope of activities and WIs;
- Defining the responsibilities of the different parties;
- Agreement on time frame and different milestones:
  - ensuring time to deal with harmonization elements;
  - consideration of comments and assessments.
 Standards Development Process

Home-grown

TC  CCMC and NSB/NC secretariat  ENQUIRY/FORMAL VOTE
Preparation/editing/translation/finalisation

DRAFTING  ENQUIRY  DRAFTING  FV  PUB.

Consultant(s)  Consultant(s)  Consultant(s)

HAS Contractor

Desk officer

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#MachineryDirective
Key elements

- Need to convey European voice to ISO and IEC TCs:
  - awareness of Essential Requirements of the Machinery Directive;
  - awareness on specific drafting elements;
  - which elements to exclude;

- Informed decision on whether to develop harmonized or non-harmonized standard;

- Good management group between CEN-ISO and CLC-IEC leadership.
1. Coordination with ISO and IEC

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Responsibility for CEN and CLC TCs

- Prepare and agree on relevant WIs;
- Ensure that reference to Sreq/Mandate and Directive is correct;
- Preparation of harmonization elements:
  - Annex ZA/ZZ (even for ISO lead);
  - Annex ZA (for CENELEC);
  - Ensuring that European requirements are considered in the international work;
  - Development of Common Modifications in CENELEC (if needed).
Responsibility for CEN and CLC TCs

- During standards development:
  - requesting HAS assessment in the first working drafts;
  - ensuring that HAS comments (if any) are considered;
  - consideration on normative references;
- Provide necessary replies to HAS consultant comments;
- Keep any records of technical decisions related to harmonization elements;
- Ensuring a good coordination with ISO/TCs and IEC/TCs.
1. Coordination with ISO and IEC
2. Role of CEN and CENELEC TCs

3. How to handle ‘Lack of compliance’ assessments

4. Final remarks
Lack of compliance at FV

- When at FV stage;
- Besides all interactions and technical work;
- The outcome of the assessment at FV is:
  - Lack of Compliance
### Possible Options

<table>
<thead>
<tr>
<th>Result of the HAS assessment</th>
<th>ISO</th>
<th>CEN</th>
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<tbody>
<tr>
<td>Lack of compliance</td>
<td><strong>Option 1</strong> – Publication of a harmonized deliverable (only possible when HAS assessment is resolved through editorial changes)</td>
<td></td>
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<tr>
<td></td>
<td>ISO publishes under VA without waiting for CEN publication (with any relevant editorial modifications)</td>
<td>CEN publishes under VA (after approval by CEN/BT of any required changes to e.g. Annex Z)</td>
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<td><strong>Option 2</strong> – Publication of a non-harmonized deliverable (when modifications cannot be resolved through editorial changes)</td>
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<td></td>
<td>ISO may publish under VA directly without waiting for CEN publication</td>
<td>CEN publishes under VA but deliverable is not harmonized (after approval by CEN/BT, i.e. Annex Z and links to legislation are removed)</td>
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<td><strong>Option 3</strong> – 2nd parallel ballot</td>
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<td></td>
<td>2nd FDIS vote (after ISO committee resolution)</td>
<td>2nd Formal vote (after CEN committee and CEN/BT decisions)</td>
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<td><strong>Option 4</strong> – Decoupling from VA by ISO committee resolution or CEN committee decision. Each organization proceeds in accordance with its own rules.</td>
<td></td>
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</tbody>
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14
In line with CLC BT Decisions D159/013 and D154/009:
- IEC standards adopted by CENELEC without common modifications will have a EN IEC reference.

IEC edition is adopted ‘identical’

IEC edition adopted with Common Modifications
- IEC 6xxxxx:2018 → EN IEC 6xxxxx:2018;
Lack of compliance assessment can be:
- Dealt with in common modifications;
- Allowing the parallel work to be finalized;

Common modifications:
- Can be created since the activation of the WI;
- Shall be provided ahead of Enquiry;
- Exceptionally with BT decision if not requested in phase (up to enquiry);

Annex ZA and Annex ZZ are not considered common modifications;
1. Coordination with ISO and IEC
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Key elements

- TCs leadership to ensure continuous communication between CEN-ISO and CENELEC-IEC;
- Early inclusion of harmonization elements;
- Ensuring time during development for harmonization elements;
- Request for HAS assessment in the first working draft;
- Options are available for problems at FV;
- CCMC, ISO CS and IEC CO support in the process;